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Life Sciences Industry Accounting Guide
Other Accounting and Financial Reporting Topics

March 2025

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Preface

The life sciences ecosystem encompasses a wide array of entities that discover, develop, and manufacture health care products. Such entities include pharmaceutical manufacturers; biotechnology companies; medical device, diagnostic, and equipment manufacturers; and service companies such as drug distributors, contract research organizations (CROs), contract manufacturing organizations (CMOs), and health technology companies.

Finance and accounting professionals in the life sciences industry face complex issues and must exercise significant judgment in applying existing rules to matters such as research and development (R&D) costs, acquisitions and divestitures, consolidation, contingencies, revenue recognition, income taxes, financial instruments, and financial statement presentation and disclosure. The 2025 edition of Deloitte's *Life Sciences Industry Accounting Guide* (the "Guide") addresses these and other relevant topics affecting the industry this year. It includes interpretive guidance, illustrative examples, recent standard-setting and rulemaking developments (through March 7, 2025), and key differences between U.S. GAAP and IFRS[®] Accounting Standards. [Appendix B](#) lists the titles of standards and other literature we cited, and [Appendix C](#) defines the abbreviations we used. Key changes made to this Guide since publication of the 2024 edition are summarized in Appendix D.

We hope the Guide is helpful in navigating the various accounting and reporting challenges that life sciences entities face. We encourage clients to contact their Deloitte team for additional information and assistance.

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Chapter 12 — Other Accounting and Financial Reporting Topics

12.1 Government Assistance

12.1.1 Considerations Related to Government Assistance

Governments provide assistance for a variety of reasons, such as to stimulate economies, support policy initiatives, and foster innovation. An example of government assistance is the package of loans, grants, tax credits, and other forms of government aid that the U.S. federal government provided under the CARES Act in response to the COVID-19 pandemic.

Although some forms of assistance may be referred to as “grants” or “credits,” entities should carefully look at the form and substance of the assistance to determine the appropriate accounting framework to apply. For example, assistance may be in the form of income-based tax credits that are dependent on taxable income, whereas other forms of government assistance are not dependent on taxable income (e.g., payroll tax credits). Income-based tax credits generally will be within the scope of ASC 740. Government assistance that is not dependent on taxable income is generally not within the scope of ASC 740 and would most likely be viewed and accounted for as a government grant.

12.1.1.1 Exchange Transaction Versus Contribution

The nature and form of government assistance may vary (e.g., grants, payroll tax credits, forgivable loans, price adjustments, reimbursements of lost revenues, reimbursements of expenses). In performing its accounting analysis, an entity should first consider whether the government assistance it receives represents an exchange transaction (i.e., a reciprocal transfer in which each party receives and pays commensurate value) or a contribution, which is defined in the ASC master glossary as an “unconditional transfer of cash or other assets, as well as unconditional promises to give, to an entity or a reduction, settlement, or cancellation of its liabilities in a voluntary nonreciprocal transfer by another entity acting other than as an owner.” To determine whether the government assistance represents an exchange transaction, an entity should consider the factors in the table below, which are adapted from ASC 958-605-15-5A and 15-6.

An Exchange Transaction May Not Exist if:	An Exchange Transaction May Exist if:
(1) The benefit provided by the entity is received by the general public, (2) the government only received indirect value from the entity, or (3) the value received by the government is incidental to the potential public benefit derived from using the goods or services transferred from the entity.	The transfer of assets from a government entity is part of an existing exchange transaction between the receiving entity and an identified customer (e.g., payments under Medicare and Medicaid programs). In this circumstance, “an entity shall apply the applicable guidance (for example, Topic 606 on revenue from contracts with customers) to the underlying transaction with the customer, and the payments from the [government] would be payments on behalf of” the customer, rather than payments for benefits that were received by the general public.
The entity has provided a benefit that is related to “[e]xecution of the [government’s] mission or the positive sentiment from acting as a donor.”	The expressed intent was to exchange government funds for goods or services that are of commensurate value.
The entity solicited funds from the government “without the intent of exchanging goods or services of commensurate value” and the government had “full discretion in determining the amount of” assistance provided.	Both the entity and the government negotiated and agreed on the amount of government assistance to be transferred in exchange for goods and services that are of commensurate value.
Any penalties the entity must pay for failing “to comply with the terms of the [government assistance] are limited to the [goods] or services already provided and the return of the unspent amount.”	The entity contractually incurs economic penalties for failing to perform beyond the government assistance provided.

If an entity concludes that the government assistance it received represents an exchange transaction, it should account for such assistance in accordance with the applicable U.S. GAAP (e.g., ASC 606). As discussed further below, certain payments may be considered part of an exchange transaction between the recipient entity and its customers. Further, if an NFP concludes that the government assistance represents a contribution, such assistance would be accounted for under ASC 958-605.



Connecting the Dots

The National Institutes of Health (NIH) is an agency of the U.S. government and the world’s **largest public funder of biomedical research**. It conducts research in its own laboratories and supports the research of nongovernment scientists in universities and research institutions, including business entities. The NIH provides financial support in the form of grants, cooperative agreements, and contracts to advance its mission of enhancing health, extending healthy lives, and reducing the burdens of illness and disability. Business entities that contract with the NIH in exchange for financial support need to assess whether such an arrangement represents (1) an exchange transaction (i.e., a reciprocal transfer in which each party receives and pays commensurate value) or (2) a nonreciprocal (nonexchange) transaction (which may be the case if the NIH does not receive commensurate value in return, apart from the advancement of its mission). In addition to funding received from the NIH, these transactions may include payments to the NIH based on commercial drug sales (e.g., reverse royalty payments). An entity will need to carefully consider the accounting treatment for such payments, including the appropriate classification on the income statement. For a discussion of consideration payable to a customer in arrangements representing exchange transactions, see Section 1.5.6.

Other government assistance could include complex provisions; therefore, an entity should carefully apply judgment and consider consulting with its advisers when determining the appropriate accounting treatment. For example, an entity may conclude that assistance is (1) entirely an exchange transaction or (2) partially an exchange transaction and partially a grant. Further, some provisions may only provide for a right to defer payments (for which interest is not imputed in accordance with ASC 835-30-15-3(e)), while others may solely represent a grant from the government (e.g., reimbursement of incurred costs).

12.1.1.2 Government Grants

If the government assistance an entity receives is not accounted for under ASC 740 (e.g., an income-tax-based credit), an exchange transaction (e.g., loan, equity transaction, or revenue arrangement), or a contribution within the scope of ASC 958, it would most likely be viewed as a government contribution of assets and accounted for as a government grant.

NFPs should apply ASC 958-605 to the government grants they receive. However, government grants to business entities are explicitly excluded from the scope of ASC 958.¹ Other than the guidance in ASC 905-605-25-1 on income replacement and subsidy programs for certain entities in the agricultural industry, there is no explicit guidance in U.S. GAAP on the accounting for government grants to business entities.

ASC 105 provides a hierarchy for entities to use in determining the relevant accounting framework for the types of transactions that are not directly addressed in sources of authoritative U.S. GAAP. According to ASC 105-10-05-2, an entity should “first consider [U.S. GAAP] for similar transactions” before considering “nonauthoritative guidance from other sources,” such as IFRS Accounting Standards. As discussed further below, we understand that there may be diversity in practice.

When selecting the appropriate accounting model to apply to a government grant, a business entity should consider the specific facts and circumstances of the grant. If the entity has a preexisting acceptable accounting policy for accounting for similar government grants, it should generally apply that policy. However, if the entity does not have a preexisting accounting policy or the grant is not similar to grants it has received in the past, it should carefully consider applying a model that would faithfully depict the nature and substance of the government grant.

We believe that in the absence of either directly applicable or analogous U.S. GAAP, it may be appropriate to apply IAS 20, which has been widely used in practice by business entities to account for government grants.



Connecting the Dots

While IAS 20 has been widely applied in practice by business entities in accounting for government grants, the application of ASC 450-30 may also be acceptable since we are aware that some business entities may have applied a gain contingency model by analogy for certain grants (e.g., the Electronic Healthcare Records program under the American Recovery and Reinvestment Act of 2009). Under this model, income from a conditional grant is viewed as akin to a gain contingency; therefore, recognition of the grant in the income statement is deferred until all uncertainties are resolved and the income is “realized” or “realizable.” That is, an entity must meet all the conditions required for receiving the grant before recognizing income. For example, a grant that is provided on the condition that an entity cannot repurchase its own shares before a certain date may result in the deferral of income recognition until the compliance date lapses. Such a deferral may be required even if (1) the government funded

¹ See ASC 958-605-15-6(d).

the grant, (2) the entity incurred the costs that the funds were intended to defray, and (3) the remaining terms subject to compliance are within the entity's control and virtually certain of being met. That is, it would not be appropriate under a gain contingency model for an entity to consider the probability of complying with the requirements of the government grant when considering when to recognize income from the grant. Therefore, for many grants, the recognition of income under ASC 450-30 would most likely be later than the recognition of income under IAS 20.

In addition, it may be acceptable in practice to apply other U.S. GAAP for government grants. For example, while government grants to business entities are explicitly excluded from the scope of ASC 958, the FASB staff has noted that such entities are not precluded from applying that guidance by analogy when appropriate. Therefore, a business entity may conclude that it is acceptable to apply ASC 958 by analogy, particularly if the grant received by the business entity is similar to that received by an NFP (e.g., certain subsidies provided to both nonprofit and for-profit health care providers).

Further, some may believe that loans obtained should be accounted for as debt in their entirety under ASC 470, even if all or a portion of the loan is expected to be forgiven. Under ASC 405-20, income would not be recorded from the extinguishment of the loan until the entity is legally released from being the primary obligor. Alternatively, an entity may account for the loan as an in-substance government grant if it is probable that the loan will be forgiven.

12.1.1.2.1 On the Horizon — Proposed ASU on Business Entities' Accounting for Government Grants

In November 2024, the FASB issued a [proposed ASU](#) that would add guidance to ASC 832 on the recognition, measurement, and presentation of government grants. In the absence of such guidance, many companies have analogized to other GAAP, including IAS 20 or ASC 958-605, when accounting for these grants. In developing the proposed ASU's recognition and measurement framework, the FASB largely leveraged the guidance in IAS 20.

The proposed ASU would define a government grant as “[a] transfer of a monetary asset or a tangible nonmonetary asset, other than an exchange transaction, from a government to a business entity.” All business entities other than NFPs or certain employee benefit plans would be subject to the proposed guidance. However, the proposed guidance would not apply to certain transaction types, including, but not limited to, (1) transactions within the scope of ASC 740 on income taxes, (2) government guarantees, and (3) an intangible asset or service.

Under the proposed ASU, recognition, measurement, and presentation of government grants would depend on whether the grant is related to an asset or to income. The proposed ASU would provide the following definitions:

- *Grant related to an asset* — “A government grant in which the primary condition is for an entity to purchase, construct, or otherwise acquire a long-term asset, including the direct grant of a tangible nonmonetary asset. Other conditions also may be attached, such as restricting the type or location of the asset, the periods during which the asset is to be acquired or held, or the disposal of the asset.”
- *Grant related to income* — “A government grant other than a grant related to an asset.”

Regardless of whether a government grant is related to an asset or to income, an entity would not be able to recognize the grant unless it concludes that it is probable that both of the following criteria will be met:

- “An entity will comply with the conditions attached to the government grant.”
- “The government grant will be received.”

The proposed ASU would clarify that receipt of the grant does not, by itself, indicate that both criteria are met. Under the proposed ASU, an entity would be required to account for any changes in expectations related to whether the conditions associated with grant will be met after the grant is recognized as a contingent liability or contingent asset in accordance with ASC 450.

12.1.1.2.1.1 *Grant Related to an Asset*

In accordance with the proposed ASU, ASC 832-10-25-5 would allow an entity to use either of the following approaches to recognize a grant related to an asset:

- *Deferred income approach* — Under this approach, an entity would recognize deferred income as a separate financial statement line item on the balance sheet. For a monetary grant, the deferred income recognized would be the amount of cash received or expected to be received on the date the grant meets the recognition criteria. For a nonmonetary grant of a tangible asset (e.g., equipment or land), deferred income would be measured at the fair value of the asset as of the date the grant meets the recognition criteria. According to the proposal, the deferred income “shall be recognized in earnings on a systematic and rational basis over the periods in which the entity recognizes as expenses the related costs for which the government grant is intended to compensate.” The grant should be presented in earnings either (1) “[s]eparately under a general heading such as other income” or (2) “[d]educted in reporting the related expense.”
- *Cost accumulation approach* — Under this approach, the grant would be reflected as a reduction of the “carrying amount of the asset on the balance sheet.” For a monetary grant, an entity should measure the asset on the basis of the cost incurred “to acquire or construct the asset” less the monetary government grant received or expected to be received when the grant meets the recognition criteria. Note that there may be timing differences between when the asset is acquired or constructed and when the recognition criteria for the grant are met. For a nonmonetary grant of a tangible asset (e.g., grant of equipment or land), the carrying value of the asset would be the cost to the entity, if any. In accordance with this approach, the grant would be a part of the carrying value of the asset and, since it would not be separately identifiable, no separate subsequent measurement or presentation guidance would apply. Application of the subsequent measurement and presentation guidance would depend on the nature of the asset. In other words, the cost basis (net of the grant) would be subject to depreciation, impairment, or other subsequent measurement and presentation guidance (e.g., ASC 360-10 or ASC 330) on the basis of the asset’s nature.

12.1.1.2.1.2 Grant Related to Income

A grant related to income would be “recognized in earnings on a systematic and rational basis over the periods in which the entity recognizes as expenses the related costs for which the government grant is intended to compensate.” If a grant related to income is received before an entity complies with the conditions associated with the grant (i.e., the entity has not incurred the related expenses associated with the grant), the entity would recognize a deferred credit liability that would be reduced as grant income is earned. Alternatively, if a grant related to income is received (1) after the expenses or losses have been incurred or (2) to provide financial support to the entity, the grant would be recognized in earnings in the period in which the recognition criteria (discussed above) are met.

12.1.1.2.1.3 Statement of Cash Flows Presentation

Rather than providing prescriptive guidance on the presentation of government grants in the statement of cash flows, the proposed ASU refers to ASC 230. The Board clarifies in paragraph BC44 of the proposal that an “entity may classify proceeds from a grant related to income as a cash flow from an operating activity or as a cash flow from a financing activity.” For grants related to an asset, an entity may classify proceeds “as a cash flow from an operating activity, an investing activity, or a financing activity.” Entities would need to apply significant judgment when determining the underlying nature of the grant and the resulting presentation in the statement of cash flows.

12.1.1.2.1.4 Disclosure

Under the proposed ASU, the current disclosure requirements in ASC 832 for government assistance would apply to government grants. The proposal would clarify that for a grant related to an asset accounted for under the cost accumulation approach, an entity only needs to disclose the line items on the balance sheet and income statement that are affected by the grant and the amounts applicable to each financial statement line item in the period in which the grant was recognized. Further, the proposed ASU would add a requirement to disclose the fair value of nonmonetary tangible assets that are received as a government grant even if accounted for under the cost accumulation approach.

12.1.1.2.1.5 Additional Information

For more information about the proposed ASU, see Deloitte’s November 26, 2024, [Heads Up](#).

12.1.1.3 IAS 20 Accounting Framework

An entity that elects an IAS 20 framework to account for government grants should consider that a government grant cannot be recognized (even if payment is received up front) until there is reasonable assurance that the entity will (1) comply with the conditions associated with the grant and (2) receive the grant. While “reasonable assurance” is not defined in IAS 20, for a business entity that is subject to U.S. GAAP, we believe that reasonable assurance is generally the same threshold as “probable” as defined in ASC 450-20 (i.e., “likely to occur”).

When an entity has met the reasonable assurance threshold, it applies IAS 20 by recognizing government grants in its income statement on a “systematic basis over the periods in which the entity recognises as expenses the related costs for which the grants are intended to compensate.” To help an entity meet this objective, IAS 20 provides guidance on two broad classes of government grants: (1) grants related to long-lived assets (capital grants) and (2) grants related to income (income grants).

12.1.1.3.1 Capital Grants

A capital grant is a grant received by an entity with conditions tied to the acquisition or construction of long-lived assets. An entity may elect an accounting policy to initially recognize such a grant as either deferred income or a reduction in the asset's carrying amount. If the entity classifies the grant as deferred income, it will recognize the grant in the income statement over the useful life of the depreciable asset that it is associated with (e.g., as an offset against depreciation expense). If the entity classifies the grant as a reduction in the asset's carrying amount, the associated asset will have a lower carrying value and a lower amount of depreciation over time. Further, with respect to nondepreciable assets, IAS 20 observes that "[g]rants related to non-depreciable assets may also require the fulfilment of certain obligations and would then be recognised in profit or loss over the periods that bear the cost of meeting the obligations. As an example, a grant of land may be conditional upon the erection of a building on the site and it may be appropriate to recognise the grant in profit or loss over the life of the building."

12.1.1.3.2 Income Grants

An income grant is a grant that is not related to long-lived assets. An entity may present the receipt of such a grant in the income statement as either (1) a credit to income (in or outside of operating income) or (2) a reduction in the related expense that the grant is intended to defray. As discussed above, the main objective of the accounting for government grants under IAS 20 is for an entity to recognize a grant in the same period or periods in which it recognizes the corresponding costs in the income statement. Therefore, an entity should assess the specific compliance requirements that it must meet to receive or retain any funds from the government.



Connecting the Dots

Income-related government grants that are intended to compensate for expenses incurred over time may also include over time compliance requirements. Applying IAS 20 could therefore allow for recognition of the grant over time if the entity can assert that it is likely to comply with the conditions (i.e., the grant is reasonably assured).

However, if an entity instead applied the ASC 450-30 gain contingency framework to these types of grants, recognition of the government grant would generally be delayed until all conditions were met because the probability of compliance is not taken into consideration in the application of ASC 450-30.

While IAS 20 identifies two broad classes of grants, it is worth noting that some grants may include multiple requirements and have aspects of both capital grants and income grants. That is, such grants may be intended to subsidize the purchase of long-lived assets and certain operating costs. Therefore, an entity receiving a grant that is subject to multiple requirements should carefully assess how to allocate such a grant into components on a systematic and rational basis to accomplish the overall objective of matching recognition of the grant to recognition of the cost in the income statement.

12.1.1.4 Statement of Cash Flows

In determining the appropriate cash flow presentation of government grants (that are not tax credits recognized as a reduction of income tax and accounted for in accordance with ASC 740 and that are not accounted for in accordance with ASC 958), an entity should consider the nature of the grants since government assistance can take many different forms. See Sections 6.2.4 through 6.2.4.2 for a discussion of considerations related to the treatment of government grants in the statement of cash flows.

12.1.1.5 Disclosures

Business entities are subject to certain disclosure requirements when they (1) have received government assistance and (2) use a grant or contribution accounting model by analogy to other accounting guidance (e.g., a grant model under IAS 20 or ASC 958-605).

Under ASC 832-10-50-3 and 50-4, a business entity that has received government assistance is required to provide disclosures for annual periods as follows:

ASC 832-10
<p>Nature of the Assistance, Related Accounting Policies, and Effect on Financial Statement Amounts</p> <p>50-3 An entity shall disclose the following about transactions with a government within the scope of this Topic:</p> <ol style="list-style-type: none"> a. The nature of the transactions, including a general description of the transactions and the form in which the assistance has been received (for example, cash or other assets) b. The accounting policies used to account for the transactions as required by paragraph 235-10-50-1 c. The line items on the balance sheet and income statement that are affected by the transactions, and the amounts applicable to each financial statement line item in the current reporting period. <p>Significant Terms and Conditions</p> <p>50-4 An entity shall disclose information about the significant terms and conditions of transactions with a government within the scope of this Topic. Terms and conditions that might be appropriate to disclose include, but are not limited to, any of the following:</p> <ol style="list-style-type: none"> a. The duration or period of the agreement b. Commitments made by both the reporting entity and the government c. Provisions, if any, for recapture (for example, when the government can recapture amounts awarded), including the conditions under which recapture is allowed d. Other contingencies.

Further, ASC 832-10-50-5 notes that in certain situations, the terms of the government assistance may legally prohibit an entity from disclosing the required information. In such circumstances, the entity must disclose a description of the general nature of the information and indicate that it is excluding the disclosures because of legal prohibitions.

12.2 Common-Control Transactions

Life sciences entities seeking to balance their portfolios may undergo internal reorganizations in preparation for public offerings or sale transactions. Because such internal reorganizations do not result in a change in control over the assets and liabilities, they are accounted for as common-control transactions.

A common-control transaction is typically a transfer of net assets or an exchange of equity interests between entities under the control of the same parent. While a common-control transaction is similar to a business combination for the entity that receives the net assets or equity interests, such a transaction does not meet the definition of a business combination because there is no change in control over the net assets. Therefore, the accounting and reporting for a transaction between entities under common control is outside the scope of the business combinations guidance in ASC 805-10, ASC 805-20, and ASC 805-30 and is addressed in the “Transactions Between Entities Under Common Control” subsections of ASC 805-50. Since there is no change in control over the net assets from the parent’s perspective, there is no change in basis in the net assets. ASC 805-50 requires that the receiving entity recognize the net assets received at their historical carrying amounts, as reflected in the ultimate parent’s financial statements.

For more information and interpretive guidance on common-control transactions, see [Appendix B](#) of Deloitte's Roadmap *Business Combinations*.

12.3 Discontinued-Operations Reporting

While many life sciences entities have sought ways to expand their pipeline of products in development or to acquire additional commercial products, others have explored how to generate additional returns on assets that are no longer a strategic focus. When an entity sells or abandons a business or product line, questions often arise about whether the assets and related operations should be reported as a discontinued operation. The reporting of discontinued operations separately from continuing operations is meant to provide stakeholders with information on assessing the effects of a disposal on an entity's ongoing operations.

Discontinued operations may include a component, or group of components, of an entity. An entity will need to use judgment in determining whether a disposition qualifies for discontinued-operations reporting. A disposal of a component, or group of components, of an entity may be presented as a discontinued operation only if (1) the assets (and liabilities) meet the criteria to be classified as HFS, have been sold, or have been otherwise disposed of (e.g., abandonment) and (2) the disposal represents a strategic shift that has or will have a major effect on the entity's operations and financial results. Therefore, not all disposal transactions qualify for discontinued-operations reporting.

Example 12-1

Entity B is a life sciences entity whose primary strategy is to focus on R&D for clinical-stage products, including commercialization upon regulatory approval. To provide liquidity for its ongoing R&D programs, B divests Drug X, one of its commercialized products.

To determine whether the divestment of Drug X qualifies for discontinued-operations reporting, B must first consider whether Drug X represents a component. If Drug X does not represent a component, B's divestment of Drug X is not a disposal that represents a discontinued operation.

If B determines that Drug X represents a component, it must next consider whether the disposal represents a strategic shift that has or will continue to have a major effect on B's operations and financial results. A strategic shift implies that the disposal must result from a change in the way management had intended to run the business. Therefore, if B has a history of divesting commercial products to provide a source of liquidity for ongoing R&D programs, its disposal of Drug X might not represent a strategic shift regardless of whether the disposal has a major effect on B's operations and financial results.

The determination of whether a disposal represents a strategic shift will be based on the entity's specific facts and circumstances. Because of the judgment involved, discussion with accounting advisers is encouraged.

For more information about discontinued-operations reporting, including interpretations of the accounting guidance on the topic, see [Chapter 5](#) of Deloitte's Roadmap *Impairments and Disposals of Long-Lived Assets and Discontinued Operations*.

12.3.1 SEC Comment Letter Themes Related to Discontinued Operations

Examples of SEC Comments

- You disclose that . . . you sold all of the assets comprising your [Component A] to [Company X] and have presented the operations of [Component A] as discontinued operations for all periods presented. Please explain to us how you determined that the disposal of [Component A] results in a strategic shift in your operations given that you continue to hold other [Component A technology-related products] in your product candidate portfolio.
- [D]escribe the expected future business activities of [Component A] represented by the “interest retained” of \$[X] million and explain your consideration of criteria for discontinued operations in reporting this deconsolidation.

Given the assessment of qualitative and quantitative factors and the use of judgment to determine whether operations qualify for discontinued-operations presentation, the SEC staff has asked registrants, including those in the life sciences industry, to provide more information about how they concluded that a disposal either did or did not qualify for such presentation.

For additional discussion, see Deloitte’s Roadmap [SEC Comment Letter Considerations, Including Industry Insights](#).

12.4 Carve-Out Financial Statements

Carve-out financial statements are prepared to reflect a portion of a parent entity’s balances and activities. Examples of transactions in which carve-out financial statements may be requested or required include, but are not limited to, the following:

- *Potential sale* — An entity wishing to dispose of a portion of its assets and operations may prepare carve-out financial statements to help potential acquirers evaluate a prospective transaction.
- *Completed sale* — A public entity acquires, or it is probable that it will acquire, a portion of an entity’s business, and the acquisition is deemed “significant” to the acquirer under SEC Regulation S-X, Rule 3-05. Consequently, the acquiring entity may request (or need to have prepared) audited carve-out financial statements of the business acquired for inclusion in a Form 8-K filing, registration statement, or proxy statement of the acquirer.
- *Spin-off* — A public entity plans to distribute a portion of its assets that constitute a business by spinning the business off to its shareholders as a separate public company. Therefore, carve-out financial statements of the spinnee (i.e., the new legal spun-off entity) must be included in the SEC registration statement in connection with the spin-off.
- *Split-off* — A public entity plans to offer to its existing shareholders, in exchange for some or all of the existing shareholders’ shares in the public entity, shares in a newly formed entity that represents a portion of its assets that constitute a business (the “splitee”). Therefore, carve-out financial statements of the new legal entity to be split off must be included in the SEC registration statement in connection with the exchange transaction.
- *IPO and SPAC transactions* — An entity wishes to segregate a portion of itself to effect an IPO of a newly created subsidiary or to enter into a transaction with a SPAC. Therefore, carve-out financial statements of the operations to be segregated and transferred to the newly created subsidiary or to a SPAC must be included in the SEC registration statement in connection with the transaction.

Typical SEC filing forms in which carve-out financial statements may be provided include:

- *Form S-1* — Used to register shares of a carve-out entity as a new registrant through an IPO.
- *Form S-4* — Used to register shares of (1) the registrant for the acquisition of a carve-out entity (e.g., if the carve-out entity is acquired by an SEC registrant or a SPAC) or (2) the splitee in a split-off transaction involving the exchange of shares of the splitee for shares of the parent.
- *Form 8-K* — Used to provide financial statements for an acquiree if the acquiree is significant to the registrant that acquired it.
- *Form 10* — Used to register classes of securities for which no other form is prescribed, such as spin-off transactions in which shares are distributed to the parent company's shareholders.

Also, the parent may be required to provide pro forma financial information reflecting the disposition of a significant business or asset in either a current report on Form 8-K or certain registration statements.

The carve-out entity may consist of all or part of an individual subsidiary, multiple subsidiaries, an individual segment, multiple segments, or a specific group of products. In some cases, one or more portions of a previously consolidated parent entity's subsidiaries may create the newly defined carve-out operations.

"Carve-out financial statements" is a general term used to describe financial statements derived from the financial statements of a larger parent entity. The form and content of those financial statements may vary, however, depending on the users of the financial statements and the purpose for which the financial statements are being prepared. For example, if the acquisition is small, a strategic buyer of a carve-out entity may be satisfied with an unaudited balance sheet and income statement for the most recent fiscal year. A public buyer, however, may require a full set of SEC-compliant audited financial statements, including footnotes, for the two most recent fiscal years. Further, a third buyer may require that the periods be audited but may not be concerned with SEC reporting considerations. The existence of a foreign buyer could present different requirements and challenges in addition to those noted above, such as working closely with the foreign buyer on IFRS conversion of certain financial statement line items. The purpose of the financial statements also greatly affects the timeline, since carve-out financial statements filed for a public spin-off via Form 10 would need to be available at least 60 days before the spin-off, while carve-out financial statements prepared for compliance with SEC Regulation S-X, Rule 3-05,² would need to be available within 75 days post-closing.

Accordingly, assessing the potential audience and any regulatory requirements applicable to the transaction is critical to understanding the basis of presentation, the periods of financial information required, and the level of effort and organizational focus that may be necessary to meet the needs of the potential transaction. Such an assessment can be particularly difficult when the carve-out financial statements are being prepared before any potential buyers are identified or when the potential buyer pool is numerous or diverse. SEC registrants are encouraged to consult with their legal advisers and independent accountants regarding these requirements.

² Under Rule 3-05, registrants, including entities undertaking an IPO, are required to file the separate preacquisition financial statements for a significant acquired or to be acquired business (acquiree). The significant acquisition rules focus on three principal criteria: the investment test, the asset test, and the income test. In accordance with the SEC's [final rule](#) issued on May 20, 2020, if the results of any of those tests exceed a threshold of 20 percent, at least financial statements for the most recent fiscal year (audited) and the latest year-to-date interim period that precedes the acquisition date (unaudited) — and, potentially, financial statements for the two most recent fiscal years (audited), the latest year-to-date interim period that precedes the acquisition date (unaudited), and the corresponding interim period of the prior year (unaudited) if the results of any of the tests exceed a threshold of 40 percent — will be required.

12.4.1 Management Considerations

Preparing carve-out financial statements can be challenging, often requiring management to use judgment and carefully plan ahead. Below are some considerations management should take into account when preparing carve-out financial statements.

12.4.1.1 *Assembling the Right Team*

Involving the appropriate personnel is an integral step in preparing accurate and complete carve-out financial statements. Management should determine which employees can help provide the information it needs to prepare such statements, which may include individuals outside accounting (e.g., in operations or human resources) as well as those involved in negotiating the transaction. In addition, management may need to engage external specialists (e.g., tax or valuation experts).

12.4.1.2 *Determining the Transaction's Structure and Scope*

In many divestiture transactions, planning for and preparing carve-out financial statements starts before the final transaction structure is determined or negotiations begin. Identifying the expected structure and which entities or operations will be included within it is a key step in developing the carve-out financial statements. Carve-out financial statements may be in the form of (1) public-entity financial statements subject to SEC requirements, (2) nonpublic-entity financial statements to which certain U.S. GAAP presentation and disclosure requirements do not apply and for which reporting alternatives developed by the PCC may be elected, and (3) special-purpose financial information that a user may ask for in a specific form or may request to be prepared in accordance with another comprehensive basis of accounting. Thus, the transaction structure can affect the form and content of the financial statements, the years to be provided, and the audit procedures required.

12.4.1.3 *Materiality and Evaluating Misstatements*

Because the materiality thresholds related to the carve-out financial statements will most likely be lower than those associated to the consolidated parent entity, management may need to assess the carve-out entity's accounts and balances in even more detail than they may have been subjected to during preparation of the parent entity financial statements. The parent entity's historical corrected or uncorrected misstatements and disclosures related to the carve-out entity that were previously considered immaterial to the parent's financial statements would need to be reconsidered on the basis of materiality thresholds applicable to the carve-out financial statements.

12.4.1.4 *Internal Controls*

Management should design and implement processes and controls for preparing the carve-out financial statements (e.g., management may need to design, implement, and execute controls related to the appropriate determination and recording of income statement and balance sheet allocations to the carve-out financial statements). Although an entity may often be able to leverage existing financial statement preparation controls, management should evaluate whether it needs to modify such controls to accommodate process changes related to preparing the carve-out financial statements.

12.4.1.5 Supporting Documentation

Management should consider the type of documentation necessary to support the assumptions made and results achieved in preparing carve-out financial statements. In some cases, the supporting documentation may already exist (e.g., compensation expense is usually calculated and allocated on an employee-by-employee basis). However, management may need to develop and maintain new documentation for the allocations made for the carve-out financial statements (e.g., a rational and systematic method for allocating SG&A expenses). In other cases, intercompany transactions may have historically been eliminated within the parent's financial statements; however, those transactions would be reported in the carve-out financial statements, and appropriate supporting documentation would be required.

Management may choose to use existing accounting systems as much as possible when preparing carve-out financial statements. However, the ability to use such systems may be limited depending on the level of detail at which the account balances are maintained as well as the structure of the carve-out entity (e.g., whether the carve-out represents a segment of the parent or only part of a segment). If the carve-out entity represents a segment or component for which discrete financial information is readily available, management may be able to readily extract information from its existing accounting records. However, if the carve-out entity includes portions of different segments, further involvement of IT specialists may be required.

12.4.1.6 Significant Judgments and Estimates

In preparing carve-out financial statements, management will often need to make significant accounting judgments and estimates related to allocating account balances and activities to the carve-out financial statements and determining the appropriate disclosures to include in these financial statements. Such judgments and estimates may include the following:

- The allocation of goodwill to the carve-out financial statements and the assessment of goodwill for impairment in the periods presented in such financial statements.
- The identification of the carve-out entity's operating and reportable segments and the preparation and presentation of segment disclosures in the periods presented in the carve-out financial statements.
- The allocation of pension and postretirement expenses, obligations, and plan assets, as well as share-based compensation expense, to carve-out financial statements.
- The allocation of expenses for shared assets and facilities or corporate functions to carve-out financial statements.
- The preparation of the income tax provision and the allocation of DTAs and DTLs to carve-out financial statements.
- The identification of subsequent events applicable to the carve-out entity and the determination of whether the effects of subsequent events need to be recorded and disclosed in the carve-out financial statements.

For more information and interpretive guidance on significant judgments and estimates related to the preparation of carve-out financial statements, see Deloitte's Roadmap [Carve-Out Financial Statements](#).

12.4.1.7 Working With Auditors

If, as part of the preparation of carve-out financial statements, external auditors need to perform an audit and issue an audit opinion, the auditors will need to understand the process undertaken by management for collecting and maintaining all supporting documentation used in such preparation. For balances in which judgment or complex estimates are required, management should ensure that its documentation contains enough detail for auditors to reach conclusions about the reasonableness of the amounts allocated to, and balances presented in, the carve-out financial statements. Topics on which up-front and regular dialogue with auditors may help include (1) identifying the carve-out entity and the carve-out entity's financial statements, (2) materiality and evaluating misstatements, (3) ICFR, and (4) significant management judgments and management estimates.

12.4.2 Regulatory Considerations

In addition to defining the business and financial information required and determining the specific approach to the preparation of the financial information, management should consider any regulatory restrictions that may exist related to the divestiture of a business or the transfer of contracts to the buyer. For example, it is common in the life sciences industry for operations in a specific country to have a delayed closing whereby one or more elements of the business do not fully transfer to a buyer at the time of the divestiture. The delays are frequently linked to jurisdictional requirements for the buyer to obtain the marketing authorizations needed to distribute pharmaceutical products or to negotiate changes to government contracts when nontransferable tender agreements exist. Management may need to (1) determine which statutory financial statements are required and (2) consider the audit of those financial statements.

When transitional services agreements (TSAs) are put in place, management should also consider the financial reporting treatment of any activities performed by the seller on behalf of the buyer and how profits earned during the period that are transferred to the buyer should be reported.

12.4.3 “RemainCo” Considerations

Carve-out financial statements typically include an allocation of corporate costs to the business to be divested, such as those related to executive management, IT, tax, insurance, accounting, legal and treasury services, and certain employee benefits. Upon the disposal, the individuals performing these activities may not transfer to the divested business. As a result, the remaining business would retain these “stranded costs.”

Under ASC 205-20, the parent entity is required to evaluate whether the effect of a disposal resulting from a carve-out transaction should be presented as a discontinued operation. Depending on the form of the carve-out transaction, this evaluation may occur when the carve-out entity (1) meets the criteria in ASC 205-20-45-1E to be classified as HFS, (2) is disposed of by sale, or (3) is disposed of other than by sale in accordance with ASC 360-10-45-15 (e.g., by abandonment or in a distribution to owners in a spin-off). If the disposal meets the conditions to be reported as a discontinued operation by the parent entity, it would be unlikely that amounts presented as discontinued operations for the disposal in the parent-entity financial statements would equal the operations reflected in the carve-out entity's financial statements (e.g., because of differences between how expenses may have been allocated in the carve-out financial statements and how expenses associated with the discontinued operation are determined). See [Section 12.3](#) of this Guide and Deloitte's Roadmap [Impairments and Disposals of Long-Lived Assets and Discontinued Operations](#) for further information.

Management's determination that a portion of the carve-out entity's operations should be presented in discontinued operations will also affect the carve-out entity's statement of cash flows. See [Section 3.3](#) of Deloitte's Roadmap [Statement of Cash Flows](#) for further discussion.

12.4.4 Form and Content of Carve-Out Financial Statements

The form and content of the carve-out financial statements depend on the needs or requirements of the users of the financial statements and any regulatory requirements applicable to the transaction for which the carve-out financial statements are being prepared.

Accordingly, the most common types of carve-out financial statements include:

- *Public-entity financial statements:*
 - *Registrant, predecessor, or Rule 3-05* — A registrant and its predecessor may need to prepare carve-out financial statements for an initial registration statement filed with the SEC as well as in Forms 10-K and 10-Q filed after the initial registration statement. If so, the financial statements must comply with the general financial statement requirements in SEC Regulation S-X, Rules 3-01 through 3-04. Carve-out financial statements may also be required for a significant acquired or to be acquired business in accordance with Rule 3-05 in certain SEC filings.
 - *Abbreviated financial information* — In accordance with Rule 3-05, abbreviated financial information may at times be provided for significant acquired or to be acquired businesses in certain SEC filings. These abbreviated financial statements typically consist of a statement of revenues and direct expenses (in lieu of a full statement of operations) and a statement of assets acquired and liabilities assumed (in lieu of a full balance sheet). Abbreviated income statements for acquired or to be acquired real estate operations in accordance with SEC Regulation S-X, Rule 3-14, may also be provided.
- *Nonpublic-entity financial statements* — Certain U.S. GAAP presentation and disclosure requirements do not apply to nonpublic entities. In addition, nonpublic entities may elect to apply reporting alternatives developed by the PCC. Nonpublic-entity carve-out financial statements in which PCC accounting alternatives have been elected may be appropriate when the financial statements are not included or expected to be included in an SEC filing.
- *Special-purpose financial information* — A user may ask for financial information in a specific form or for it to be prepared in accordance with another comprehensive basis of accounting. While such information may be prepared to suit the user's request, there will most likely be restrictions on the use of such information as well as the level of attestation available. Further, since the form and content of financial statements to be included in SEC filings are prescribed, the financial information prepared under a special-purpose framework may not be usable for SEC filings.

In addition, preparers of carve-out financial statements should discuss with their auditor the level of assurance that may be provided for the planned form and content. If the carve-out financial statements are reissued, the auditor may be required to reissue its opinion(s) or other form of attestation. Changes in the intended users of the carve-out financial statements or in the planned form and content of the carve-out entity's financial information may change the level of assurance sought or that can be provided. Accordingly, any such changes should be monitored throughout the carve-out transaction process.

For more information and interpretive guidance on preparing carve-out financial statements, see Deloitte's Roadmap [Carve-Out Financial Statements](#).

12.5 Cost of Doing Business

12.5.1 Introduction

The life sciences industry has been subject to increased regulation in recent years at both the federal and state level, particularly as overall pharmaceutical drug pricing has come under closer scrutiny. In some cases, fees have been imposed on industry participants as a result. Two examples, which are discussed below, are (1) the BPD fee under the federal Patient Protection and Affordable Care Act and (2) fees imposed on the sale of opioid-based products by various states.

12.5.2 BPD Fee

12.5.2.1 Background

The federal Patient Protection and Affordable Care Act imposes an annual fee on the pharmaceutical manufacturing industry for each calendar year beginning on or after January 1, 2011. An entity's portion of the annual fee is payable no later than September 30 of the applicable calendar year and is not tax deductible. The portion of the annual fee that is allocated to individual entities is determined on the basis of the amount of an entity's BPD sales for the current year as a percentage of the industry's BPD sales for the same period.

A pharmaceutical manufacturing entity's portion of the annual fee becomes payable to the U.S. Treasury once the entity has a gross receipt from BPD sales to any specified government program or in accordance with coverage under any government program for each calendar year beginning on or after January 1, 2011.

In December 2010, the FASB issued [ASU 2010-27](#) (codified in ASC 720-50) to provide guidance on accounting and reporting related to the BPD annual fee. ASC 720-50-25-1, which was added by ASU 2010-27 and subsequently amended by [ASU 2011-06](#), states, in part:

The liability related to the annual fee described in paragraphs 720-50-05-1 through 05-4 shall be estimated and recorded in full upon the first qualifying sale for pharmaceutical manufacturers . . . **in the applicable calendar year in which the fee is payable** with a corresponding deferred cost that is amortized to expense using a straight-line method of allocation unless another method better allocates the fee over the calendar year that it is payable. [Emphasis added]

On July 28, 2014, several years after the FASB issued ASU 2010-27, the IRS issued [final regulations](#)³ related to the BPD fee that introduced a new term, "covered entity status" (see the definition and related example below). The final regulations indicate that an entity's obligation to pay its portion of the BPD fee in any given calendar year is not triggered by the first qualifying sale in that calendar year but is triggered instead by the qualifying sales in the previous year.

On the basis of a discussion with the SEC staff, the accounting for the BPD fee should be based on the final IRS regulations, which require an entity to recognize expense for the BPD fee as qualifying sales occur. That is, the recognition guidance in ASU 2010-27 became inapplicable upon issuance of the final IRS regulations. However, the SEC staff indicated that it would not object if an entity continued to apply the income statement presentation guidance in ASC 720-50-45-1, which requires the BPD fee to be presented as an operating expense.

³ TD 9684, *Branded Prescription Drug Fee*.

12.5.2.2 Definition of Covered Entity Status

Section 51.2(e)(5) of the final IRS regulations defines covered entity status as follows:

- (i) *Rule.* An entity's status as a covered entity begins in the first fee year in which the entity has branded prescription drug sales and continues each subsequent fee year until there are no remaining branded prescription drug sales for that entity to be taken into account as described in §51.5(c) or used to calculate the adjustment amount described in §51.5(e).
- (ii) *Example.* The following example illustrates the rule of paragraph (e)(5)(i) of this section:
 - (A) *Facts.* Entity A is a manufacturer with gross receipts of more than \$5 million from branded prescription drugs sales in 2011. Entity A does not have any gross receipts from branded prescription drug sales before or after 2011.
 - (B) *Analysis.* Entity A is a covered entity beginning in 2011 because it had gross receipts from branded prescription drug sales in 2011. For the 2011 fee year, Entity A does not owe a fee because the 2011 fee is based on sales data from the 2009 sales year. For the 2012 fee year, Entity A does not owe a fee because the 2012 fee is based on sales data from the 2010 sales year. Entity A continues to be a covered entity for the 2012 fee year because its branded prescription drug sales from the 2011 sales year have not yet been taken into account as described in §51.5(c) and used to calculate the adjustment amount described in §51.5(e). For the 2013 fee year, Entity A continues to be a covered entity because a portion of its branded prescription drug sales from the 2011 sales year are taken into account as described in §51.5(c) for purposes of computing the 2013 fee. For the 2013 fee year, Entity A is also liable for the adjustment amount described in §51.5(e) for the difference between its 2012 fee computed using sales data from the 2010 sales year, which is \$0, and what the 2012 fee would have been using sales data from the 2011 sales year. For the 2014 fee year, Entity A continues to be a covered entity because a portion of its branded prescription drug sales for the 2011 sales year are used to calculate the adjustment amount described in §51.5(e). Therefore, for the 2014 fee year, Entity A will receive an adjustment amount for the difference between its 2013 fee computed using sales data from the 2011 sales year, and what the 2013 fee would have been using sales data from the 2012 sales year, which is \$0. After the 2014 fee year, there are no remaining branded prescription drug sales to be taken into account as described in §51.5(c) or used to calculate the adjustment amount described in §51.5(e) for Entity A. Accordingly, Entity A is not a covered entity after the 2014 fee year.

12.5.3 Fees on Opioid-Based Products

Entities involved in the sale of opioid-based products have most likely experienced an increased cost of doing business as various states have either enacted or considered enacting laws imposing a fee on the sale of such drugs. The nature of the fee, its amount, its effective date, and the related documentation and reporting requirements vary by state. For example, some states characterize the fee as an excise tax, while others characterize the fee as a value-based tax, gross receipts tax, or license fee. As a result, entities involved in the sale of opioid-based products will need to be cognizant of the changing regulatory landscape to ensure current compliance with enacted state laws as well as future compliance with proposed laws whose enactment is expected or at least reasonably possible.

12.6 Going Concern

12.6.1 Introduction

Much of the life sciences industry consists of small, research-focused private biotechnology firms that represent an important source of innovation. These firms are generally focused on a specific technology platform, a mechanism of action, or a handful of early-stage compounds, and many of these firms are not profitable or do not have commercial revenue streams. Given the substantial costs and timelines associated with biopharmaceutical R&D, attracting and sustaining investment remains an ongoing challenge. This landscape requires many life sciences entities to evaluate the going-concern uncertainty in their financial statements.

ASC 205-40 provides guidance on when and how to disclose going-concern uncertainties in the financial statements. It requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable).⁴ Under ASC 205-40, an entity must provide certain disclosures if conditions or events "raise substantial doubt about the entity's ability to continue as a going concern."

12.6.2 Disclosure Threshold

An entity is required to disclose information about its potential inability to continue as a going concern when there is "substantial doubt" about its ability to continue as a going concern, which ASC 205-40 defines as follows:

ASC 205-40 — Glossary

Substantial Doubt About an Entity's Ability to Continue as a Going Concern

Substantial doubt about an entity's ability to continue as a going concern exists when conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). The term *probable* is used consistently with its use in Topic 450 on contingencies.

When applying this disclosure threshold, entities are required to evaluate "relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued." Reasonably knowable conditions or events are those that can be identified without undue cost and effort.

ASC 205-40-55-2 provides the following examples of events that suggest that an entity may be unable to meet its obligations:

- a. Negative financial trends, for example, recurring operating losses, working capital deficiencies, negative cash flows from operating activities, and other adverse key financial ratios
- b. Other indications of possible financial difficulties, for example, default on loans or similar agreements, arrearages in dividends, denial of usual trade credit from suppliers, a need to restructure debt to avoid default, noncompliance with statutory capital requirements, and a need to seek new sources or methods of financing or to dispose of substantial assets
- c. Internal matters, for example, work stoppages or other labor difficulties, substantial dependence on the success of a particular project, uneconomic long-term commitments, and a need to significantly revise operations
- d. External matters, for example, legal proceedings, legislation, or similar matters that might jeopardize the entity's ability to operate; loss of a key franchise, license, or patent; loss of a principal customer or supplier; and an uninsured or underinsured catastrophe such as a hurricane, tornado, earthquake, or flood.

12.6.3 Time Horizon

In each reporting period (including interim periods), an entity is required to assess its ability to meet its obligations as they become due for one year after the date the financial statements are issued or available to be issued.⁵

⁴ An entity that is neither an SEC filer nor a conduit bond obligor for debt securities that are traded in a public market would use the date on which the financial statements are available to be issued (in a manner consistent with ASC 205-40's definition of the term "financial statements are available to be issued").

⁵ See footnote 4.

12.6.4 Disclosure Content

If an entity triggers the substantial-doubt threshold, its footnote disclosures must contain the following information, as applicable:

Substantial Doubt Is Raised but Is Alleviated by Management's Plans	Substantial Doubt Is Raised and Is Not Alleviated
<ul style="list-style-type: none"> • Principal conditions or events. • Management's evaluation. • Management's plans. 	<ul style="list-style-type: none"> • Principal conditions or events. • Management's evaluation. • Management's plans. • Statement that there is "substantial doubt about the entity's ability to continue as a going concern."

ASC 205-40 explains that these disclosures may change over time as new information becomes available and that disclosure of how the substantial doubt was resolved is required in the period in which substantial doubt no longer exists (before or after consideration of management's plans). In addition, the mitigating effects of management's plans to alleviate substantial doubt should be evaluated only if (1) the plans are approved before the financial statement issuance date and (2) both of the following conditions in ASC 205-40-50-7 are met:

- a. It is probable that management's plans will be effectively implemented within one year after the date that the financial statements are issued.
- b. It is probable that management's plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued.

12.6.5 Impairment Considerations Related to Long-Lived Assets and Indefinite-Lived Intangible Assets Other Than Goodwill

When an entity concludes that there is substantial doubt about its ability to continue as a going concern, it should consider whether there is an indicator of impairment of long-lived assets. ASC 360-10-35-21 requires that an entity test a long-lived asset (asset group) classified as held and used for impairment "whenever events or changes in circumstances indicate that its carrying amount may not be recoverable." ASC 360-10-35-21 gives examples of events or changes in circumstances that may indicate that the carrying amount of a long-lived asset (asset group) may not be recoverable. Although a substantial doubt about an entity's ability to continue as a going concern is not explicitly provided as an example of impairment, the examples in ASC 360-10-35-21 are not all-inclusive. Entities will need to assess their specific facts and circumstances in determining whether there is an indicator of impairment of long-lived assets.

If an entity determines that an indicator of impairment of long-lived assets exists, it must test its long-lived assets for recoverability. Provided that the entity's financial statements continue to be presented on a going-concern basis (i.e., not on a liquidation basis of accounting), the cash flow estimates the entity uses for recoverability testing may extend beyond one year on the basis of the remaining useful life of the primary asset. However, an entity should ensure that its cash flow estimates are reasonable given the circumstances. In addition, if there is substantial doubt about an entity's ability to continue as a going concern, it is more likely that the entity is considering alternative courses of action and, therefore, that use of a probability-weighted approach to estimate cash flows may be warranted.

Indicators of impairment of indefinite-lived intangible assets such as capitalized IPR&D may also exist as a result of a substantial doubt about the entity's ability to continue as a going concern. ASC 350-30-35-18B provides examples of events and circumstances that could affect the significant inputs used to determine the fair value of an indefinite-lived intangible asset. Although substantial doubt about an entity's ability to continue as a going concern is not explicitly listed as an example of such events and circumstances, ASC 350-10-30-18B does explicitly include in its list of examples the contemplation of bankruptcy and other relevant entity-specific events that could affect significant inputs used to determine the fair value of the indefinite-lived intangible asset, which are events and circumstances that may lead to substantial doubt about an entity's ability to continue as a going concern.

The impairment test for indefinite-lived intangible assets other than goodwill compares an asset's fair value with its carrying value. Under ASC 820, fair value is determined on a market-participant basis, whereas a substantial doubt about an entity's ability to continue as a going concern is a circumstance that is specific to the entity. While the existence of substantial doubt may not directly affect the determination of an indefinite-lived intangible asset's fair value, an entity should consider whether the events and circumstances that resulted in substantial doubt also affect any significant inputs that are used to determine the fair value of the indefinite-lived intangible asset.

12.7 Health Tech

The health tech marketplace remains a high-growth environment in which participants provide technology and service solutions to a wide spectrum of health care incumbents, including providers, payers, life sciences organizations, and transactional players. It encompasses a wide range of digital tools, devices, and platforms designed to enhance the efficiency, accessibility, and quality of health care services. Health tech entities may provide clinical decision support, drug discovery/bioinformatics software, health care administration software, and medical imaging software. They may also offer other products or services, including clinical trial database management, decision support tools for drug discovery, online marketplaces for pharmaceuticals R&D, medicinal prediction using artificial intelligence (AI), and Web-based simulation for R&D.

Health tech entities continue to disrupt long-standing business models and methods of health care delivery as well as sources of health information and ways to access it. Emerging technologies (e.g., AI, virtual and augmented reality, telehealth, blockchain) and monitoring devices (e.g., sensors, wearables, ingestibles) are providing real-time and continuous data about our health and our environment. Such innovations are redefining the future of health care and health delivery. Health care and health tech companies can use these innovations to provide more accurate diagnoses, deliver personalized treatment, and predict risk or deterioration and intervene early.

Health tech product and service offerings are enablers in digital transformation for health care, which remains a key focus in the life sciences industry and is driven by advancements in cloud computing, generative AI, and other digital technologies. According to Deloitte's [2025 US Health Care Outlook](#) (the "outlook report"), "[s]ixty-five percent of health care executives [surveyed by the Deloitte Center for Health Solutions] identified 'developing growth strategies to increase revenue' as a priority, making it the top action for 2025. However, growth is unlikely to be driven by a single strategy. Instead, survey respondents indicated they intend to take a multidimensional approach," which, as recommended in the outlook report, should include (1) investments in digital platforms and consumer-facing digital technologies and (2) expanding services for virtual health.

Much of the interpretive guidance in this Guide is likely to be applicable to health tech entities. Further, given the development and use of software in connection with the product/service offerings within the health tech space, some of the more narrow-scope considerations related to the use of software that have historically been the focus of more traditional technology companies — in particular, considerations related to the capitalization of software costs and the recognition of revenue from the sale of software products and services — could be important to entities operating in the health tech space. Such considerations are discussed below.

For additional information about the technical accounting topics discussed below, see Deloitte's [Health Tech Industry Accounting Guide](#), which is aimed at providing in-depth information on these topics for our clients and industry professionals.

12.7.1 Capitalized Software

As technology evolves, health tech companies typically incur myriad costs related to software. For example, cloud-based arrangements have revolutionized the business and technology landscape, offering more flexible and often lower-cost IT solutions that allow health tech companies to outsource traditional in-house systems to off-site, on-demand solutions designed to support health and wellness. In addition, an increasing number of processes are managed by using automated solutions. This has resulted in entities' incurring increasing amounts of software-related costs as they either purchase licenses to on-premise software products or contract with vendors to access and use software solutions over the Internet (e.g., cloud computing or software as a service [SaaS]). Health tech companies also frequently use hybrid deployments, in which they purchase or develop on-premise software (some of which may be deployed in a private cloud environment) and use that software in conjunction with another cloud-based third-party platform (i.e., a public cloud). Further, health tech companies may incur costs to develop software for their own internal use as well as for external sales to customers. Entities incurring such costs will need to determine whether they represent assets that can be capitalized under the applicable accounting standards. Different accounting guidance exists for costs related to software that is (1) obtained or developed for internal use ("internal-use software," such as software that will be used to provide a service, including SaaS arrangements), (2) accessed in a cloud-based (or hosting) arrangement that is a service contract, or (3) to be sold, leased, or marketed ("external use software"):

- *Internal-use software* — In determining whether software meets the definition of internal-use software, an entity should consider the guidance in ASC 350-40-15-2A, which states:

Internal-use software has both of the following characteristics:

- a. The software is acquired, internally developed, or modified solely to meet the entity's internal needs.
- b. During the software's development or modification, no substantive plan exists or is being developed to market the software externally.

In certain situations, software accessed in a hosted environment could be considered internal-use software under ASC 350-40. In determining whether hosted software meets the definition of internal-use software, a customer (i.e., the purchaser of such service) should consider the guidance in ASC 350-40-15-4A, which states:

The guidance in the General Subsections of this Subtopic applies only to internal-use software that a customer obtains access to in a hosting arrangement if both of the following criteria are met:

- a. The customer has the contractual right to take possession of the software at any time during the hosting period without significant penalty.
- b. It is feasible for the customer to either run the software on its own hardware or contract with another party unrelated to the vendor to host the software.

Health tech entities will have to carefully evaluate whether the criteria in ASC 350-40-15-4A are met. If both of the criteria are met, the related software is considered internal-use software regardless of whether it is (1) being hosted by a third-party vendor or (2) interacting with software that is subject to a cloud computing arrangement (i.e., software that the entity cannot take possession of). If either of the criteria in ASC 350-40-15-4A is not met, the software is considered part of a hosting arrangement that is a service contract.

- *Software accessed in a cloud-based (or hosting) arrangement that is a service contract* — Capitalized costs associated with a service contract differ in character from costs that are capitalized in connection with developing or obtaining internal-use software. As a result, costs that are capitalized in connection with implementing a service contract are likely to be presented differently. Many entities, including health tech companies, are implementing software solutions that combine hosted software in a service contract with owned or licensed (i.e., internal-use) software. Eligible costs incurred to implement a cloud computing arrangement that is a service contract should be deferred as a prepaid asset and presented in a company's financial statements in the same line item in the income statement as the hosting service expense (e.g., as an operating expense). Such presentation is consistent with the classification of other service costs and assets related to service contracts. That is, these costs would be capitalized as part of the service contract, and the financial statement presentation of the cash flows, the resulting asset, and the related subsequent expense would be consistent with the ongoing periodic costs of the underlying cloud computing arrangement that is a service contract.
- *External-use software* — ASC 985-10-15-3 indicates that costs of "computer software to be sold, leased, or otherwise marketed as a separate product or as part of a product or process" should be accounted for as costs of external-use software under ASC 985-20 regardless of whether the computer software is (1) purchased or (2) internally developed and produced. The guidance in ASC 350-40 does not apply to any software for which a "substantive plan exists or is being developed to market the software externally." Therefore, if an entity purchases or develops software that it intends to use internally, but it also has a substantive plan to market that software externally, the full amount of the cost of the software should be accounted for under ASC 985-20 (i.e., costs should not be allocated between customer-facing and internal solutions). In addition, if a health tech company incurs costs to develop a software product as a licensed on-premise solution and also offers the software solution as a service to its customers, it should account for such costs under ASC 985-20.

It is critical for health tech companies to properly identify software development costs and determine how to account for them since the guidance on capitalization varies significantly depending on the type of software involved. Further, if an entity begins to sell, lease, or otherwise market what it previously classified as internal-use software as a separate product or as part of a product or process, the entity should reconsider the guidance on capitalizing internal-use software costs.

12.7.2 Revenue Recognition

Common go-to-market products and services of health tech companies include the following:

- *SaaS* — A health tech entity's contract to sell SaaS to a customer is typically referred to as a cloud computing arrangement, in which the customer does not take possession of the product and the performance obligation is considered a service provided by the health tech entity.
- *On-premise perpetual or subscription licenses* — These are considered promises related to products sold by the health tech entity to its end customer at a point in time. Such products are commonly sold along with postcontract customer support and other goods or services.

Many health tech companies use SaaS as their preferred customer delivery mechanism as they digitize current service offerings and update current software offerings. Health tech companies often develop a SaaS platform on which they provide their services to customers via access to a hosted platform rather than giving their customers the software code. In contrast, the software delivery model, often referred to as an “on-premise” model, involves the delivery of the underlying software code to customers at a point in time.

Health tech entities should carefully assess the products and services they are providing since the nature of those products and services, and the related determination of the performance obligations in a contract, can significantly affect the timing and amount of revenue to be recognized. The core principle of the revenue standard is to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which an entity expects to be entitled in exchange for those goods and services. Significant judgments frequently need to be made when an entity evaluates the appropriate recognition of revenue from contracts with customers. These judgments are often required throughout the revenue standard’s five-step process that an entity applies to determine when, and how much, revenue should be recognized.

When third parties are involved in providing goods or services to customers, health tech companies may also encounter challenges related to whether they should recognize revenue and the associated cost of services at a gross amount or record the revenue and cost on a net basis. For an entity to determine whether the nature of its promise to a customer is to transfer goods or services on its own (in which case, the entity acts as a principal) or to arrange for another party to transfer goods or services (in which case, the entity acts as an agent), the entity must first identify each specified good or service (or bundle of goods or services) that is distinct and then assess whether the entity obtains control of each specified good or service (or a right to a good or service) before it is transferred to the customer. ASC 606-10-25-25 defines control as “the ability to direct the use of, and obtain substantially all of the remaining benefits from, the asset.” Determining whether the entity controls the specified good or service before transferring it to the customer — and, therefore, is the principal in the arrangement — may be clear in some circumstances but may require significant judgment in others. In arrangements involving more than one distinct good or service, an entity could be a principal for certain aspects of a contract with a customer and an agent for others.

12.7.3 Costs of Obtaining a Contract

Health tech companies may need to recognize as an asset the incremental costs of obtaining a contract with a customer, such as sales commissions, if recovery of those costs is expected. Determining which items qualify as incremental costs of obtaining a contract may be complex since certain cost structures, such as commission plans, may have different terms for each health tech company that would require additional assessment.

In many circumstances, it may be clear whether particular costs are costs that a health tech entity incurs to obtain a contract. For example, if an entity incurs a commission liability solely as a result of obtaining a contract with a customer, the commission would be an incremental cost of obtaining that contract. However, in other circumstances, an entity may need to exercise judgment and consider existing accounting policies for liability accruals when determining whether a cost is incurred in connection with obtaining a contract with a customer. If the determination of whether a cost has been incurred is affected by other factors (i.e., factors in addition to obtaining a contract with a customer), an entity will need to take additional considerations into account when assessing whether a cost is an incremental cost associated with obtaining a contract with a customer.

Therefore, health tech companies should refer to ASC 340-40, which contains comprehensive guidance on accounting for costs of obtaining a contract within the scope of ASC 606.

The example below illustrates an entity's accounting for sales commissions.

Example 12-2

Entity A's internal salespeople earn a commission based on a fixed percentage (4 percent) of sales invoiced to a customer. Half of the commission is paid when a contract with a customer is signed; the other half is paid after 12 months, but only if the salesperson is still employed by A. Entity A concludes that a substantive service period is associated with the second commission payment, and A's accounting policy is to accrue the remaining commission obligation ratably as the salesperson provides ongoing services to A.

Entity A enters into a three-year noncancelable service contract with a customer on January 1, 20X7. The total transaction price of \$3 million is invoiced on January 1, 20X7. The salesperson receives a commission payment of 2 percent of the invoice amount (\$60,000) when the contract is signed; the other half of the 4 percent commission will be paid after 12 months if the salesperson continues to be employed by A at that time. That is, if the salesperson is not employed by A on January 1, 20X8, the second commission payment will not be made. Entity A records a commission liability of \$60,000 on January 1, 20X7, and accrues the second \$60,000 commission obligation ratably over the 12-month period from January 1, 20X7, through December 31, 20X7.

Entity A concludes that only the first \$60,000 is an incremental cost incurred to obtain a contract with a customer. Because there is a substantive service condition associated with the second \$60,000 commission, A concludes that the additional cost is a compensation cost incurred in connection with the salesperson's ongoing service to A. That is, the second \$60,000 commission obligation was not incurred solely to obtain a contract with a customer but was incurred in connection with ongoing services provided by the salesperson.

If the salesperson would be paid the commission even if no longer employed, or if A otherwise concluded that the service condition was not substantive, the entire \$120,000 would be an incremental cost incurred to obtain a contract and would be capitalized in accordance with ASC 340-40-25-1. Entities will need to exercise professional judgment when determining whether a service condition is substantive.

12.8 PCAOB Requirements Related to CAMs in the Auditor's Report

PCAOB AS 3101, *The Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion* (the "standard"), requires CAMs to be included in the auditor's report. CAMs are intended to increase the informational value, usefulness, and relevance of the auditor's report.

12.8.1 Critical Audit Matters

Under the standard, a CAM is defined as "any matter arising from the audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved especially challenging, subjective, or complex auditor judgment."

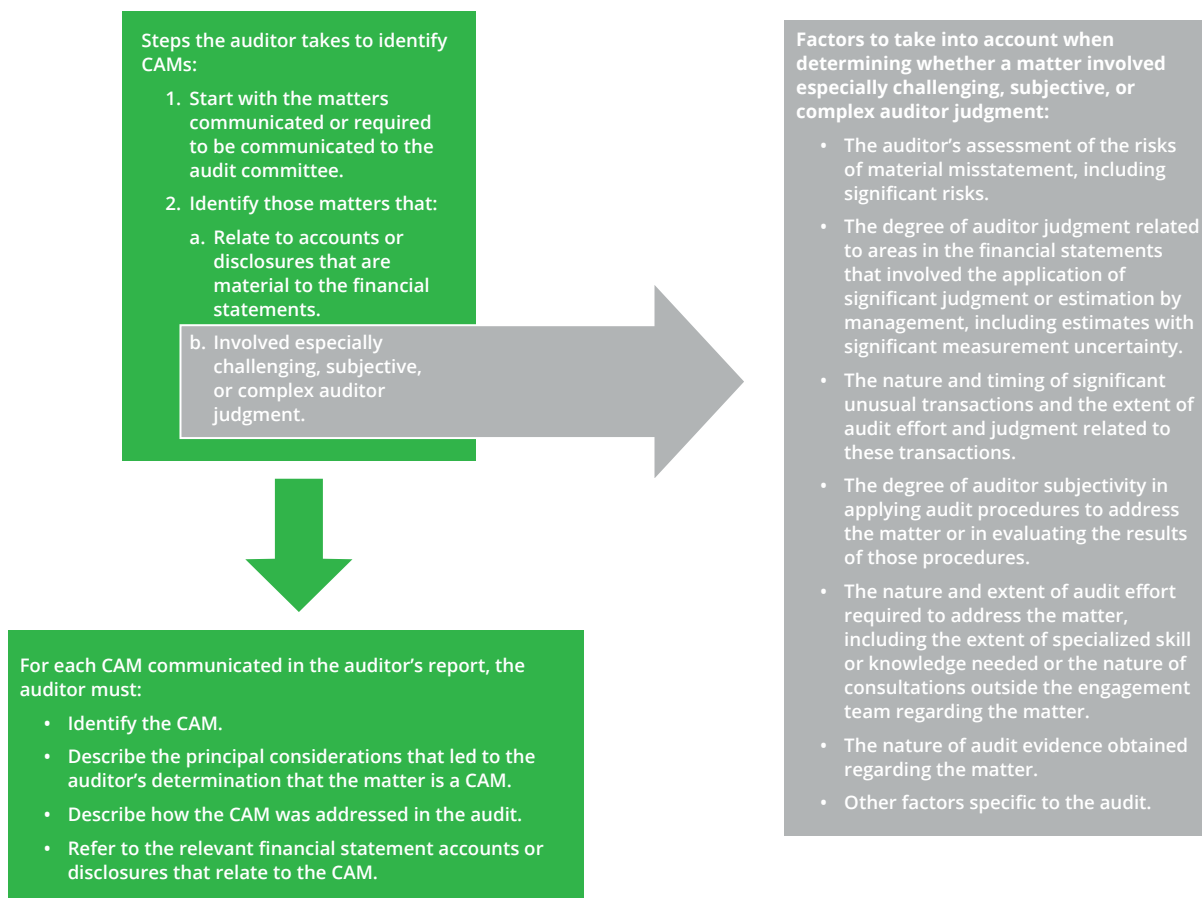
The standard includes a nonexclusive list of factors for the auditor to take into account, alone or in combination, in determining whether a matter involved especially challenging, subjective, or complex auditor judgment.

In accordance with the standard, CAMs are identified and described in a separate section of the auditor's report titled "Critical Audit Matters." Specific language precedes the description of the CAMs, stating that (1) CAMs do not alter the opinion on the financial statements and (2) the auditor is not providing a separate opinion on the CAMs or the accounts or disclosures to which they relate. For each CAM communicated in the auditor's report, the auditor is required to:

- "Identify the [CAM]."
- "Describe the principal considerations that led the auditor to determine that the matter is a [CAM]."
- "Describe how the [CAM] was addressed in the audit."
- "Refer to the relevant financial statement accounts or disclosures that relate to the [CAM]."

As stated in the PCAOB's [release](#) announcing its adoption of the standard (the "adopting release"), the determination of a CAM "should be made in the context of [a] particular audit, with the aim of providing audit-specific information rather than a discussion of generic risks." It is expected that in most audits to which the CAM requirements apply, the auditor would identify at least one CAM. If no CAMs are identified, the auditor is required to make a statement to that effect in the auditor's report.

The chart below, which is adapted from the adopting release, illustrates the auditor's decision process for identifying and communicating CAMs.



12.8.2 Applicability

Communication of CAMs is not required for audits of (1) brokers and dealers reporting under Rule 17a-5 of the Exchange Act; (2) investment companies registered under the Investment Company Act of 1940, other than companies that have elected to be regulated as business development companies; (3) employee stock purchase, savings, and similar plans; and (4) EGCs (as defined in Section 3(a)(80) of the Exchange Act). Auditors of these entities may consider voluntarily including communication of CAMs as described in the standard.

12.8.3 Considerations for Auditors, Management, and Audit Committees

The auditor is encouraged to discuss with management and the audit committee the types of matters related to the current-year audit that have been identified by the auditor and may be communicated as CAMs, including all matters communicated or required to be communicated to the audit committee.

Potential questions for management and audit committees regarding CAMs may include the following:

- What matters could be CAMs?
- How will management and audit committees engage with the auditor as CAMs are identified and the auditor's descriptions of the CAMs are developed and finalized?
- How do the auditor's statements regarding CAMs compare with management's disclosures regarding the same matters? Has management considered whether disclosures related to matters that may be CAMs need to be enhanced?

12.9 Structured Trade Payable Arrangements

When an entity purchases goods or services on credit from a supplier (vendor), a trade payable arises for the invoice amount owed to the supplier. Sometimes, life sciences entities with trade payables enter into arrangements with a bank or other intermediary under which the intermediary offers to purchase receivables held by the entity's suppliers. Such arrangements are known by various names, such as "structured payable arrangements," "vendor payable programs," "open account structured vendor payable programs," "reverse factoring," "supplier finance," or "supplier-chain finance."

Examples of structured payable arrangements include (1) open account platforms that permit an entity's suppliers to elect to sell trade receivables to one or more participating intermediaries, (2) an entity's use of charge cards issued by a financial institution to settle invoices, and (3) an entity's issuance of negotiable instruments (e.g., bills of exchange) to settle invoices.

Typically, open account platforms give participating suppliers the option to settle trade receivables by obtaining a payment from an intermediary either (1) before the invoice date at a discounted amount or (2) on the invoice due date for its full amount. Although the supplier may receive payment early, the purchasing entity is not required to settle its trade payable with the intermediary until the original invoice date.

Depending on its terms, a structured trade payable arrangement offers the parties various potential benefits, such as the following:

- *Suppliers' ability to monetize trade receivables and reduce the associated credit exposure* — By selling their trade receivables to an intermediary, suppliers can receive payment before the invoice due date and reduce their credit exposure.
- *Purchasers' ability to obtain extended payment terms* — Suppliers may be more willing to offer extended payment terms to purchasers if they can obtain early payment from intermediaries. Further, intermediaries may offer purchasers extended payment terms.
- *Intermediaries' ability to benefit from early-payment discounts, rebates, and transaction fees and charges* — Intermediaries earn a spread on the basis of the relationship between their funding costs and the amount of early-payment discounts, rebates, and other fees and charges received from suppliers.
- *Operational benefits* — Because of an intermediary's involvement, the arrangement may enhance the processing, administration, and control of the associated payments for purchasers and suppliers.
- *Extended early-payment discount period* — If an intermediary pays a supplier within the period during which the supplier offers an early-payment discount (e.g., a 2 percent discount for payment within 10 days of an amount due in 30 days, or 2/10 net 30), for instance, the intermediary may offer the purchasing entity a discount on the amount due for an extended period (e.g., 1/10 net 60).
- *Reduction in the amount due or other similar rebate* — The intermediary may offer the purchasing entity a reduction of the amount due or a reimbursement of part of the amount paid on the basis of net amounts paid to suppliers. (A supplier may agree to pay the intermediary a fee or reduce the amount due because of benefits it receives from the arrangement, such as a lowered credit risk exposure on the amount due or earlier payment of such amount.)

If an entity has a trade payable arrangement involving an intermediary, it should consider how to appropriately present and disclose the amount payable. SEC Regulation S-X, Rule 5-02(19)(a), requires SEC registrants to present amounts payable to trade creditors separately from borrowings on the face of the balance sheet. Accordingly, a purchasing entity that participates in a trade payable program involving an intermediary should consider whether the intermediary's involvement changes the appropriate presentation of the payable from a trade payable to a borrowing from the intermediary (e.g., bank debt). Entities often seek to achieve trade payable classification because trade payables tend to be treated more favorably than short-term indebtedness in the calculation of financial ratios (e.g., balance sheet leverage measures) and in the determination of whether financial covenants are met. Further, the determination of whether the payable should be presented as an amount owed to trade creditors or as an amount borrowed from the intermediary may affect the appropriate cash flow classification (see below for further discussion).

Generally, a supplier's decision to factor a trade receivable to a bank or other financial institution does not affect the purchaser's presentation of the associated trade payable if the factoring terms are negotiated and agreed to independently by the supplier and the institution without any involvement of the purchaser, which may not even be aware of the factoring transaction. Similarly, an entity's decision to outsource its supplier processing payments to an intermediary does not necessarily cause a reclassification of associated trade payables if the terms of the payables remain unaffected and the entity is not involved in, or does not benefit from, transactions between the suppliers and the intermediary. In other words, if the intermediary's involvement does not change the nature, amount, and timing of the entity's payables and does not provide the entity with any direct economic benefit,

continued trade payable classification may be appropriate. However, reclassification may be required if such changes or benefits result from the intermediary's involvement (e.g., because fees or rebate payments were received from the intermediary).

In speeches at the 2003 and 2004 AICPA Conferences on Current SEC and PCAOB Developments, Robert Comerford, then a professional accounting fellow in the OCA, discussed the SEC staff's views about the presentation of certain trade payable arrangements involving an intermediary as trade payables or short-term borrowings. At the 2004 event, he **stated** the following:

As a general rule, the OCA Staff does not believe that it is possible to determine the appropriate accounting for structured transactions simply via reference to checklists and templates. Rather, . . . an entity must perform a thorough analysis of all the facts and circumstances specific to the individual transaction in order to ensure that the entity's accounting for the transaction serves investors well. [T]his necessitates meeting not just the letter, but the spirit of the accounting literature.

Mr. Comerford identified a number of points (summarized below) that the SEC staff encourages preparers and auditors to consider in determining whether amounts due in trade payable arrangements involving an intermediary should be classified as trade payables or borrowings. He also noted that a registrant may wish to preclear its proposed classification with the OCA if there is a risk that its position could be subject to challenge. Given the subjective nature of the evaluation and the lack of prescriptive guidance, alternative views may be acceptable in some circumstances.

SEC Staff Consideration Point	Related SEC Staff Observations	Deloitte Observations
What are "the roles, responsibilities and relationships of each party" to the arrangement? What is "the totality of the arrangement"?	By analogy to a supplier's factoring of accounts receivables, the definition of factoring "does not make any mention of the [purchaser] actively or passively participating in the process."	It can be helpful to consider whether the intermediary's role in the arrangement is primarily that of (1) a factor of supplier receivables, (2) a finance provider to the entity, or (3) the entity's paying agent. If the intermediary's involvement does not change the nature, amount, and timing of the entity's payments and does not provide the entity with any direct economic benefit, continued trade payable classification may be appropriate. See below for further discussion.
"Does the financial institution make any sort of referral or rebate payments" to the purchaser?	By analogy to a supplier's factoring of accounts receivables, the definition of factoring "does not make any mention of [the supplier's] customer receiving . . . any referral fees or rebates."	If the entity receives no fees, rebates, payments, or other direct economic benefits from transactions between suppliers and the intermediary, continued trade payable classification may be appropriate. An entity's receipt of referral or rebate payments from the intermediary (e.g., on the basis of fees, early-settlement discounts collected by the intermediary, or a dollar-volume-based rebate) suggests that continued classification of a payable as an amount owed to trade creditors may no longer be appropriate. In practice, classifying payables as trade payables has been considered unacceptable when the purchaser shares in early-settlement discounts collected by the intermediary from the supplier (e.g., the intermediary provides a rebate to the purchaser that is equivalent to half of a 2 percent early-settlement discount received from the supplier).

(Table continued)

SEC Staff Consideration Point	Related SEC Staff Observations	Deloitte Observations
"Has the financial institution reduced the amount due . . . , such that the amount due is less than the amount the [entity] would have had to pay to the vendor on the original payable due date?"	By analogy to a supplier's factoring of accounts receivables, the definition of factoring does not "make any mention of the [supplier's] customer receiving any reductions in the amount of its obligation."	If the entity's original invoice terms remain the same, continued trade payable classification may be appropriate. An intermediary's reduction of the amount due from the entity may suggest that continued classification of a payable as an amount owed to trade creditors is no longer appropriate.
"Has the financial institution extended beyond the payable's original due date, the date on which payment is due?"	By analogy to a supplier's factoring of accounts receivables, the definition of factoring does not "make any mention of [the supplier's] customer receiving . . . any extension of its trade payable maturity dates beyond that which were customary prior to inception of the arrangement [e.g.,] 2/10 net 30."	Payment terms and amounts that remain consistent with those of the entity's other vendor payables and industry practice may suggest that continued classification as a trade payable may be appropriate. However, if the intermediary is not merely facilitating the payment of the entity's invoice but extending the entity's due date to a date after the original invoice due date and the date the intermediary pays suppliers, the entity's arrangement may, in substance, be a borrowing from the intermediary.
The literal definition of the term "trade creditor."	"The OCA Staff believes that a trade creditor is a supplier that has provided an entity with goods and services in advance of payment."	Generally, third-party factoring arrangements involving an entity's payables do not preclude trade payable classification if the entity has no involvement and is not a party to contracts entered into between the supplier and the factor. If the creditor at origination is a supplier, therefore, the supplier's subsequent sale of its receivable to a factor does not necessarily change the nature of that trade payable so that reclassification is required.

As noted above, one of the consideration points is related to the roles, responsibilities, and relationships among the parties and the totality of the arrangement, such as whether the intermediary's primary role in the arrangement is that of a factor of supplier receivables, a finance provider to the purchaser, or a paying agent of the purchaser. In some arrangements, the intermediary may serve both as a paying agent and a factor or finance provider (e.g., if the intermediary gives suppliers the option to either receive payment on the original invoice due date or to transfer trade receivables to the intermediary before the due date at a discounted amount).

Further, the determination of whether the payable should be presented as an amount owed to trade creditors or an amount borrowed from the intermediary may affect the appropriate cash flow statement classification. If a trade payable arrangement involving an intermediary must be classified as a borrowing, the entity should consider the associated cash flow statement implications (see [Section 7.13](#) of Deloitte's Roadmap *Statement of Cash Flows*).

For more information, see [Section 14.3.1.3.1](#) of Deloitte's Roadmap *Issuer's Accounting for Debt*.

12.9.1 Disclosure Considerations

ASC 405-50 requires the buyer in a supplier finance program to disclose qualitative and quantitative information about the program. Under ASC 405-50-15-2, such a program is defined as “an arrangement that has all the following characteristics:”

- “An entity enters into an agreement with a finance provider or an intermediary.”
- “The entity confirms supplier invoices as valid to the finance provider or intermediary under the agreement.”
- “The entity’s supplier has the option to request early payment from a party other than the entity for invoices that the entity has confirmed as valid.”

The disclosure requirements in ASC 405-50 apply regardless of whether the entity classifies its liabilities under a supplier finance program as a trade payable or on another balance sheet line (e.g., debt).

ASC 405-50 does not apply to any of the following:

- The intermediary or supplier in a supplier finance program.
- Traditional credit card programs for which an intermediary is directed to pay the supplier on behalf of an entity.
- Payment processing arrangements that do not give a supplier the option to request early payment.
- Arrangements that extend, or give an entity the option to extend, the payment terms associated with the payment due date in the related invoice.
- Credit enhancements, such as letters of credit or financial guarantees, provided by an intermediary to a supplier on an entity’s behalf.

ASC 405-50-50-3 and 50-4 specify the disclosures for annual and interim periods, and ASC 405-50-55-4 and 55-5 illustrate how to disclose the rollforward information required under ASC 405-50-50-3(b)(2). (Note that entities do not have to provide these disclosures until fiscal years beginning after December 15, 2023, although early adoption is permitted.)



Connecting the Dots

ASC 405-50-50-3(b) requires entities to provide certain disclosures related to “[t]he amount of obligations outstanding at the end of the reporting period that the entity has confirmed as valid to the finance provider or intermediary under the program.” Questions have arisen related to whether these disclosures are limited to the amount that the finance provider or intermediary has funded (i.e., the amount the supplier has been paid by the finance provider or intermediary before the related invoice due date). However, this requirement applies to the amount that remains unpaid by the entity irrespective of whether the supplier has been paid. There is no requirement in ASC 405-50 to disclose the amount funded by the finance provider or intermediary.

For more information, see [Section 14.3.1.2](#) of Deloitte’s Roadmap *Issuer’s Accounting for Debt*.

12.10 Foreign Currency Accounting Considerations

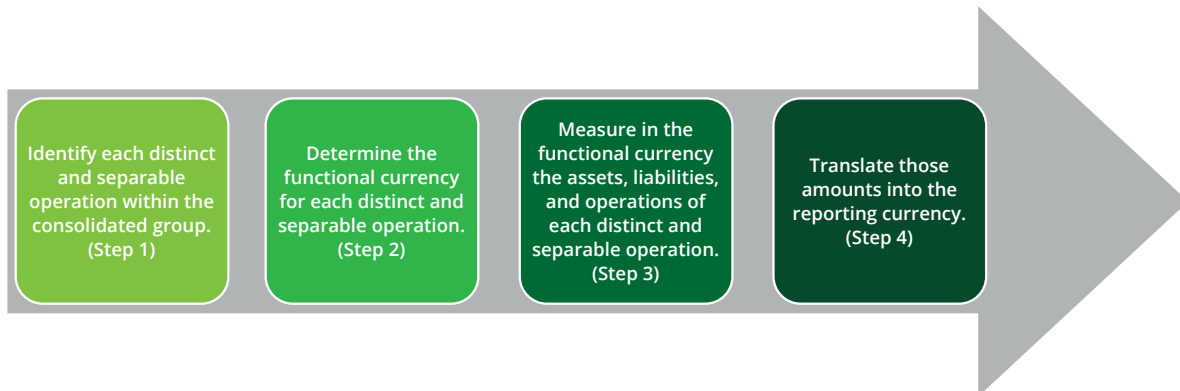
12.10.1 Overview

Since the issuance of FASB Statement 52 (codified in ASC 830) in 1981, domestic and international economies have become more interdependent. As a result, international operations have become more complex and generally represent a much larger portion of a company's overall financial results. This globalization has led many life sciences companies to consider strategic opportunities through international expansion, reorganize their operating models, and often transact with customers and partners in multiple currencies.

The primary objective of ASC 830 is for reporting entities to present their consolidated financial statements as though they are the financial statements of a single entity. Therefore, if a reporting entity operates in more than one currency environment, it must translate the financial results of those operations into a single currency (referred to as the reporting currency). However, this process should not affect the financial results and relationships that were created in the economic environment of those operations.

In accordance with the primary objective of ASC 830, a reporting entity must use a “functional-currency approach” in which all transactions are first measured in the currency of the primary economic environment in which the reporting entity operates (i.e., the functional currency) and then translated into the reporting currency.

Under the functional-currency approach, the reporting entity must perform four steps:



Because the functional-currency approach requires an entity to measure the assets, liabilities, and operations in the functional currency, an entity that enters into transactions in currencies other than its functional currency must first remeasure those amounts in its functional currency before they are translated into the reporting currency.



Connecting the Dots

It is important to understand the difference between *remeasurement* and *translation* under ASC 830. By remeasuring financial results in the functional currency, an entity provides information about its future net cash flows. That is, as exchange rates fluctuate, so too will the related cash flows. For this reason, the effects of remeasurement are generally reported in the income statement. Translation, on the other hand, simply refers to the process of converting the financial statements from the functional currency into a different currency. In other words, the translation process has no impact on an entity's future cash flows. For this reason, the effects of translation are reported in equity.

12.10.1.1 Decision Points



The first step in applying the functional-currency approach under ASC 830 is to identify each distinct and separable operation within the consolidated group. While ASC 830 does not explicitly define “distinct and separable operation,” ASC 830-10-45-5 states:

An entity might have more than one distinct and separable operation, such as a division or branch, in which case each operation may be considered a separate entity. If those operations are conducted in different economic environments, they might have different functional currencies.

ASC 830-10-45-5 highlights that the functional currency could be different for each distinct and separable operation, even if those operations are part of the same entity. Therefore, to correctly determine the functional currency under ASC 830, reporting entities must evaluate whether a single entity contains two or more distinct operations.



Connecting the Dots

ASC 830-10-45-5 clarifies that each distinct and separable operation of the reporting entity is considered a separate “entity” when the requirements of ASC 830 are applied. Furthermore, ASC 830-10-20 defines a “foreign entity” and “reporting entity” as follows:

Foreign Entity

An operation (for example, subsidiary, division, branch, joint venture, and so forth) whose financial statements are both:

- a. Prepared in a currency other than the reporting currency of the reporting entity
- b. Combined or consolidated with or accounted for on the equity basis in the financial statements of the reporting entity.

Reporting Entity

An entity or group whose financial statements are being referred to. Those financial statements reflect any of the following:

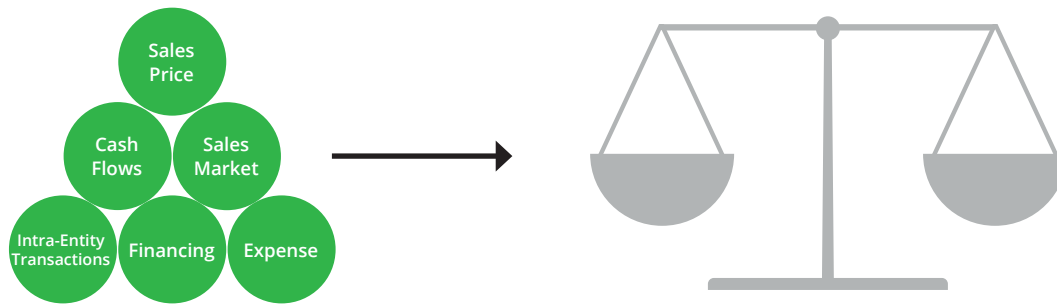
- a. The financial statements of one or more foreign operations by combination, consolidation, or equity accounting
- b. Foreign currency transactions.

Accordingly, each “distinct and separable operation” whose financial statements are prepared in a currency other than the reporting currency of the reporting entity (i.e., the direct parent entity) would be considered a “foreign entity.” Therefore, throughout this Guide’s discussion of foreign currency accounting considerations, the terms “distinct and separable operation” and “foreign entity” are used interchangeably.

After identifying the distinct and separable operations, the reporting entity must determine the functional currency of each one. This step is critical to the successful application of ASC 830 since the functional currency directly affects the identification and measurement of foreign currency transactions and the translation of the financial statements.

ASC 830 defines functional currency as “the currency of the primary economic environment in which the entity operates; normally, that is the currency of the environment in which an entity primarily generates and expends cash.” ASC 830-10-45-6 further states that the “functional currency of an entity is, in principle, a matter of fact.” That is, the functional currency of an entity is not simply an election that the reporting entity makes but a determination that is made on the basis of facts.

It can be challenging to determine an entity’s functional currency, depending on the nature of the entity’s operations. Therefore, to help reporting entities determine the functional currency of their entities, ASC 830 provides the following indicators, which must be assessed both individually and collectively:



Once an entity has determined the functional currency on the basis of evaluating the indicators above, it is generally rare that this currency would change in the future. ASC 830-10-45-7 indicates that there must be “significant changes in economic facts and circumstances” to justify changing an entity’s functional currency. However, ASC 830 also requires an entity to change its functional currency to the reporting currency of its immediate parent if the economy in which the entity operates becomes highly inflationary.

12.10.2 Determining the Functional Currency

The first step in the functional-currency approach is to determine which foreign entities make up the reporting entity. To be considered a foreign entity, an operation (or set of operations) should have its own financial statements or be able to produce such statements. Accordingly, a foreign entity most likely would have a management team that uses dedicated resources to run the entity’s operations. The concept of “distinct and separable operations” is important to making this determination.

From a practical standpoint, a reporting entity may begin the determination of its distinct and separable operations by identifying each legal entity in its organizational structure. Next, the reporting entity must determine whether any of those legal entities have two or more distinct and separable operations (e.g., divisions, branches, product lines).

If a legal entity has more than one distinct and separable operation, a reporting entity would consider each operation a separate entity when applying the guidance in ASC 830. Otherwise, the legal entity itself would generally be considered the entity subject to ASC 830. Judgment must be used in the determination of whether a single legal entity has more than one separate and distinct operation, and the reporting entity must thoroughly understand how and where the legal entity conducts business.



Connecting the Dots

The term “foreign entity,” as used in ASC 830, refers to an entity that prepares its financial statements in a currency other than the reporting currency but does not refer to the entity’s geographic location. Therefore, an entity that is domiciled in the United States would meet the definition of a foreign entity under ASC 830 if it was consolidated by a reporting entity that has a reporting currency other than USD. Similarly, an entity that is domiciled in a foreign country would not meet the definition of a foreign entity under ASC 830 if it was consolidated by a reporting entity that has the same reporting currency as the entity. Therefore, the reporting entity must determine the functional currency of each distinct and separable operation (i.e., entity) within the consolidated group, regardless of where that operation is geographically located. The identification of foreign entities is important, since ASC 830 requires that the financial statements of each foreign entity be translated into the reporting currency.

12.10.2.1 Identifying Distinct and Separate Operations

ASC 830-10

45-5 An entity might have more than one distinct and separable operation, such as a division or branch, in which case each operation may be considered a separate entity. If those operations are conducted in different economic environments, they might have different functional currencies.

55-6 In some instances, a foreign entity might have more than one distinct and separable operation. For example, a foreign entity might have one operation that sells parent-entity-produced products and another operation that manufactures and sells foreign-entity-produced products. If they are conducted in different economic environments, those two operations might have different functional currencies. Similarly, a single subsidiary of a financial institution might have relatively self-contained and integrated operations in each of several different countries. In those circumstances, each operation may be considered to be an entity as that term is used in this Subtopic, and, based on the facts and circumstances, each operation might have a different functional currency.

ASC 830-10-45-5 presents the notion of a “distinct and separable operation” but offers no definition of or qualifying criteria related to such an operation. Further, a distinct and separable operation may or may not meet the definition of a business in ASC 805-10. Thus, management will need to use judgment and consider all facts and circumstances in determining which operations are distinct and separable. However, the following factors, while not exhaustive, may indicate that an operation is distinct and separable for purposes of the functional-currency analysis:

- The operation has specifically identifiable assets and liabilities (i.e., not shared or commingled with other operations’ assets and liabilities).
- The operation can be managed separately and apart from other operations of the reporting entity.
- Accounting records for the operation could be produced.

As noted previously, distinct and separable operations may be identified at a lower level than the legal entity itself. For instance, divisions or branches of the same legal entity (e.g., a subsidiary) may operate in different economic environments, in which case each may be considered a distinct and separable operation.

Under ASC 830, a reporting entity is not required to separate the accounting records of its operations if doing so is impracticable. Further, just because certain operations may be separable in some way (e.g., the operations have their own set of accounting records), the operations are not necessarily distinct and separable.

Reporting entities should carefully consider all facts and circumstances when determining whether an operation is distinct and separable. The following are some factors (not all-inclusive) indicating that operations may not be distinct and separable, even if separate accounting records are maintained:

- A legal entity's foreign division is solely responsible for manufacturing certain product lines for its parent.
- A holding company is essentially an extension of its parent or affiliate.
- A subsidiary or division functions only as a foreign sales office for its parent.
- Individual retail stores are managed centrally.
- A foreign subsidiary or division operates only as the treasury or internal administrative function for its parent.

For more information, see [Section 2.2.1](#) of Deloitte's Roadmap *Foreign Currency Matters*.

12.10.2.2 Definition of Functional Currency and Indicators

Once the distinct and separable operations have been identified, the next step is to determine the "currency of the primary economic environment in which the [distinct and separable operation] operates." An entity may be required to use significant judgment in making this determination, depending on the nature of the operation being evaluated. The following are two scenarios illustrating the determination of the functional currency:

- Entity A, a subsidiary of a U.S. parent, is an operating company located in France that is relatively autonomous. Entity A conducts all of its operations in France, and all of its transactions are denominated in EUR.
- Entity B, a subsidiary of a U.S. parent, is a holding company located in Germany and obtains a loan denominated in USD from its U.S. parent. In addition, B borrows additional funds denominated in EUR from an unrelated third party and invests the entire amount, denominated in EUR, in Entity C, an operating company also located in Germany. Entity B intends to use dividends received from its investment in C to remit dividends to the parent in USD.

In the first scenario, the determination of the functional currency is relatively straightforward: A's functional currency is the EUR. However, in the second scenario, it is not clear whether B's functional currency is USD or the EUR. Management would need to use judgment in determining B's functional currency in the second scenario.

Further, it should not be assumed that the functional currency is either that of the parent or that of the jurisdiction in which the distinct and separable operation operates (i.e., the local currency). Management may also conclude, on the basis of the facts and circumstances, that the functional currency is that of another jurisdiction (although such a conclusion is not as common).

In determining the appropriate functional currency, management should consider each of the economic factors in ASC 830-10-55-5(a)–(f) and thoroughly document the conclusions reached.

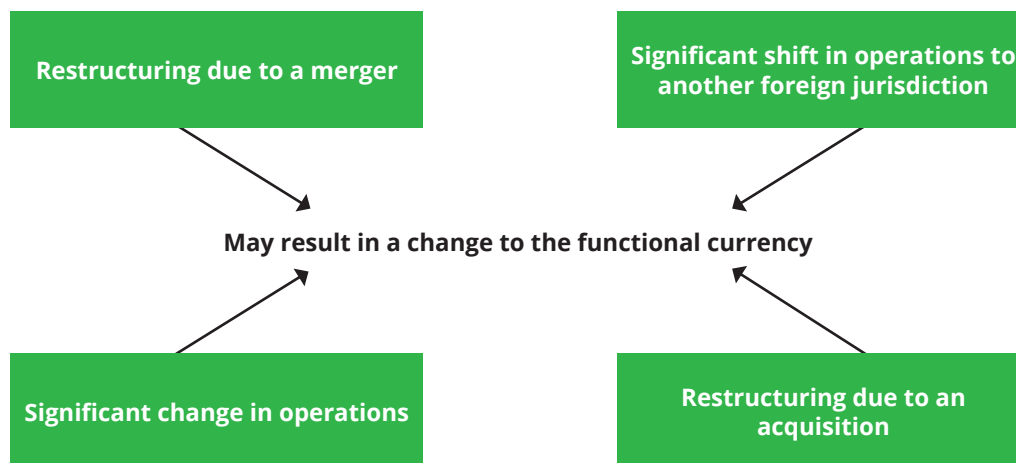
It should be noted that ASC 830 does not address how the economic factors in ASC 830-10-55(a)–(f) should be applied (e.g., weightings or hierarchy may differ for certain factors). Rather, ASC 830-10-55-5 states that these "factors, and possibly others, should be considered both individually and collectively when determining the functional currency."

However, because changes in functional currency are expected to be infrequent, management should place greater emphasis on long-term considerations related to each factor than it does on short-term considerations. For example, start-up operations may receive significant financing from the parent in the parent’s functional currency but ultimately plan to operate primarily in a foreign economic environment. In such cases, the facts and circumstances may indicate that, while the start-up operation’s financing was in the currency of its parent in the short term, the start-up operation may eventually operate primarily in the foreign economic environment. Therefore, consideration of the factors in ASC 830-10-55-5(a)–(f) would most likely lead to a conclusion that the start-up operation’s functional currency is, in fact, different from the parent’s.

12.10.3 Change in Functional Currency

As previously noted, ASC 830-10-45-7 indicates that there must be “significant changes in economic facts and circumstances” to justify a change in functional currency. Except when an economy is identified as highly inflationary, ASC 830 does not define or provide examples related to what constitutes a significant change in facts and circumstances. An entity must therefore use judgment in determining whether significant changes in facts and circumstances have occurred. However, such changes are expected to be rare.

Changes in the functional currency may result from one-time transactions, such as a merger or acquisition, or from a longer-term shift in an entity’s operations. Regardless of the reason, it is important that management carefully consider whether such an event is significant enough to warrant a change in the functional currency. Because ASC 830 does not provide guidance on how to determine whether a change is “significant,” preparers may find it helpful to compare the indicators before and after the change in making the determination. Entities are encouraged to consult with their accounting advisers in such situations.



SEC Considerations

The SEC’s *Frequently Requested Accounting and Financial Reporting Interpretations and Guidance*, released by the Division of Corporation Finance (the “Division”), provides an additional example in which a change in functional currency may be appropriate. This guidance states that “[r]egistrants with foreign operations in economies that have recently experienced economic turmoil should evaluate whether significant changes in economic facts and circumstances have occurred that warrant reconsideration of their functional currencies.” The Division warns, however, that it may be difficult to conclude that “currency exchange rate fluctuations alone would cause a self-contained foreign operation to become an extension of the parent company.” Regardless of the underlying reason for the change in functional currency, the Division suggests that, although

ASC 830 does not require them to do so, “[r]egistrants should consider the need to disclose the nature and timing of the change, the actual and reasonably likely effects of the change, and economic facts and circumstances that led management to conclude that the change was appropriate. The effects of those underlying economic facts and circumstances on the registrant’s business should also be discussed in MD&A.”

12.10.3.1 Determining When to Change the Functional Currency

In accordance with ASC 830-10-45-7, a change in functional currency should be reported as of the date on which it is determined that “significant changes in economic facts and circumstances” have occurred. Although such a change could occur on any date during the year, it is acceptable to use a date at the beginning of the most recent reporting/accounting period.

12.10.3.2 Accounting for a Change in the Functional Currency

ASC 250-10-45-1 states that the “[a]doption or modification of an accounting principle necessitated by transactions or events that are clearly different in substance from those previously occurring” is not considered a change in accounting principle. Because a change in functional currency is necessitated by a significant change in facts and circumstances that are “clearly different in substance from those previously occurring,” such a change does not meet the definition of a change in accounting principle and therefore should not be accounted for as such (i.e., previously issued financial statements should not be restated).

For more information, see [Section 2.4.2](#) of Deloitte’s Roadmap *Foreign Currency Matters*.

12.10.4 Other Special Considerations

12.10.4.1 Exchange Rates

In remeasuring foreign-currency-denominated transactions into the entity’s functional currency and translating financial statements into the parent’s reporting currency, an entity must identify the appropriate exchange rate. While ASC 830 provides some guidance on which exchange rates should be used, it may not always be clear that a particular exchange rate is appropriate. Significant judgment may be required when multiple legal exchange rates coexist (e.g., when an official exchange rate and an unofficial exchange rate exist).

For more information, see [Chapter 3](#) of Deloitte’s Roadmap *Foreign Currency Matters*.

12.10.4.2 Intra-Entity Transactions

Intra-entity foreign currency transactions can have unique effects on an entity’s financial statements, including the (1) creation and transfer of foreign currency risk from one entity in a consolidated group to another, (2) creation of transaction gains and losses that “survive” consolidation, and (3) application of exceptions to the general rules outlined in ASC 830. In some situations, the remeasurement of loans between entities within a consolidated group creates transaction gains or losses that are recognized in earnings. In other situations, the remeasurement is recognized within equity.

For more information, see [Chapter 6](#) of Deloitte’s Roadmap *Foreign Currency Matters*.

12.10.4.3 *Highly Inflationary Economies*

In economies with significant inflation, the local currency may be deemed unstable. Therefore, ASC 830 requires that entities operating in environments deemed to be highly inflationary remeasure their financial statements into the reporting currency. That is, the reporting currency of the entity's immediate parent is used as the functional currency of the foreign entity. An entity may need to use significant judgment in determining whether a foreign entity has a highly inflationary economy. If such an economy is determined to be highly inflationary, the guidance in ASC 830 on applying the functional-currency approach must be applied. The application of such guidance can be time-consuming and complex.

For more information, see [Chapter 7](#) and [Section 9.2.3](#) of Deloitte's Roadmap *Foreign Currency Matters*.

12.11 Financial and Sustainability Reporting Considerations Related to Environmental Events and Activities

12.11.1 Introduction

Over the past few years, there has been an increasing focus on sustainability reporting. Until recently, entities have been using sustainability reporting frameworks or standards to report on a voluntary basis. However, sustainability reporting is moving quickly toward becoming mandatory in some jurisdictions, with standard setters and regulators working to develop and adopt sustainability reporting standards. Currently, the most significant sustainability-related reporting regulations and standards are those established by (1) the European Union via the [E.U. Corporate Sustainability Reporting Directive \(EU\) 2022/2464](#) (CSRD) and [European Sustainability Reporting Standards](#) (ESRS), (2) the International Sustainability Standards Board (ISSB) within the IFRS Foundation, and (3) the state of California and the SEC in the United States.

In addition, the FASB, SEC, and CAQ have all provided public information⁶ regarding the importance of considering environmental matters, for both preparers of financial statements and auditors. Given the increased interest in ESG matters from various parties, entities in virtually all industries are considering how these matters will affect their business strategies, operations, and long-term value. As entities develop business strategies related to the evolving ESG landscape, they will need to incorporate ESG considerations into their preparation of financial statements. In doing so, they should ensure that any plans or commitments related to environmental initiatives are considered in a consistent manner for both sustainability reporting and the preparation of the financial statements.

12.11.2 Regulation and Standard Setting

12.11.2.1 CSRD Requirements

12.11.2.1.1 Background

In November 2022, the European Council adopted the CSRD, effective January 2023, to support the [European Green Deal](#) — a package of initiatives to cut greenhouse gas (GHG) emissions, direct investment toward sustainability initiatives, invest in research and innovation, and preserve Europe's natural environment. Each E.U. member state was required to incorporate the CSRD into its national laws and establish regulations and administrative provisions upon adoption of the CSRD. Further, E.U. member states were permitted to include certain additional local requirements, which will be mandatory for compliance with the CSRD in those jurisdictions.

⁶ See the FASB staff's March 19, 2021, educational paper [Intersection of Environmental, Social, and Governance Matters With Financial Accounting Standards](#); the SEC's February 8, 2010, interpretive release [Commission Guidance Regarding Disclosure Related to Climate Change](#) (the "2010 interpretive release") and March 15, 2021, request for input [Public Input Welcomed on Climate Change Disclosures](#); and the CAQ's September 9, 2021, white paper [Audited Financial Statements and Climate-Related Risk Considerations](#).

The CSRD will affect all companies with significant operations in E.U. jurisdictions, including U.S.-based companies with as little as one subsidiary or branch in the European Union. Entities within the scope of the CSRD will need to report under ESRS and meet the requirements related to the [EU Taxonomy for Sustainable Activities](#) (the “EU Taxonomy”), as discussed below.

12.11.2.1.2 European Sustainability Reporting Standards

The CSRD requires entities to report under ESRS, which were adopted by the European Commission (EC) in July 2023 and published in the *Official Journal of the European Union* in December 2023. Drafted by the European Financial Reporting Advisory Group (EFRAG), the ESRS must be applied by entities within the CSRD’s scope.

The ESRS consist of 12 standards that apply to all sectors and address the sustainability matters specified in the CSRD. [ESRS 1](#) establishes principles and general requirements for disclosure, and [ESRS 2](#) establishes disclosure requirements that apply to entities regardless of materiality. The remaining 10 ESRS are topical and address various environmental (including climate), social, and governance matters.

To determine the disclosures necessary to comply with the 10 topical standards, entities must perform a “double materiality” assessment. Under this approach, a sustainability matter is material for entities when it meets the following criteria related to impact materiality, financial materiality, or both:

- *Impact materiality* — In accordance with Section 3.4 of ESRS 1, a “**sustainability matter** is material from an impact perspective when it pertains to the undertaking’s material actual or potential, positive or negative **impacts** on people or the environment over the short-, medium- or long-term.” These impacts can originate from the entity’s operations and extend through its entire value chain.
- *Financial materiality* — In accordance with Section 3.5 of ESRS 1, a “sustainability matter is material from a financial perspective if it triggers or could reasonably be expected to trigger material **financial effects** on the undertaking.”

All entities must apply the requirements of ESRS 1 and ESRS 2. Disclosures required under the 10 topical ESRS are subject to an entity’s double materiality assessment. However, if an entity determines that climate change is not material and therefore omits all of the disclosures required under ESRS E1, the entity must disclose a detailed explanation of its materiality assessment conclusions related to climate change, including a forward-looking analysis of the conditions that could lead the entity to decide that climate change is material in the future. If an entity determines that a topic other than climate change is not material, it can consider providing additional explanation of this materiality conclusion; however, an explanation is not required to comply with topical ESRS other than ESRS E1 on climate change.

12.11.2.1.3 EU Taxonomy

E.U. entities within the CSRD’s scope will also be within the scope of the [EU Taxonomy Regulation](#). The EU Taxonomy Regulation establishes the EU Taxonomy, a classification system for “environmentally sustainable” economic activities that are consistent with one (or more) of the six E.U. environmental objectives laid out in the regulation. Under the EU Taxonomy, nonfinancial entities must report key performance indicators related to turnover, capital expenditure, and operating expenditure to indicate the proportion of their economic activities (individually and in the aggregate) that is environmentally sustainable. Financial entities within the scope of the guidance need to disclose relevant ratios for their industry.

12.11.2.1.4 Effective Date

The CSRD is being applied in four stages. The date on which an entity is subject to the CSRD depends on its structure and size. The timeline below describes the requirements introduced at each stage from the perspective of a U.S.-based company.

	Reporting for Calendar-Year-End Filers				Enterprise Level
	2024 (Reporting in 2025)	2025 (Reporting in 2026)	2026 (Reporting in 2027)	2028 (Reporting in 2029)	
Scope	Companies already subject to the NFRD,* including large U.S. companies with more than 500 employees and listed on an E.U.-regulated market	All large** U.S. companies listed on E.U.-regulated markets and all large E.U. subsidiaries of U.S. companies	SME subsidiaries of U.S. companies listed on E.U.-regulated market***	U.S.-based companies that generate a net turnover of more than €150M in the European Union in each of the last two financial years and have any of the following: (1) At least one large** subsidiary (2) An SME subsidiary listed on an E.U.-regulated market (3) A branch with more than €40M net turnover	
Required standards	ESRS (or equivalent† standards)		ESRS or specific standards for SMEs	ESRS, equivalent standards, or alternative specific standards for non-E.U. entities to be developed	
Reporting level	Stand-alone subsidiary, unless included in the parent’s report prepared under ESRS or equivalent standards for non-E.U. parent (i.e., consolidated group level)			Consolidated group, including non-E.U. activity	
Assurance	Yes, limited assurance over all reported sustainability information			Yes, limited assurance over all reported sustainability information	

* Companies already subject to the Non-Financial Reporting Directive (NFRD) are large public-interest companies with more than 500 employees. Public-interest companies include companies listed on an E.U.-regulated market, banks, insurance companies, and other companies designated by national authorities as public-interest entities.

** Large undertaking/large group is defined by the CSRD as an E.U. entity or an E.U. parent entity (on a consolidated basis) that meets two or more of the following three criteria: >250 employees on average, >€25M balance sheet, >€50M turnover.

*** Small and medium-sized undertakings (SMEs) can choose to defer reporting for two years until 2028.

† What may be deemed “equivalent” is yet to be determined by the EC.

In addition, certain disclosure requirements in the ESRS are phased in for all entities, but some phase-ins depend on an entity’s size.



Changing Lanes

On February 26, 2025, the EC published two omnibus proposals — [COM\(2025\) 80](#) and [COM\(2025\) 81](#) — aimed at significantly reducing the sustainability reporting and due diligence requirements for entities within the scope of the CSRD. These proposals will be submitted to the European Parliament and the European Council for scrutiny under the European Union’s ordinary legislative procedure.

For more information about the proposed updates to the CSRD requirements, see Deloitte’s March 7, 2025, [Heads Up](#).

12.11.2.1.5 Additional Information

For more information about the CSRD and ESRS, see Deloitte's August 17, 2023 (updated February 23, 2024), [Heads Up](#). For more information about the double materiality assessment, see Deloitte's June 27, 2024, [Heads Up](#).

12.11.2.2 ISSB Standards

12.11.2.2.1 Background

Entities should also be mindful of the international progress toward developing a common set of sustainability reporting standards on climate change and other climate-related topics. In June 2023, the ISSB issued its first two standards: [IFRS S1](#) (on disclosure requirements associated with sustainability-related financial information) and [IFRS S2](#) (on climate-related disclosures). These standards are intended to improve the alignment and interoperability of global ESG standards, reducing the reporting burden for preparers and enhancing the usefulness of sustainability disclosures for investors in making decisions.

The IFRS Foundation [reported](#) in May 2024 that “[j]urisdictions representing over half the global economy by gross domestic product (GDP) have announced steps to use the [ISSB standards] or to fully align their sustainability disclosure standards with those of the ISSB.” These jurisdictions include China, Brazil, Canada, Japan, and the United Kingdom, among others. In a July 2023 [media release](#), the International Organization of Securities Commissions (IOSCO) endorsed the ISSB standards and encouraged its member jurisdictions — which regulate more than 95 percent of the world’s financial markets — to consider how they “might adopt, apply or otherwise be informed by the ISSB Standards within the context of their jurisdictional arrangements.” The IFRS Foundation maintains a list of open and completed [jurisdictional sustainability consultations](#) to track jurisdictional progress toward adoption.

12.11.2.2.2 Effective Date

IFRS S1 and IFRS S2 are effective for annual reporting periods beginning on or after January 1, 2024; however, the specific effective date varies by jurisdiction. For more information on the adoption status of the ISSB standards by jurisdiction, see Deloitte's [ISSB adoption tracker](#).

12.11.2.2.3 Additional Information

For more information about IFRS S1 and IFRS S2, see Deloitte's June 30, 2023, [Heads Up](#).

12.11.2.3 California Climate Legislation

In addition to monitoring international regulatory and standard-setting developments related to climate and sustainability, entities will need to keep abreast of climate- and sustainability-related regulatory developments in the United States at the state level.

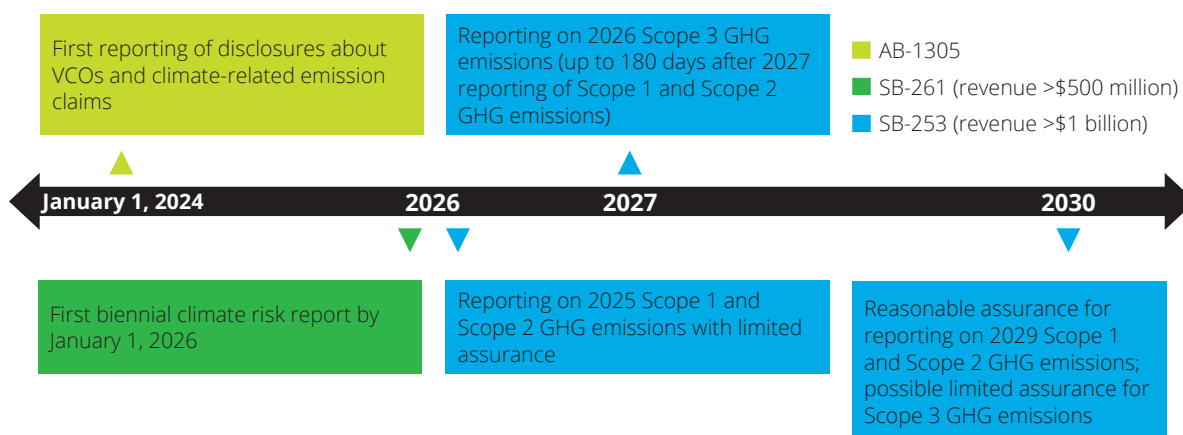
In October 2023, three climate bills — [SB-253](#), [SB-261](#), and [AB-1305](#) — were signed into law in California. The new legislation will significantly affect certain public and private companies doing business or operating in that state. Under SB-253 and SB-261, entities will have to report GHG emissions and climate risks. AB-1305, which is intended to combat company “greenwashing” of climate-related emission claims, establishes requirements for entities that market or sell voluntary carbon offsets (VCOs) in California as well as entities that operate in California and make certain climate-related emission claims. The table below summarizes the applicability of the three bills.

	SB-253	SB-261	AB-1305
	Climate Corporate Data Accountability Act	Greenhouse Gases: Climate-Related Financial Risk	Voluntary Carbon Market Disclosures
Companies affected	Public and private U.S. businesses with total annual revenues exceeding \$1 billion and that do business in California.	Public and private U.S. businesses with total annual revenues exceeding \$500 million and that do business in California.	Public and private businesses that (1) sell and market VCOs in California; (2) purchase or use VCOs sold in California, make climate-related emission claims, and operate in California; or (3) make climate-related emission claims in California and operate in California.

On September 27, 2024, California state senate bill [SB-219](#) was signed into law. This legislation amends portions of Sections 38532 and 38533 of the California Health and Safety Code that were established upon the passage of California state senate bills SB-253 and SB-261. Intended to help reduce the financial burden of complying with SB-253 and SB-261, SB-219 does not affect the reporting timeline established by those bills.

12.11.2.3.1 Effective Date

The timeline below outlines the initial requirements for disclosure under SB-253, SB-261, and AB-1305. Unlike other climate disclosure regulations, including the SEC’s climate disclosure rule and European regulations under the CSRD, the California rules do not allow for a phase-in of applicability.



Under SB-253, entities would report Scope 1 and Scope 2 GHG emissions starting in 2026 or by a date to be determined by the California Air Resources Board (CARB). Entities' reports that are publicly disclosed in 2026 would include 2025 GHG emission data. Entities would begin reporting Scope 3 GHG emissions in 2027, on the basis of 2026 GHG emission data, in accordance with a schedule specified by CARB.

Under SB-261, an entity must post a climate-related financial risk report on its Web site on or before January 1, 2026, and biennially thereafter. The report should be prepared in accordance with the recommended framework and disclosures of the Task Force on Climate-related Financial Disclosures (TCFD)⁷ and include information pertaining to the most recent fiscal year an entity would need to use to meet the deadline (e.g., entities with a calendar year-end may prepare a report as of December 31, 2024, to comply with the January 1, 2026, due date).

12.11.2.3.2 Additional Information

For more information about SB-253, SB-261, and AB-1305, see Deloitte's October 10, 2023 (updated December 19, 2023), [Heads Up](#). For more information about SB-219's amendments to California's climate legislation, see Deloitte's October 1, 2024, [Heads Up](#).

Life sciences entities are encouraged to monitor legislative and rulemaking developments in their home state, as well as those in other states in which they operate or do business, for potential reporting requirements.

12.11.2.4 SEC Reporting Considerations and Climate Disclosure Rule

12.11.2.4.1 SEC Reporting Considerations

Life sciences entities should be mindful of SEC reporting requirements regarding climate-related disclosures. In recent years, the SEC staff has increased its focus on climate-related disclosures in its review of public companies' filings, including assessing the extent to which the information provided by such companies is consistent with the SEC's [2010 interpretive release](#). On September 22, 2021, the SEC publicly released a [sample letter](#) that highlighted the types of comments the SEC staff may issue to public companies regarding climate-related disclosures. Since the release of this sample letter, the SEC staff has issued comments to public companies in a variety of industries. The SEC staff has been issuing comments to entities about their climate-related disclosures under existing requirements. These comments primarily focus on the business, risk factors, and MD&A sections of SEC filings.

12.11.2.4.2 SEC Climate Disclosure Rule

On March 6, 2024, the SEC issued a [final rule](#) requiring registrants to provide climate-related disclosures in their annual reports and registration statements. Specifically, the final rule provides that registrants must disclose certain climate information in the notes to the financial statements and outside the financial statements. However, on April 4, 2024, the SEC voluntarily [stayed](#) the effective date of the final rule.

For more information about SEC communications regarding climate-related matters, see Deloitte's [March 6, 2024 \(updated April 8, 2024\)](#), and [March 15, 2024 \(updated April 8, 2024\)](#), [Heads Up](#) newsletters.

⁷ SB-261 provides that entities may prepare their climate-related financial risk reports in accordance with TCFD-equivalent reporting requirements, such as the IFRS Sustainability Disclosure Standards as issued by the ISSB.

12.11.3 GHG Protocol Reporting Considerations

The GHG Protocol is a set of standards and related guidance on accounting for and reporting GHG emissions. Each regulator and standard setter discussed above (the European Union, the ISSB, California, and the SEC) refers to the GHG Protocol, whose standards and guidance have been broadly applied for disclosing GHG emissions. The GHG Protocol provides a framework for companies and other types of organizations preparing an inventory of GHG emissions. Specifically, it addresses the accounting for and reporting of seven GHGs: carbon dioxide, methane, nitrous oxide, hydrofluorocarbons, perfluorocarbons, sulfur hexafluoride, and nitrogen trifluoride. While there are seven GHGs, preparers should note that the GHG emissions are to be reported in metric tons of carbon dioxide equivalent.

Under the GHG Protocol, GHG emissions are classified into three scopes as follows:

Scope 1 emissions	Represent emissions generated directly from sources owned or controlled by the reporting company. Examples of Scope 1 emissions include GHG emissions from the generation of heat, electricity, and steam; GHG emissions from physical or chemical processing; fugitive emissions; and GHG emissions from the transportation of materials, products, waste, and employees.
Scope 2 emissions	Represent indirect emissions that are derived from purchased electricity, heat, steam, and cooling. Scope 2 emissions are often the most significant source of emissions for office-based or service companies. Two calculation methods are used to report on Scope 2 emissions: the location-based method and the market-based method. The location-based method reflects the average emission intensity of grids on which energy consumption occurs, while the market-based method reflects emissions from electricity that companies have purposefully chosen.
Scope 3 emissions	Represent all other indirect emissions that are a consequence of the activities of the reporting company but occur at sources not owned or controlled by the company. Reporting on Scope 3 emissions generally involves the greatest amount of estimation in the current reporting landscape because of the infancy of data collection and data quality. There are 15 categories of reportable Scope 3 emissions.

Companies reporting under the GHG Protocol generally apply the following steps:

1. *Identify the company's organizational boundary* — In a manner similar to its preparation of consolidated financial statements, a company is required to consolidate its operations⁸ for GHG emission reporting purposes. That is, a reporting company needs to determine what companies or assets (or portions thereof) contribute to its consolidated GHG emissions. This determination is referred to as the reporting company's organizational boundary. For more information, see [Chapter 2](#) of Deloitte's Roadmap *Greenhouse Gas Protocol Reporting Considerations*.
2. *Set operational boundaries* — While an organizational boundary identifies the operations to include in consolidated emission reporting, an operational boundary identifies the activities that generate the GHG emissions included in such reporting. After a company sets its organizational boundary, it sets an operational boundary to identify the emissions associated with its operations and further classify them by scope. An operational boundary defines the scope of direct and indirect emissions for operations within a company's organizational boundary. For more information, see [Chapter 3](#) of Deloitte's Roadmap *Greenhouse Gas Protocol Reporting Considerations*.

⁸ The GHG Protocol's *The Greenhouse Gas Protocol: A Corporate Accounting and Reporting Standard* (the "Corporate Standard") defines an operation as a "generic term used to denote any kind of business, irrespective of its organizational, governance, or legal structures. An operation can be a facility, subsidiary, affiliated company or other form of joint venture."

3. *Calculate GHG emissions* — As the Corporate Standard notes, “the established organizational and operational boundaries together constitute a company’s inventory boundary.” Once an inventory boundary has been established, a company identifies and calculates GHG emissions by (1) identifying the GHG emission sources by defined category within the inventory boundary, (2) selecting a GHG emission calculation approach, (3) collecting data and choosing emission factors, (4) applying calculation tools if appropriate, and (5) rolling up the data to the corporate level. For more information, see [Chapter 4](#) of Deloitte’s Roadmap *Greenhouse Gas Protocol Reporting Considerations*.



Connecting the Dots

While the new climate and sustainability standards and regulations are driving change in the reporting landscape, there may be business value in monitoring a company’s GHG emissions. Such monitoring may allow companies to identify business and financial risks that arise from their operations and provide management with insight into how to effectively manage those risks. In addition, it may help companies identify opportunities for transformation and growth so that they can differentiate themselves in the market.

12.11.4 Potential Accounting and Reporting Implications of Environmental Objectives

The next sections in this chapter examine certain potential impacts of climate-related matters on a life sciences entity’s financial accounting and reporting in the context of the existing accounting guidance. While these impacts may vary depending on the nature of the entity’s business, along with factors such as relevant regulatory, legal, and contractual obligations, all life sciences entities should evaluate environment-related financial accounting and reporting implications. For example, when preparing financial statements, an entity that has plans to reduce its carbon footprint should evaluate the impact of those plans, if any, on topics such as the useful life of assets, impairment of assets, asset retirement obligations (AROs), other liabilities, and disclosure requirements under current U.S. GAAP.

Entities may also pursue specific arrangements or transactions in connection with climate-related objectives that involve complex accounting issues, require significant judgment, or both. For example, entities may enter into energy service agreements (ESAs), which are often marketed as an “off-balance-sheet financing solution” that will allow entities to capture the benefits of new efficient equipment without incurring the up-front capital expenditures associated with it. Entities that enter into certain types of ESAs may need to evaluate whether those arrangements contain an embedded lease (see [Section 12.11.10.2](#) for further discussion). In addition, for other types of transactions with climate-related objectives, such as compensation arrangements linked to the achievement of company-specific environmental metrics, entities may be required to assess the probability of achieving such metrics.

Entities from various industries have begun issuing public statements regarding their plans to address the impacts of climate change on their businesses, and recent news headlines have often highlighted these statements — for example, “Entity A commits to being carbon neutral by 2030” or “Entity B pledges to reduce greenhouse gas emissions by 90% by 2040.” As a result, questions have arisen about the accounting and disclosure considerations related to such statements.

It is critical to understand how the plans and actions of management (i.e., personnel with the appropriate authority) align with its specific public statements (e.g., those made by the two entities in the preceding paragraph). By obtaining such an understanding, an entity will be better able to assess the effect of its climate-related public statements and supporting plans and actions on its net assets, including whether any assets are impaired or any contractual liabilities exist. For example, Entity A may operate in a jurisdiction or industry in which it is required to provide a certain level of carbon offsets, either internally generated or purchased, to meet jurisdictional regulations mandating that all companies become carbon neutral. Depending on the facts and circumstances of the government regulation and A's specific operation, A's obligation to provide carbon offsets for carbon emissions may result in a liability that needs to be recorded, potentially disclosed, or both.

12.11.4.1 Assessing the Impact on Assets

Life sciences entities should evaluate how their climate-related public statements and supporting plans and actions affect various aspects of their businesses as well as the related accounting implications of those plans in light of existing accounting standards. For example, if Entity B plans to reduce its GHG emissions by replacing its current manufacturing equipment with new technology and equipment that emit fewer GHGs, it should evaluate whether there has been a triggering event⁹ related to the recoverability of its existing manufacturing equipment and reassess whether the current useful life of its existing manufacturing equipment remains appropriate. Further, if B has goodwill related to a reporting unit that includes the product lines produced by the existing equipment, it should assess whether its future manufacturing process will result in a different profit margin profile. Lower future profit margins could affect the expected future cash flows of the reporting unit and ultimately could alter the results of the entity's goodwill impairment test. See [Sections 12.11.5, 12.11.12, and 12.11.13](#) for more detailed information.

12.11.4.2 Assessing the Incurrence of Liabilities

In addition to considering whether it has any contractual obligations to address climate-related issues, an entity should consider whether government or regulator actions or the entity's own public statements, plans, or actions could give rise to any other legal or constructive obligations that the entity would be required to account for, disclose, or both, in its financial statements.

Paragraph E38 of [FASB Concepts Statement 8, Chapter 4](#) (released in December 2021), identifies two essential characteristics of a liability:

- "It is a present obligation."
- "The obligation requires an entity to transfer or otherwise provide economic benefits to others."

These two characteristics are further discussed below.

⁹ See ASC 360-10-35-21 for examples of events or changes in circumstances that may indicate a long-lived asset (asset group) may not be recoverable.

12.11.4.2.1 Characteristic 1 — Present Obligation

In the assessment of whether a present obligation exists, the determination of whether there is a legal obligation is often unambiguous. However, the definition of the term legal obligation in the ASC master glossary acknowledges that such an obligation can be established by “an existing or enacted law, statute, ordinance, or written or oral contract or by legal construction of a contract under the doctrine of promissory estoppel.” If an entity makes a promise to a third party, including the public at large, about its intentions to undertake certain activities, the entity may be required to use significant judgment to determine whether it has created a legal obligation under the legal doctrine of promissory estoppel, which is defined as the “principle that a promise made without consideration may nonetheless be enforced to prevent injustice if the promisor should have reasonably expected the promisee to rely on the promise and if the promisee did actually rely on the promise to his or her detriment.”¹⁰

Entities should evaluate the existence of legal obligations on the basis of current laws, regulations, and contractual obligations, as well as the related interpretations and facts and circumstances; they should not forecast changes in laws or in the interpretations of laws and regulations. The impacts of any changes in laws or regulations should be considered in the period in which the new or amended laws or regulations are enacted. In addition, in determining whether a public statement has created a legal obligation under the notion of promissory estoppel, entities should work closely with legal counsel to evaluate their own specific facts and circumstances. If the results of this determination are unclear, they may wish to obtain a legal opinion to support their conclusions.

According to paragraph E43 of FASB Concepts Statement 8, Chapter 4, “[l]iabilities necessarily involve other parties, society, or law. The identity of the other party or recipient need not be known to the obligated entity before the time of settlement.” Further, paragraph E45 notes that the present obligation of a liability must exist as of the financial statement date and that “[t]ransactions or other events or circumstances expected to occur in the future do not in and of themselves give rise to obligations today.” In issuing Concepts Statement 8, Chapter 4, the FASB was aiming to shift the emphasis away from identifying a past or future transaction or event and to focus instead on the term “present.”

FASB Concepts Statement 8, Chapter 4, states that to be presently obligated for a liability, “an entity must be bound, either legally or in some other way, to perform or act.” For instance, many obligations can stem from legally enforceable contracts and agreements, resulting in a recorded liability. However, the FASB also indicates that a constructive obligation may be “created, inferred, or construed from the facts in a particular situation rather than contracted by agreement.” In describing constructive obligations, FASB Concepts Statement 8, Chapter 4, further states that an “entity’s past behavior also may give rise to a present obligation.”

In assessing whether it has a constructive obligation that is not a legal obligation, an entity must employ significant judgment and consider its specific facts and circumstances. For an event or circumstance (e.g., a public statement) to rise to the level of a constructive obligation that should be recognized as a liability, the entity must, as a result of the event or circumstance, be obligated to sacrifice assets in the future and have little or no discretion to avoid the future sacrifice. The assessment of whether an entity has a constructive obligation related to its climate-related public statements, plans, or actions should not be a one-time evaluation; rather, the entity should continue to assess its facts and circumstances as its climate-related initiatives progress.

¹⁰ See ASC 410-20-20, which cites the definition of promissory estoppel that is used in *Black’s Law Dictionary*, seventh edition.

If an entity determines that it has or may have an obligation (contractual, legal, or constructive) that should be recorded in its financial statements, the entity should carefully consider (1) the point in time at which the entity's obligation began and (2) whether the obligation exists as of the financial statement date. Liabilities arise as a result of a past event. For example, as employees render services to an entity, the entity incurs the liability to pay the employees for their services. The rendering of services in exchange for payment is an example of a reciprocal transaction in which one party exchanges a good or service with another party (in this case, the employee rendering services in exchange for payment). However, obligations arising as a result of a government action or an entity's climate-related public statements, plans, or actions may not be reciprocal transactions but obligations to the public at large or other relevant stakeholders. In assessing the point in time at which an entity has incurred an obligation that does not result from a reciprocal transaction, an entity may need to use significant judgment and consider all relevant facts and circumstances. For example, an entity's obligation may arise as a result of future carbon emissions, which may indicate that the obligation does not exist as of the financial statement date.

12.11.4.2.2 Characteristic 2 — Obligation to Provide Economic Benefits

As outlined in paragraphs E54 through E60 of FASB Concepts Statement 8, Chapter 4, a second essential characteristic of a liability is that “the obligation requires an entity to transfer or provide economic benefits to others or to be ready to do so.” Such an entity often must transfer cash or other assets to one or more other entities. However, FASB Concepts Statement 8, Chapter 4, states that an obligation “can be fulfilled, satisfied, or settled in a number of other ways, including by granting a right to use an asset, providing services, replacing that obligation with another obligation, converting the obligation to equity, or, in certain circumstances, transferring shares of the entity.”

12.11.4.3 Disclosure Considerations

Entities should also evaluate whether any of their climate-related public statements, plans, or actions must be disclosed in the financial statements, even if they conclude that there is nothing to record in the current-period financial statements. ASC 275 requires an entity to disclose information that helps financial statement users assess major risks and uncertainties. Specifically, ASC 275-10-50-1 requires disclosure of risks and uncertainties related to the following:

- a. Nature of operations, including the activities in which the entity is currently engaged if principal operations have not commenced
- b. Use of estimates in the preparation of financial statements
- c. Certain significant estimates
- d. Current vulnerability due to certain concentrations.

Example 12-3

Pharmaceutical Entity X manufactures and distributes diabetes medicines that are administered by using fossil-based plastic pens. Entity X expects to shift to more sustainable material for its devices and to explore the ability to reclaim and reuse the plastic in these devices. In a manner consistent with its public statements, X is actively engaging with vendors of alternative fuel sources to identify a green alternative and expects such an alternative to be available for use in the near term. On the basis of its facts and circumstances, X concludes that it does not have any present obligations (contractual, legal, or constructive) or impacts on other financial statement accounts to record in its financial statements; however, X may be required to disclose the risks and uncertainties related to the future of this key product line in accordance with ASC 275.

To assess whether its plans or actions result in risks or uncertainties that must be disclosed in accordance with ASC 275, an entity must apply professional judgment after considering all relevant facts and circumstances.

In addition, an entity should assess whether any of its public statements regarding climate-related initiatives give rise to commitments that must be disclosed in the financial statements. The ASC master glossary defines a firm commitment as “[a]n agreement with an unrelated party, binding on both parties and usually legally enforceable,” that (1) is specific in “all significant terms, including . . . fixed price, and the timing of the transaction,” and (2) “includes a disincentive for nonperformance that is sufficiently large to make performance probable.”

ASC 440 requires an entity to disclose certain situations that are not recorded in the financial statements. Specifically, ASC 440-10-50-1 requires disclosures as follows:

ASC 440-10

50-1 Notwithstanding more explicit disclosures required elsewhere in this Codification, all of the following situations shall be disclosed in financial statements:

- a. Unused letters of credit
- b. Leases (see Section 842-20-50)
- c. Assets pledged as security for loans
- d. Pension plans (see Section 715-20-50)
- e. The existence of cumulative preferred stock dividends in arrears
- f. Commitments, including:
 1. A commitment for plant acquisition
 2. An obligation to reduce debts
 3. An obligation to maintain working capital
 4. An obligation to restrict dividends.

Pending Content (Transition Guidance: ASC 105-10-65-7)

50-1 Notwithstanding more explicit disclosures required elsewhere in this Codification, all of the following situations shall be disclosed in financial statements:

- a. Unused letters of credit
- b. Leases (see Section 842-20-50)
- c. Assets mortgaged, pledged, or otherwise subject to lien; the approximate amounts of those assets; and the related obligations collateralized
- d. Pension plans (see Section 715-20-50)
- e. The existence of cumulative preferred stock dividends in arrears
- f. Commitments, including:
 1. A commitment for plant acquisition
 2. An obligation to reduce debts
 3. An obligation to maintain working capital
 4. An obligation to restrict dividends.

In addition, ASC 440-10-50-2 requires disclosure of an “unconditional purchase obligation” that has certain characteristics.

These examples are not an exhaustive list of commitments to be disclosed, and entities should evaluate their specific facts and circumstances to determine whether they have any commitments that should be disclosed in their financial statements in accordance with ASC 440.

Note that in addition to the disclosure requirements set forth by U.S. GAAP, entities should consider SEC reporting requirements, as discussed above. For further information, see Deloitte’s September 27, 2021, [Heads Up](#) and the [SEC Climate-Related Disclosures](#) section in Deloitte’s November 16, 2022, [Financial Reporting Alert](#).

12.11.5 Developing Estimates and Maintaining Consistency of Assumptions and Estimates

As life sciences entities focus on climate-related initiatives and make changes to their businesses, they may face challenges related to selecting appropriate assumptions and developing reliable estimates. Nevertheless, they will still be required by U.S. GAAP to develop estimates that underlie various accounting conclusions. To develop such estimates, entities will need to consider all available information.

Further, entities may be required to use assumptions or estimates for more than one purpose (e.g., forecasted revenues or cash flows may be an assumption that is used in multiple impairment tests, assessments of the realizability of DTAs, and the evaluation of an entity’s ability to continue as a going concern). When a single assumption is used in multiple analyses, entities should verify that the same assumption is being used in each analysis unless the guidance in U.S. GAAP permits otherwise. In addition, entities should verify that assumptions and estimates outside of the financial statements (e.g., sustainability reports) are consistent with those used when preparing estimates required by U.S. GAAP.

Life sciences entities should also consider external events and circumstances, including changes in regulatory environments, when assessing whether (1) the changes they made in assumptions and estimates from the previous period were appropriate or (2) it was appropriate in the current period *not* to have updated or changed the assumptions used in the previous period.

12.11.6 Use and Recoverability of Long-Lived Assets

As an entity considers climate-related matters, it should continue to evaluate the accounting and reporting impacts of its goals or targets with respect to its carbon footprint. Understanding how its business shifts to support these goals or targets is critical to evaluating the ongoing use and recoverability of its long-lived assets, including goodwill, as well as other indefinite-lived intangible assets and PP&E.

12.11.6.1 Indefinite-Lived Intangible Assets Other Than Goodwill

An entity should assess changes to its business as a result of climate-related initiatives, since these could affect the value of its indefinite-lived intangible assets. As stated in ASC 350-30-35-4, an indefinite-lived intangible asset is one for which “there is no foreseeable limit on the period of time over which it is expected to contribute to the cash flows of the reporting entity.” Brands and trademarks are common examples of indefinite-lived intangible assets.

Indefinite-lived intangible assets are tested annually for impairment and more frequently if an event or a change in circumstances indicates that it is more likely than not that the intangible asset is impaired in accordance with ASC 350-30. ASC 350-30-35-18B provides examples of these events or changes in circumstances, which include, but are not limited to, financial performance, legal or political factors, entity-specific events, and industry or market considerations. On the basis of this assessment, if an entity determines that it is more likely than not that the carrying value of the intangible asset exceeds its fair value, the entity performs a valuation to determine the fair value of the asset and recognizes an impairment loss equal to the excess of the carrying amount of the intangible asset over its fair value.

A valuation technique that is often applied to the measurement of a brand or trademark is the relief-from-royalty method. This method, which focuses primarily on expected revenues and royalty rates, requires the entity to make fewer assumptions than other income methods. However, an entity may find it challenging to project revenues because of an expected shift in demand for its product due not only to changes in consumer buying decisions, as consumers seek to purchase more environmentally friendly products, but also to a change in the entity's ability to continue producing and selling its current products while also meeting any internal climate-related targets (such as a commitment to being carbon neutral by a certain date). Entities may also need to consider whether an intangible asset's useful life is no longer indefinite, in which case the asset would begin to be amortized over its remaining useful life. Entities are expected to use their best estimate of all required business and valuation assumptions for this method or other income methods used to measure the fair value of an indefinite-lived intangible asset.

In addition to evaluating the need for an interim impairment test, an entity should consider whether there are any indicators that an intangible asset classified as indefinite-lived has become finite-lived, which might occur if the entity changes its expected use of the asset in response to its strategy to produce more environmentally friendly products.

12.11.6.2 Recoverability of Long-Lived Assets

A life sciences entity should consider whether it expects to experience (1) a decline in revenues, (2) an increase in costs (i.e., a decline in net cash flows), or (3) both, as a result of changes to its business to undertake climate-related initiatives. If so, such changes may indicate that the entity should test its long-lived assets for recoverability.

Entities are required by ASC 360-10-35-21 to test a long-lived asset (asset group) that is classified as held and used for recoverability "whenever events or changes in circumstances indicate that its carrying amount may not be recoverable" — for example, if there is a "significant adverse change . . . in the business climate that could affect the value of a long-lived asset (asset group)." Events or changes in circumstances that prompt a recoverability test are commonly referred to as "triggering events." As an entity adjusts its business to align with climate-focused initiatives, it may experience one or more of the triggering events listed in ASC 360-10-35-21. For example, depending on the nature of the entity's business and its assets, it may determine that certain product lines will be phased out (as well as the related assets producing them) or that products will be produced by more environmentally friendly assets. Triggering events that may be present as a result of an entity's response to climate-related initiatives include, but are not limited to, a "significant adverse change in the extent or manner in which a long-lived asset (asset group) is being used or in its physical condition," a "significant adverse change in legal factors or in the business climate that could affect the value of a long-lived asset (asset group), including an adverse action or assessment by a regulator," or a "current expectation that, more likely than not, a long-lived asset (asset group) will be sold or otherwise disposed of significantly before the end of its previously estimated useful life."

ASC 360-10-35-23 states, in part, that “a long-lived asset or assets shall be grouped with other assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities.” Such a combination is called an asset group.

An asset group may include not only long-lived assets that are within the scope of ASC 360-10 but also other assets such as receivables, inventory, indefinite-lived intangible assets, or goodwill. ASC 360-10-15-5 provides a list of assets that are not within the scope of ASC 360-10. Note that ASC 360-10 applies to long-lived assets that are not within the scope of other GAAP, such as PP&E, finite-lived intangible assets (e.g., customer relationships, technology, brands, and trade names), and ROU assets.

To test a long-lived asset (asset group) for recoverability, an entity compares the carrying value of the asset (asset group) with the undiscounted net cash flows generated from the asset’s (asset group’s) use and eventual disposal. While the use of undiscounted cash flows generally indicates that a long-lived asset (asset group) is less prone to impairment, a long-lived asset (asset group) may not be recoverable if reductions in the estimates of undiscounted cash flows are based on changes to the entity’s business operations as it supports climate-related initiatives in response to consumer demand. For example, the net cash flows expected to be generated from the eventual disposal of a piece of machinery may decline if the machinery is not deemed environmentally friendly and demand for the related product has decreased as a result of a heightened focus on climate-related initiatives by both entities and consumers. Therefore, the decline in expected salvage value may result in an impairment of the asset (asset group).

If an entity estimates future cash flows to test the recoverability of a long-lived asset (asset group), such an estimate should include only the future cash flows (cash inflows minus associated cash outflows) that are (1) directly associated with the asset (asset group) and (2) expected to arise as a direct result of the use and eventual disposition of the asset (asset group). To estimate future cash flows, the entity must consider both cash inflows and cash outflows. Note that ASC 360-10-35-30 states, in part, that the “assumptions used in developing [cash flow estimates should] be reasonable in relation to the assumptions used in developing other information used by the entity for comparable periods, such as internal budgets and projections, accruals related to incentive compensation plans, or information communicated to others.”

In addition, ASC 360 indicates that it may be useful for the entity to apply a probability-weighted approach when considering alternative courses of action to recover the carrying amount of a long-lived asset (asset group). Such an approach may be beneficial when the entity is considering alternative courses of action it may take as a result of its climate-related initiatives.

If the entity determines that the carrying amount of the long-lived asset (asset group) is not recoverable, it performs the next step in the impairment test by recognizing an impairment loss for the amount by which the carrying amount of the long-lived asset (asset group) exceeds its fair value. Then, in accordance with ASC 360-10-35-28, it allocates that amount to the long-lived assets that are within the scope of ASC 360-10 “on a pro rata basis using the relative carrying amounts of those assets, except that the loss allocated to an individual long-lived asset of the group shall not reduce the carrying amount of that asset below its fair value whenever that fair value is determinable without undue cost and effort.”

By contrast, if an entity determines that a long-lived asset (asset group) is recoverable, it does not recognize an impairment loss, even if the carrying value of that asset (asset group) exceeds its fair value. Regardless of whether an entity recognizes an impairment loss, it should still consider whether the existence of a trigger indicates that there has been a change in the useful life or salvage value of its long-lived assets. For example, although a certain asset (asset group) is not impaired, an entity may determine that the asset (asset group) will not be in operation as long as originally intended, or that its salvage value has decreased, because it will be phased out as more environmentally friendly assets are placed into service. In that case, the entity should revise the asset's (asset group's) useful life and depreciation or amortization estimates accordingly.

Sometimes, an entity may conclude that the affected long-lived assets will be sold, abandoned, or otherwise disposed of. Under ASC 360, if the HFS criteria in ASC 360-10-45-9 are met, the entity is required to measure the asset (asset group) "at the lower of its carrying amount or [its] fair value less cost to sell" in accordance with ASC 360-10-35-43. A long-lived asset that will be abandoned will continue to be classified as held and used until it is disposed of. Such an asset is disposed of when it ceases to be used. However, as indicated in ASC 360-10-35-49, a "long-lived asset that [is] temporarily idled shall not be accounted for as if abandoned." Further, ASC 360-10-35-48 states, in part, that when "a long-lived asset ceases to be used, the carrying amount of the asset should equal its salvage value, if any."

12.11.7 Goodwill

As an entity continues to adjust its business operations to support climate-related initiatives, it should consider whether such adjustments result in a triggering event that would require it to test the goodwill of one or more reporting units for impairment between annual testing dates. In addition, even if the entity does not identify a triggering event in between annual testing dates, it should consider its climate-related initiatives and their impacts on business operations when testing goodwill for impairment annually.

Under ASC 350-20-35-28 through 35-30, an entity is required to test goodwill for impairment at the reporting-unit level at least annually or "between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying amount." ASC 350-20-35-3C provides examples of events and circumstances that may meet such a threshold and hence necessitate the testing of goodwill for impairment between annual tests. These include "a deterioration in general economic conditions," "a deterioration in the environment in which an entity operates," "a change in the market for an entity's products or services," "[o]verall financial performance such as negative or declining cash flows or a decline in actual or planned revenue or earnings compared with actual and projected results of relevant prior periods," and, "[i]f applicable, a sustained decrease in share price (consider in both absolute terms and relative to peers)."

A reporting unit with only a small cushion (excess of fair value over carrying amount) at the time of its most recent quantitative test is generally more susceptible to impairment, which may have been noted in prior disclosures related to goodwill of reporting units at higher risk for impairment.

An entity may choose to qualitatively evaluate relevant events or circumstances to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. Alternatively, an entity may skip the qualitative assessment and proceed directly to step 1 of the goodwill impairment test. In step 1 of the test, the entity compares the reporting unit's carrying amount, including goodwill, with its fair value and recognizes an impairment loss for any excess.

When performing a quantitative test, an entity must develop certain business and valuation assumptions. If the entity is using an income approach to perform its fair value measurements, it must use judgment when developing its prospective financial information and consider the impacts of its climate-related initiatives as well as potential shifts in consumer behaviors. For example, an entity may have plans to shut down a manufacturing facility and build a new one with new, more environmentally friendly equipment. In such a case, the entity should consider the impact of these plans, including the costs to close the current manufacturing facility, in its business assumptions. Uncertainty regarding the changes in an entity's business and the impact of those changes to support the entity's climate-related initiatives should also be considered. The entity is expected to use its best estimates of those business and valuation assumptions.

12.11.8 Inventory

ASC 330 requires an entity to initially value its inventory at the cost needed to bring the inventory to its current condition and location. An entity generally determines that cost by using an acceptable cost flow method such as first in, first out or last in, first out (LIFO). Inventory that is measured by using any method other than LIFO or the retail inventory method (RIM) is subsequently valued at the lower of cost or net realizable value (i.e., the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation). However, if inventory is measured by using LIFO or RIM, it is subsequently valued at the lower of cost or market.¹¹

When estimating the net realizable value of inventory, management is required to consider all relevant facts and circumstances. If certain climate-related events occur, the estimates of net realizable value could be materially affected. For example, hurricanes could significantly damage a manufacturing facility's inventories, or floods could significantly damage goods held in a warehouse. In addition, an entity's operations may be affected by new regulations, customer preferences, or its own initiatives related to environmental concerns — for example, changes in consumer preferences for products purchased from companies that are known to be more environmentally friendly or an entity's initiatives to shift to more sustainable component parts for the production of its medical devices.

Historically, changes in regulations have typically come with enough advance notice for entities to prepare for such changes, and consumer behavior changes have in many cases been gradual. However, with the current focus on sustainability and environmental matters, both regulatory actions and changes in consumer behavior may occur more rapidly and frequently in the future; therefore, entities should closely monitor such potential developments and any related impacts on inventory values.

12.11.9 Taxes

The tax effects of law changes designed to bring about environmental changes (e.g., the elimination or introduction of certain environmental tax credits) should not be anticipated; rather, entities should account for a change in tax law in the period in which the change is enacted.

¹¹ ASC 330-10-20 defines market as follows: "As used in the phrase lower of cost or market, the term market means current replacement cost (by purchase or by reproduction, as the case may be) provided that it meets both of the following conditions:
a. Market shall not exceed the net realizable value
b. Market shall not be less than net realizable value reduced by an allowance for an approximately normal profit margin."

12.11.10 Leases

12.11.10.1 ROU Asset Impairment (Lessee Accounting)

Impairments of ROU assets could occur as a result of an entity's decision to abandon a current lease in favor of a lease for environmentally sustainable PP&E (e.g., if an entity decides to change the location of its corporate headquarters or manufacturing facilities). Such a decision could negatively affect the future cash flows expected to be derived from the original underlying PP&E.

ROU assets are subject to the impairment and disposal guidance in ASC 360; therefore, a lessee must test its ROU assets for impairment in a manner consistent with the treatment of other long-lived assets. In accordance with ASC 842-20-35-9, a "lessee shall determine whether a right-of-use asset is impaired and shall recognize any impairment loss in accordance with Section 360-10-35 on impairment or disposal of long-lived assets." Therefore, the impairment analysis of ROU assets would be included as part of the analysis for long-lived assets that are held and used.

In accordance with ASC 842-20-35-10, an impaired ROU asset should be subsequently measured at its carrying amount (after the impairment) less any accumulated amortization. Subsequent amortization of the ROU asset (for both operating and finance leases) would be on a straight-line basis unless another systematic basis is more representative of the pattern over which the lessee expects to consume the remaining economic benefits of the right to use the underlying asset.

In connection with its reevaluation of leases or lease portfolios on a go-forward basis, an entity should consider whether a decision to no longer use a leased asset constitutes an abandonment of the asset from an accounting standpoint. The entity's conclusion may represent a triggering event that prompts it to perform a recoverability test. For a leased asset to be deemed abandoned, an entity must not have the intent and ability to sublease the leased asset at any point during the remaining lease term. When determining whether it would have the intent and ability to sublease the asset, the entity should consider the economic environment and the expected demand in the sublease market. Consequently, an entity may be required to use greater judgment when assessing leases with longer remaining terms. An entity that has the intent and ability to sublease an asset at any point in the future would be precluded from considering an asset to be abandoned.

12.11.10.2 ESAs That May Contain Embedded Leases

As a result of increased focus on the environment and corporate accountability, many entities have been actively seeking out ways to transform their current operations to maximize environmental sustainability while limiting up-front capital expenditures. One increasingly common method is through use of an ESA. As previously noted, ESAs are often marketed as an "off-balance-sheet financing solution" that will allow entities to capture the benefits of new efficient equipment without incurring the up-front capital expenditures associated with it. The typical term of an ESA is anywhere between 5 and 15 years. Under an ESA, the vendor will analyze the company's current energy infrastructure and understand its level of energy consumption. This evaluation forms the "base-line" energy consumption that the vendor promises to reduce.

In addition to performing various services in connection with the ESA, the vendor will often replace all, or a portion, of the entity's existing energy infrastructure (e.g., HVAC systems, boilers, lightbulbs) with new high-efficiency, environmentally sustainable equipment. The vendor usually bears the costs associated with the new machinery and its installation and retains title to the equipment. In many ESAs, the vendor pays for required maintenance throughout the duration of the contract. Payments to the vendor are generally based on the company's actual cost savings — for example, as a percentage of the actual savings or according to some type of formula linked to the entity's cost savings.

To determine the appropriate accounting for an ESA, an entity should consider whether the agreement includes an embedded lease for the underlying equipment. As indicated in ASC 842-10-15-3, a “contract is or contains a lease if the contract conveys the right to control the use of identified property, plant, or equipment (an identified asset) for a period of time in exchange for consideration.” The concept of “control” is expanded upon in ASC 842-10-15-4, which states, in part, that “[t]o determine whether a contract conveys the right to control the use of an identified asset . . . for a period of time, an entity shall assess whether, throughout the period of use, the customer has both of the following:” the “right to obtain substantially all of the economic benefits from use of the identified asset” and the “right to direct the use of the identified asset.” Although an entity must use judgment in determining whether an agreement includes a lease, a key indicator that an embedded lease exists within a service agreement is a situation in which the service provider conveys control of the equipment to the entity. We have observed that in many instances, ESAs will be deemed to include a lease because the entity is able to control when the equipment is actually used and at what levels, among other factors.

If, on the basis of the terms of an ESA, the entity concludes that a lease exists, it will need to determine the lease payments so that it can ascertain the lease classification and calculate the associated ROU asset and lease liability. In many ESAs, the entity only pays the vendor to the extent that there are energy cost savings, which will vary from month to month. On the surface, this may appear to be an entirely variable lease payment stream, which would result in no lease liability and therefore no ROU asset at lease inception. However, the entity must consider the specific terms of the ESA to determine whether these payments, or a portion of these payments, constitute an in-substance fixed payment. Under ASC 842-10-55-31, “in substance fixed payments are payments that may, in form, appear to contain variability but are, in effect, unavoidable;” therefore, these payments are indistinguishable from fixed payments and should be considered in the calculation of the ROU asset and lease liability. However, if all payments are determined to be variable, from a lease accounting standpoint, an entity would not record an ROU asset or a lease liability. It is essential for an entity to understand what is driving the variability in its ESA when making this determination, since different ESAs may have different drivers of variability. Relevant considerations include whether the customer has any minimum usage requirements and whether the vendor is exposed to genuine economic downside on the basis of the PP&E’s performance (e.g., downside risk if the PP&E fails to meet predefined efficiency standards). Portfolio considerations may also arise because a large volume of equipment typically is deployed and monitored in the aggregate for performance.

As ESAs continue to rise in popularity and evolve, entities are encouraged to consult with their advisers regarding the appropriate accounting treatment.

12.11.11 Insurance Recoveries

Entities that incur losses stemming from climate-related events may be entitled to insurance recoveries. For example, in certain cases, losses from closed facilities or disrupted supply chains may be insured if they are associated with property damage from hurricanes, wildfires, or tornados. Furthermore, entities may have business interruption insurance that provides coverage for lost profits that are caused by a suspension of their operations due to certain weather-related events. See Section 5.4 for further discussion of the accounting for insurance recoveries.

12.11.12 Financial Instruments and Contract Assets

12.11.12.1 Sustainability-Linked Debt Instruments (Issuer's Considerations)

Entities that seek to demonstrate their corporate social responsibility may issue debt instruments tied to environmental factors (sometimes also referred to as sustainability factors). Such environmentally linked debt instruments include sustainability-linked bonds and sustainability-linked loans. With regard to structure, the terms of sustainability-linked debt instruments and conventional debt instruments may be largely similar. However, each sustainability-linked debt instrument may be issued for different purposes and have unique environmental linkage. For example, (1) debt instruments may be subject to early redemption if the borrower fails to meet a target sustainability metric (e.g., on the basis of S&P Global ESG Scores) on a specified date, (2) the contractual interest rate may be reduced if the borrower achieves predefined targets for reducing GHG emission, or (3) the contractual interest rate might increase if the borrower fails to achieve the targets. When issuing debt instruments with cash flows linked to environmental factors, an entity needs to consider whether the arrangement contains an embedded feature or features that must be separately accounted for as a derivative under ASC 815-15 (if the FVO is not applied).

Under ASC 815-15-25-1, an entity is required to separately account for a feature embedded within another contract (the host contract) if the following three conditions are met:

- The embedded feature and the host contract have economic characteristics and risks that are not clearly and closely related.
- The hybrid instrument (i.e., the combination of the embedded feature and its host contract) is not remeasured at fair value, with changes in fair value recorded immediately through earnings (e.g., under the FVO election in ASC 815-15-25-4 or ASC 825-10).
- The embedded feature — if issued separately — would be accounted for as a derivative instrument under ASC 815-10. In evaluating whether this condition is met, the entity considers the definition of a derivative in ASC 815-10 and the derivative accounting scope exceptions in ASC 815-10 and ASC 815-15.

The following outlines considerations related to the bifurcation analysis of certain features embedded in sustainability-linked debt instruments:¹²

- *Redemption features* — Debt instruments may contain features that trigger an acceleration or deferral of the due date or an adjustment of the repayment amount (1) upon the occurrence or nonoccurrence of a specified environmental event or events or (2) on the basis of an environmental metric. Generally, a redemption feature embedded in a debt host meets the definition of a derivative irrespective of whether the debt host contract is readily convertible to cash under the guidance in ASC 815-10-15-107 because neither party is required to deliver an asset associated with the underlying. The scope exceptions under ASC 815-10-15-13 and ASC 815-15-15-3 are usually not applicable for redemption features embedded in a debt host (e.g., there is no specific scope exception for sustainability-linked features). If no scope exception is available, a borrower's determination of whether a redemption feature must be bifurcated as a derivative is based on whether the feature is considered clearly and closely related to the debt host contract. Typically, the borrower should evaluate whether the redemption feature is clearly and closely related to the debt host under the four-step decision sequence in ASC 815-15-25-42.

¹² Note that this discussion assumes that the debt is not measured at fair value on a recurring basis (e.g., the issuer has not elected the FVO in ASC 815-15-24-4 or ASC 825-10). In addition, an entity should always consider the terms and conditions of a specific feature in light of the applicable accounting guidance before reaching a conclusion.

- *Contingent interest rate features* — Debt instruments may specify that the contractual interest rate (1) will be reduced by a certain amount if the borrower achieves predefined targets, such as reaching carbon neutral by a specified date, or will be increased if the borrower fails to achieve those targets or (2) will vary on the basis of changes in an index tied to specified environmental metrics. ASC 815-15-25-26 addresses whether an embedded feature whose only underlying is an interest rate or interest rate index should be considered clearly and closely related to a debt host contract. The guidance does not address features that are indexed to or contingent on something other than an interest rate or interest rate index, including features that are indexed to both an interest rate or interest rate index and other underlyings (e.g., environmental targets or key performance indicators). Under the existing guidance, generally, only certain features that are based on a market interest rate, an entity's credit risk, or inflation are viewed as clearly and closely related to a debt host contract. Therefore, features that adjust the interest rate of a debt instrument on the basis of an environmental factor typically are determined to be not clearly and closely related to a debt host and might have to be bifurcated as a derivative unless a specific scope exception is available.

Given the wide variety of environmentally linked terms and the evolving nature of these instruments, entities are strongly encouraged to discuss their accounting analyses with their advisers.

For more details about the manner in which specific embedded features should be evaluated to determine whether they require bifurcation as derivatives, see [Section 8.4](#) of Deloitte's Roadmap *Issuer's Accounting for Debt*.



Changing Lanes

In July 2024, the FASB issued a [proposed ASU](#) that would refine the scope of ASC 815 to exclude certain "contracts with underlyings based on operations or activities specific to one of the parties to the contract." Contracts that may qualify for this exception would include those in which the underlying is a business operation or an event such as obtaining regulatory approval or achieving specific business milestones. Because the proposed ASU's potential changes could affect the accounting for arrangements with environmentally linked terms, entities are encouraged to monitor activity at the FASB for additional standard-setting developments. For more information about the proposed ASU, see Deloitte's August 2, 2024, [Heads Up](#).

If the environmental-factor-related embedded derivatives must be accounted for separately from the debt host contract, the issuing entity must appropriately allocate the proceeds between the debt instrument and the features that are accounted for separately. Specifically, under the allocation method in ASC 815-15-30-2, the borrower is required to record "the embedded derivative at fair value and [determine] the initial carrying value assigned to the [debt] host contract as the difference between the basis of the hybrid instrument and the fair value of the embedded derivative."

Note that the determination of the fair value of environmental-factor-related embedded derivatives involves complexity and often requires the involvement of valuation specialists.

Depending on the likelihood that a payment feature will be triggered and, if so, on its potential amount, the fair value of a payment feature embedded in debt host might be minimal (e.g., a feature in which a minor adjustment must be made to the interest rate upon an event whose likelihood of occurring is remote). In practice, therefore, entities sometimes determine and document that they are not required to make accounting entries upon debt issuance to recognize a feature that must be bifurcated as a derivative under ASC 815-15. Any such conclusion must be appropriately supported on the basis of materiality. A determination that a feature has a minimal fair value at inception does not negate the requirement to account for it as a derivative. Accordingly, if an entity makes such a determination, it should also monitor its facts and circumstances in each reporting period to evaluate whether the feature's fair value or a change to it is significant and therefore must, under U.S. GAAP requirements, be reflected in the entity's financial statements.

12.11.12.2 Sustainability-Linked Debt Instruments (Holder's Considerations)

Holders of sustainability-linked debt instruments (e.g., an investor or a lender) can account for such instruments at fair value by (1) applying an FVO election in accordance with ASC 815-15 or ASC 825-10 or (2) classifying the instruments as trading securities in accordance with ASC 320-10-25-1 if they qualify as debt securities. If sustainability-linked debt instruments are not accounted for at fair value (e.g., the FVO is not applied), with changes in fair value recorded immediately through earnings, holders also need to consider whether the environmental factor is an embedded feature that must be separately accounted for as a derivative under the aforementioned guidance and considerations.

12.11.13 Environmental Obligations

Changes in laws and regulations may affect the timing and cost of environmental remediation obligations, which have a direct impact on the associated environmental remediation liability. An entity should consider whether changes to current laws and regulations in the jurisdictions in which it operates affect its recording of environmental remediation obligations.

ASC 410-30 provides guidance on measuring an estimated environmental remediation liability, including how to consider the effects of future developments. Specifically, ASC 410-30-35-4 requires entities to recognize the "impact of changes in laws, regulations, and policies . . . when such changes are enacted or adopted." If the estimated costs of remediation obligations change on the basis of new information, such changes are considered changes in estimates under ASC 250 and should be recognized in the period in which the laws or regulations are enacted or adopted.

For example, an entity may be remediating an environmental site in a state in which laws and regulations require it to remediate groundwater contamination and subsequently monitor water quality at the site to verify the efficacy of the remedy for a stated number of years before declaring the site closed. The recorded environmental liability would be based on (1) the remaining time and cost needed to achieve the remediation plan in accordance with the state laws and regulations, (2) costs related to postremediation monitoring, and (3) an assumption that the site would receive remedial closure or a "no further action" letter once the specific criteria are met (i.e., the environmental obligation would be zero at that point in time). If, perhaps in response to concerned citizens demanding more stringent requirements, the state amends its laws and regulations to include indefinite monitoring of the site (i.e., the site would not officially close), the entity would account for the cost of those changes in the period the new laws and regulations go into effect and should measure the environmental obligation in accordance with ASC 410-30.

Note that, as indicated in ASC 410-30-15-3(c), the guidance in ASC 410-30 does not apply to “[e]nvironmental remediation actions that are undertaken at the sole discretion of management and that are not induced by the threat . . . of litigation or of assertion of a claim or an assessment.” Therefore, ASC 410-30 does not require the recognition of a liability for environmental remediation activities that are voluntarily undertaken by a reporting entity. The decision to incur the costs of performing such activities in the future does not give rise to a present liability since the entity has considerable discretion in changing its plans and avoiding the expenditure.

12.11.14 Asset Retirement Obligations

Unlike environmental liabilities that result from the improper use of an asset, AROs are legal or contractual obligations to perform remediation activities resulting from the proper, intended use of a long-lived asset. Entities should consider whether changes to their operations trigger a remeasurement of their AROs. Changes in operations that result in a change in management’s intended use of an asset — including a change in its plans to maintain the asset, extend its useful life, or abandon the asset earlier than previously expected — may affect the recorded amount of an ARO associated with the asset, including the timing associated with the retirement activities.

ASC 410-20 provides the relevant guidance on accounting for AROs, including subsequent measurement considerations related to revising either the timing or amount of the original estimate of cash flows used for measuring the fair value of the obligation. Specifically, ASC 410-20-35-8 states, in part, that “[c]hanges resulting from revisions to the timing or the amount of the original estimate of undiscounted cash flows shall be recognized as an increase or a decrease in the carrying amount of the liability for an asset retirement obligation.”

For example, consider an entity that has pledged to reduce its carbon emissions in response to pressure from investors to transition to greener operations. To achieve this reduction, the entity plans to retire certain carbon-emitting assets and replace them with greener, low-carbon assets. If the older, carbon-emitting assets were required to be decommissioned and removed under the contractual agreement between the entity and the landowner and, as a result, the entity recorded an ARO on its books, it should consider whether (1) the early retirement of the carbon-emitting assets also results in the acceleration of the cash flows associated with retirement activities necessary to satisfy the ARO and (2) it is required to revise the ARO in accordance with ASC 410-20.

12.11.15 Compensation Agreements

As a means of driving sustainability, some entities link incentive pay for executives and employees to environmental metrics. For example, a life sciences entity’s executives might be rewarded for achieving goals related to carbon dioxide emissions, energy consumption, environmental management, or water usage. In such cases, there may be various accounting considerations, which depend on the specific climate-related metrics used, how performance is measured against those metrics, and the terms of the bonus arrangement.

Many entities use cash bonus plans to compensate their executives and employees. Annual bonus plans may be based on specific formulas and performance targets and are communicated early in the year. In some plans, annual bonus amounts are linked to environmental targets based on metrics that are unknown until after the end of a fiscal year and, thus, the bonus amounts may not be finalized until after the financial statements are issued. In addition, bonuses may be forfeited if an employee is terminated or resigns.

Entities should have a clear method of measuring and monitoring performance related to environmental metrics that are included in an annual or multiyear compensation agreement so that they can calculate the bonus accrual and update such amounts throughout the year under ASC 450-20 and ASC 710 (when the cash bonus plan is not subject to other applicable U.S. GAAP, such as ASC 718). If the amount of the bonus that will be achieved or granted is uncertain, the entity should compute a range in accordance with ASC 450-20-30-1, which indicates that if “no amount within the range is [considered] a better estimate than any other amount,” the low end of the range should be selected. Entities must carefully evaluate bonuses that are based on achievement of a target to determine whether such achievement is probable and reasonably estimable.

Once an entity has determined the amount of the probable bonus, it should recognize that amount over the service period. Recognizing compensation expense in this manner is analogous to recognizing expense in connection with stock-based compensation arrangements over the related service period, as required by ASC 718. Under this model, the obligating event giving rise to the liability is considered the employee’s performance of service. Recognition of a bonus liability should not be delayed just because the bonus would not be paid if the employee were to terminate employment before the end of the service period. Rather, if a reliable estimate of employee turnover is possible, the entity may factor this estimate into the range of estimates when determining the probable liability. Any difference between the actual bonus paid and the amount accrued is considered a change in accounting estimate. For more information, see Deloitte’s Roadmap [Contingencies, Loss Recoveries, and Guarantees](#).

Similarly, the compensation arrangement could be in the form of a company’s own stock instead of cash. For example, a life sciences entity may grant its senior executives a sustainability performance stock award related to environmental metrics such as reducing carbon emissions by 2 million metric tons. Entities should pay particular attention to plan details that describe how the environmental metrics are defined and how the related performance against those metrics is measured. In some instances, entities may seek assistance from appropriate environmental specialists when establishing and evaluating these type of compensation arrangements.

ASC 718 requires that the related cost be recognized over the employee’s requisite service period when a service period exists. For awards with performance conditions, an entity should assess the probability of meeting the performance condition and will only recognize compensation cost if it is probable that the condition will be met. The total compensation cost recognized will ultimately be based on the outcome of the performance condition. Share-based payment transactions are recognized by using a fair-value-based measurement method under ASC 718.

Note also that when a share-based compensation award with environment-related factors is indexed to a factor other than a service, performance, or market condition, the award may be classified as a liability. Liability-classified awards are generally remeasured by using fair-value-based measurement as of each reporting date until settlement. That is, changes in the fair-value-based measure of the liability at the end of each reporting period are recognized as compensation cost, either (1) immediately or (2) over the employee’s requisite service period. Therefore, companies need to carefully evaluate the classification of their share-based awards. For more information, see Deloitte’s Roadmap [Share-Based Payment Awards](#).

12.11.16 Environmental Credits

In December 2024, the FASB issued a [proposed ASU](#) as part of its project (added to the Board’s technical agenda in May 2022) on the accounting for environmental credit programs. Comments on the proposal are due by April 15, 2025.

The objective of the FASB's project on environmental credit programs is to improve the recognition, measurement, presentation, and disclosure requirements related to (1) environmental credits and, when applicable, (2) compliance obligations that may be settled with environmental credits. Currently, the treatment of such credits and liabilities is not explicitly addressed in U.S. GAAP.

The guidance in the proposed ASU is expected to have broad impacts given the number of companies with operations subject to emission regulations and that acquire environmental credits to achieve internal targets related to carbon footprint initiatives. An entity's accounting under the proposed standard is based on its determinations of the expected use of the credits. The determination of whether an environmental credit will be used for compliance, exchange, or voluntary purposes can change over the life of the credit, and changes in management's intent will affect subsequent measurement of the credit. If the standard is issued as proposed, entities will want to have strong processes and controls related to establishing intent, given the risk that subsequent changes in intent affect subsequent measurement. For more information about the proposed ASU, see Deloitte's December 20, 2024, [Heads Up](#).

Life sciences entities that participate in environmental credit activity should monitor the Board's ongoing deliberations for future standard-setting developments related to environmental credits.

Pending the finalization of the proposed ASU on the accounting for environmental credit programs, various approaches are currently being used in practice to account for and report environmental credits. For a discussion of those approaches and other considerations related to environmental credits, see Deloitte's November 16, 2022, [Financial Reporting Alert](#).

Entities should carefully consider all relevant facts and circumstances when selecting an appropriate accounting model to use. They should then apply the selected model consistently. In addition, they should disclose their selection if it is material.

12.12 Accounting for Generative AI Software Applications Used as Internal-Use Software

12.12.1 Overview

More and more companies are considering purchasing or developing software that uses or leverages AI to enhance internal productivity or are incorporating generative AI into their revenue-generating products. As stated in Deloitte's April 2024 report [Realizing Transformative Value From AI & Generative AI in Life Sciences](#), generative AI in the life sciences industry "can transform value streams (e.g., product launch, clinical development) across functional areas." In internal communication and support, AI-powered chatbots and virtual research assistants are streamlining communication and providing instant access to information, freeing up human resources for more complex tasks. Operational efficiency is also being improved through automation of documents and enhanced management systems, among other innovations.

Although developing or enhancing generative AI applications may involve more traditional software development costs (e.g., internal or external labor), some generative AI developments may be more advanced and may incur additional costs. For example, large amounts of data are typically necessary to train generative AI applications. Businesses that invest in generative AI will need to consider the accounting impacts of the software or software-related costs associated with generative AI.

The software costs incurred for generative AI could include fees paid to use third-party foundation models or large language models (LLMs) as well as fine-tuning and other training costs. Entities developing generative AI applications will need to consider whether the developed software will be used internally or whether it will be sold as a hosting arrangement, an on-premise software license, or a hybrid software offering.

The sections below focus on the development of generative AI applications for internal use and how costs related to generative AI should be evaluated under ASC 350-40. For a discussion of accounting considerations related to generative AI technology that is sold or marketed externally, see Deloitte's October 7, 2024, *Technology Spotlight*.

12.12.2 Background

Generative AI is a subset of AI that focuses on the ability of machines to take in inputs (e.g., text, images) and create outputs in various formats (e.g., text, images, audio, code, voice, video). Generative AI applications serve as interfaces for end users. These applications are powered by significant infrastructure (e.g., cloud-based AI foundation models or LLMs) and generate content on the basis of how the underlying models were trained as well as the end user's inputs. Foundation models typically use neural networks to learn patterns from huge amounts of data and predict outcomes on the basis of historical data patterns. Like traditional AI, foundation models predict outputs by making inferences related to the inputs they receive. However, through fine-tuning, prompt engineering, and adversarial training (discussed further below), these models produce outputs on the basis of their understanding of human-generated inputs.

12.12.2.1 Generative AI Foundation Model

Generative AI applications are powered by foundation models, LLMs that use deep learning to process huge amounts of data. A foundation model can perform a wide range of tasks in natural language processing (NLP), a subfield of AI that enables computers to interpret input prompts and generate outputs such as text, translation, summarization, and answers to questions. With a foundation model, the software can predict outputs on the basis of statistical inferences it makes from the inputs received. The quality, accuracy, and relevancy of a generative AI application's outputs depend on the training the underlying foundation model receives.

Generative AI applications interact with and rely on a foundation model to generate outputs on the basis of user prompts. The dependency of AI applications on foundation models can be thought of as similar to the reliance of traditional software applications on operating systems. As a large-scale, pretrained language model, a foundation model serves as an engine that software developers train and calibrate for specific scenarios when creating their own generative AI applications. Because of the complexity of foundation models, the development of this technology is expected to be labor- and resource-intensive. Therefore, a limited number of companies have developed foundation models, and we expect most generative AI application developers to leverage existing foundation models in their applications rather than create their own.

12.12.2.2 **Generative AI Applications**

Generative AI applications often require further training of the relevant foundation models (the foundational models leveraged by the applications) through various methods, each associated with specific costs:

- *Fine-tuning* — Using specific data to train the foundation model to create outputs for a subset of prompts beyond the existing scenarios for which the model was trained. For example, a company that is creating a generative AI application to produce medical diagnoses for a user's symptoms may need to fine-tune the foundation model by acquiring information from medical encyclopedias, patient data, online databases of research articles, and scientific publications. An entity would expect to incur data acquisition and labor costs related to fine-tuning. In addition, because of the amount of data needed, entities may need to purchase specific hardware (e.g., computers with powerful CPUs, GPUs, or RAM) or platform or infrastructure services from third parties (i.e., cloud services) that offer the same computational scalability as well as incur significant storage costs.
- *Prompt engineering* — Creating or adjusting the prompt to communicate with the foundation model to output an optimal answer. A company could incur specific internal or external software development costs in creating the prompt.
- *Adversarial training* — Two different deep-learning models can be pitted against each other to train both models. In this approach, one model, the generator, creates synthetic data samples while the other model, the discriminator, receives synthetic data samples and real data samples. The generator's objective is to produce samples that are indistinguishable from real data, while the discriminator's goal is to become better at distinguishing between real and generated data. An entity would expect to incur data acquisition, software development, and other labor costs related to adversarial training.

In addition to the data and training costs, an entity may also incur traditional software development costs (e.g., costs related to developing the software application user interface, infrastructure, graphics, and content) when creating a generative AI application. These costs may also be subject to capitalization or expense under ASC 985-20, ASC 350-40, or other U.S. GAAP.

12.12.3 **Accounting Considerations Related to Generative AI Development Costs**

Because generative AI is essentially a form of software, we believe that general software development accounting considerations apply to generative AI costs, including whether the related project will be used for internal purposes (including being sold as a service) or sold or marketed externally. However, the discussions below focus on generative AI software used as internal-use software.

12.12.3.1 *Generative AI Software Used as Internal-Use Software*

Although the development of foundation models marked a crucial milestone in NLP and AI research, there was initially significant uncertainty about whether this technology would meet its specified performance requirements. Development risks affect whether costs incurred to develop software can be capitalized. Entities developing AI software for internal use would consider applying the capitalization guidance in ASC 350-40 on internal-use software. ASC 350-40-15-2A states the following:

ASC 350-40

15-2A Internal-use software has both of the following characteristics:

- a. The software is acquired, internally developed, or modified solely to meet the entity's internal needs.
- b. During the software's development or modification, no substantive plan exists or is being developed to market the software externally.

When AI software is developed for internal use, a significant portion of the software development costs may be incurred during the preliminary project stage. ASC 350-40 does not require the establishment of technological feasibility¹³ for capitalization but does have other requirements for capitalization depending on the stage of development. Generally, development costs incurred during the application development stage are capitalized, while costs incurred during the preliminary project stage and postimplementation-operation stage are expensed as incurred.

The following are some indicators of when an entity is in the preliminary project stage and when costs should therefore be expensed as incurred in accordance with ASC 350-40:

- The entity is considering allocating resources (i.e., developers, financial budget) between different projects (e.g., different AI applications or other software projects).
- The entity is still determining the performance requirements for the AI application or the infrastructure requirements necessary for the application to operate.
- The entity is holding ongoing conversations with vendors (e.g., foundation model vendors, hardware vendors, cloud computing vendors) to determine which products are best aligned with the entity's software performance requirements.
- The entity is still exploring alternatives related to achieving the performance requirements identified (i.e., using internal software developers to train foundation models versus hiring third-party consultants).
- The entity is determining whether there is an existing technology for developing a specific generative AI application to meet the identified performance requirements.

The preliminary project phases for many AI applications and software projects may be longer than those for other software development projects given the use of new and advanced technologies as well as the emergence of high-risk development issues that could affect the successful completion of the project.

Once the preliminary project stage is complete and the application development phase commences, entities developing AI applications will need to identify and capitalize the direct internal and external costs incurred to develop the AI application. As AI applications are being developed, entities will need to carefully track internal and external costs to ensure that they are appropriately deferred or capitalized in accordance with the guidance in ASC 350-40. In addition, the development and implementation of AI

¹³ ASC 350-40 stipulates that to proceed from the preliminary project stage to the application development stage, a company would have to determine that the technology it needs to meet the performance requirements exists.

applications may involve new activities (e.g., training) performed by employees who have not historically tracked time spent on developing software. In such circumstances, entities may need to create new processes and controls to track these costs accurately.

12.12.3.2 Generative AI Software Acquired as a Cloud Computing Arrangement

Rather than develop AI software for internal use, an entity may engage with a third party to develop an AI solution that will be accessed as part of a cloud computing arrangement. In such circumstances, the AI software will only be accessed as part of a hosting arrangement. The ASC master glossary defines a hosting arrangement as follows:

In connection with accessing and using software products, an arrangement in which the customer of the software does not currently have possession of the software; rather, the customer accesses and uses the software on an as-needed basis.

Under ASC 350-40, costs incurred to implement a hosting arrangement that is a service contract would be subject to the same recognition and measurement guidance as costs incurred to develop or acquire internal-use software. However, any costs deferred in accordance with this guidance would be presented in the same manner as any prepayments made for the underlying service.

12.12.3.3 Data Acquisition Costs

As noted above, entities developing AI applications may need significant amounts of data to train the models. Entities will need to consider whether the costs of acquiring the data should be (1) expensed as incurred, (2) recognized as a separate intangible asset, or (3) considered for capitalization as part of the AI application.

Costs incurred to acquire data from a third party should be evaluated to determine whether it is appropriate to capitalize the costs as a separate intangible asset. The guidance in ASC 350-30 would apply to data that are acquired individually or as a group of other assets (that do not constitute a business) and that have an alternative use (i.e., in more than one software project). ASC 350-30-25-1 states that “[a]n intangible asset that is acquired either individually or with a group of other assets shall be recognized.” Further, ASC 350-30-25-4¹⁴ states the following regarding the acquisition of intangible assets:

ASC 350-30

25-4 Intangible assets that are acquired individually or with a group of assets in a transaction other than a business combination or an acquisition by a not-for-profit entity may meet asset recognition criteria in FASB Concepts Statement No. 5, *Recognition and Measurement in Financial Statements of Business Enterprises*, even though they do not meet either the contractual-legal criterion or the separability criterion (for example, specially-trained employees or a unique manufacturing process related to an acquired manufacturing plant). Such transactions commonly are bargained exchange transactions that are conducted at arm’s length, which provides reliable evidence about the existence and fair value of those assets. Thus, those assets shall be recognized as intangible assets.

¹⁴ The amendments in [ASU 2023-05](#) — which are effective prospectively for all joint venture formations with a formation date on or after January 1, 2025 — add to the exclusions in ASC 350-35-25-4 intangible assets acquired individually or with a group of assets in a joint venture upon formation. In addition, the amendments in [ASU 2024-02](#) — which are effective for fiscal years beginning after December 15, 2024, for PBEs and fiscal years beginning after December 15, 2025, for all other entities — remove all Concepts Statement references from the Codification, including the reference to [FASB Concepts Statement 5](#) in ASC 350-30-25-4. We do not believe that the removal of the reference to Concepts Statement 5 from ASC 350-30-25-4 will affect the application of the guidance in this paragraph to data acquisition costs.

ASC 350-30 (continued)**Pending Content (Transition Guidance: ASC 805-60-65-1)**

25-4 Intangible assets that are acquired individually or with a group of assets in a transaction other than a business combination, an acquisition by a not-for-profit entity, or a joint venture upon formation may meet asset recognition criteria in FASB Concepts Statement No. 5, *Recognition and Measurement in Financial Statements of Business Enterprises*, even though they do not meet either the contractual-legal criterion or the separability criterion (for example, specially-trained employees or a unique manufacturing process related to an acquired manufacturing plant). Such transactions commonly are bargained exchange transactions that are conducted at arm's length, which provides reliable evidence about the existence and fair value of those assets. Thus, those assets shall be recognized as intangible assets.

Pending Content (Transition Guidance: ASC 105-10-65-9)

25-4 Intangible assets that are acquired individually or with a group of assets in a transaction other than a business combination, an acquisition by a not-for-profit entity, or a joint venture upon formation may qualify for recognition even though they do not meet either the contractual-legal criterion or the separability criterion for being an identifiable asset (for example, specially-trained employees or a unique manufacturing process related to an acquired manufacturing plant). Such transactions commonly are bargained exchange transactions that are conducted at arm's length, which provides reliable evidence about the existence and fair value of those assets. Thus, those assets shall be recognized as intangible assets.

Acquired data will lack physical substance and will most likely be acquired as part of a contract that defines the rights controlled by the entity. In these cases, the acquired data are likely to meet the definition of an asset (because the data are separately identifiable and provide an entity with a present right to future economic benefits) and could be recognized separately as an intangible asset. Entities would need to determine the useful life of the acquired data and perform an impairment assessment in accordance with ASC 350.

**Connecting the Dots**

The existing guidance in ASC 350-30-25-4 refers to the asset recognition criteria in [FASB Concepts Statement 5](#). However, as noted in footnote 14, ASU 2024-02 removes the references to the Concepts Statements throughout the Codification. Further, the definition of an asset in FASB Concepts Statement 5 was amended by FASB Concepts Statement 8. The definition of an asset in paragraph E17 of [FASB Concepts Statement 8, Chapter 4](#), is as follows:

An asset has the following two essential characteristics:

- a. It is a present right.
- b. The right is to an economic benefit.

A present right of an entity to an economic benefit entitles the entity to obtain this benefit from the right and to restrict others' access to it. We believe that rights to data acquired from a third party would generally meet the definition of an asset. Further, while there are differences in the definition of an asset under the two Concept Statements, the differences are not expected to significantly change what does and what does not represent an asset. Accordingly, we believe that rights to data acquired from a third party would generally meet either definition of an asset.

Although costs incurred to acquire data from a third party would generally be capitalizable as an intangible asset, data acquisition costs would be expensed as incurred under ASC 730-10 if the data will be used in R&D activities and do not have alternative future uses.¹⁵ This is because costs incurred to develop technological feasibility are considered R&D activities within the scope of ASC 730-10. ASC 730-10-25-2 states, in part:

Elements of costs shall be identified with research and development activities as follows (see subtopic 350-50 for guidance related to website development): . . .

- c. Intangible assets purchased from others. The costs of intangible assets that are purchased from others for use in research and development activities and that have alternative future uses (in research and development projects or otherwise) shall be accounted for in accordance with Topic 350. The amortization of those intangible assets used in research and development activities is a research and development cost. **However, the costs of intangibles that are purchased from others for a particular research and development project and that have no alternative future uses (in other research and development projects or otherwise) and therefore no separate economic values are research and development costs at the time the costs are incurred.** [Emphasis added]



Connecting the Dots

ASC 350-40-15-7 refers to the inclusion of costs of internal-use computer software that will be used in R&D activities as being within the scope of ASC 730-10. Therefore, when developing software for use in R&D activities, an entity should expense all costs incurred during all phases of software development as incurred. As stated in ASC 730-10-25-4, (1) costs incurred during all phases of development are considered R&D costs and (2) the alternative future use test, which applies only to intangibles purchased from others, does not apply to internally developed software.

Data may also be acquired for a specific software project that is being developed for internal use and does not have an alternative future use (e.g., other software projects). In this case, rather than being a separate intangible asset, the data costs may be direct external costs incurred to develop internal-use software within the scope of ASC 350-40. Specifically, an entity could purchase data to train generative AI applications, resulting in the creation of new functionalities. If the AI software project is in the application development stage, it may be appropriate to capitalize the data acquisition costs as direct costs incurred during that phase. Alternatively, as discussed further below, if the data and resulting training were only necessary to maintain the existing features or functionality of the generative AI application, capitalization would not be appropriate because the costs would be akin to maintenance costs. Further, any costs incurred in the preliminary project phase of development should be expensed as incurred.

If acquired data have an alternative future use (as discussed above) and are separately recorded as an intangible asset in accordance with ASC 350-30, we do not believe that the subsequent amortization of the intangible asset would be included as a cost eligible for capitalization under the internal-use software guidance. In such circumstances, the subsequent amortization would not be considered a direct cost incurred during the application development stage and would therefore not be within the scope of ASC 350-40.¹⁶

¹⁵ The term “alternative future use” is not defined in U.S. GAAP. However, Section 3.14 of the AICPA Accounting and Valuation Guide [Assets Acquired to Be Used in Research and Development Activities](#) states, “For an asset acquired in an asset acquisition for use in R&D activities to have an alternative future use, the task force believes that (a) it is reasonably expected that the reporting entity will use the asset acquired in the alternative manner and anticipates economic benefit from that alternative use, and (b) the reporting entity’s use of the asset acquired is not contingent on further development of the asset subsequent to the acquisition date (that is, the asset can be used in the alternative manner in the condition in which it existed at the acquisition date)” (footnote omitted).

¹⁶ ASC 350-40-30-1 states that the only internal-use software costs that would be capitalized include (1) “[e]xternal direct costs of materials and services consumed in developing or obtaining internal-use computer software,” (b) “[p]ayroll and payroll-related costs . . . for employees who are directly associated with and who devote time to the internal-use computer software project, to the extent of the time spent directly on the project,” and (3) “[i]nterest costs incurred while developing internal-use computer software.”

12.12.3.4 *Upgrades and Enhancements*

After the initial release of their generative AI software, entities will most likely improve the functionality of their application through additional software development and fine-tuning. An entity that develops AI software for internal use should consider whether incurring these costs is associated with an upgrade or enhancement to internal-use software as described in ASC 350-40-25-7 through 25-9:

ASC 350-40

25-7 Upgrades and enhancements are defined as modifications to existing internal-use software that result in additional functionality — that is, modifications to enable the software to perform tasks that it was previously incapable of performing. Upgrades and enhancements normally require new software specifications and may also require a change to all or part of the existing software specifications. In order for costs of specified upgrades and enhancements to internal-use computer software to be capitalized in accordance with paragraphs 350-40-25-8 through 25-10, it must be probable that those expenditures will result in additional functionality.

25-8 Internal costs incurred for upgrades and enhancements shall be expensed or capitalized in accordance with paragraphs 350-40-25-1 through 25-6.

25-9 Internal costs incurred for maintenance shall be expensed as incurred.

Maintenance activities would be expensed as incurred for all software. ASC 350-40 does not define the term “maintenance,” but ASC 985-20-20 defines it as follows:

Activities undertaken after the product is available for general release to customers to correct errors or keep the product updated with current information. Those activities include routine changes and additions.

A key consideration related to incurring data costs to train the AI software after initial deployment is whether additional training results in the creation of new functionality (e.g., whether the AI application can perform a different task) or whether ongoing training is necessary to retain the relevance of the AI application (e.g., maintain its intended functionality). Data and associated training that are intended to keep an AI application current or relevant would most likely be considered maintenance. Unless the costs are separately capitalizable as an intangible asset, such costs would be expensed as incurred.

In contrast, training that creates new functionality might be considered an upgrade or enhancement. Therefore, entities will need to determine whether the additional fine-tuning they are performing maintains the current software features of their generative AI application or whether the fine-tuning introduces additional software features that did not previously exist. This would dictate whether the data costs incurred to perform the fine-tuning should be capitalized as costs incurred to develop a software upgrade, expensed as software maintenance, or evaluated for capitalization separately as an intangible asset.

12.12.3.5 *Computation Resources and Storage Costs*

In supporting generative AI applications, an entity may incur significant costs related to (1) hardware for computation resources and (2) storage costs. Generally, such costs will be accounted for under U.S. GAAP other than ASC 985-20 and ASC 350-40. Servers, computers, GPUs, and CPUs purchased to increase an entity's computational power and build out its storage infrastructure would be accounted for as long-lived assets under ASC 360.

If an entity enters into a hosting arrangement with a vendor to leverage the vendor's computation or storage capabilities, it is likely that the arrangement will be accounted for as a service arrangement. Typically, in such circumstances, (1) the entity does not have "the contractual right to take possession of the software at any time during the hosting period without significant penalty"¹⁷ or (2) it is not "feasible for the [entity] to either run the software on its own hardware or contract with another party unrelated to the vendor to host the software."¹⁸ Accordingly, the costs incurred to implement third-party infrastructure or storage services would be evaluated for capitalization in accordance with ASC 350-40 and, if capitalized, would be deferred as a prepaid asset and recognized over the contract period (as well as over periods for which contractual renewals are reasonably certain to be exercised). Note that ongoing costs to use or maintain the third-party infrastructure or storage services would not meet the deferral criteria.

In addition, as noted above, AI applications typically need to be developed to work with one or more AI foundation or LLM models. An entity that enters into a hosting arrangement with a vendor to purchase a foundation model will need to determine whether it has (1) purchased or licensed software or (2) purchased a service arrangement. The entity must perform this assessment regardless of whether the foundation model will be used to create a generative AI application for internal use or whether it will be sold as a hosting arrangement or an on-premise license. We expect that most entities will determine that the foundation models or LLMs they acquire will be through a service contract, which could be accounted for as a prepaid asset if an up-front payment is made for the future use of the functionality.

12.12.4 On the Horizon — Proposed ASU on the Accounting for and Disclosure of Software Costs

In October 2024, the FASB issued a [proposed ASU](#) that would amend certain aspects of the accounting for and disclosure of software costs under ASC 350-40. Rather than revising the guidance on this topic in its entirety, the Board is proposing targeted improvements to address specific issues raised by stakeholders. In addition, the proposed ASU would not amend the cost guidance for software licenses that are within the scope of ASC 985-20.

To clarify that the guidance applies to both linear and nonlinear software development, the proposed ASU would remove all references to "development stages" from ASC 350-40 as well as amend the threshold for the capitalization of costs. Under current GAAP, capitalization of software development costs for internal-use software is required once the preliminary project stage is complete. The proposed ASU instead provides the following two criteria in ASC 350-40-25-12 that must be met for entities to begin capitalizing software costs:

- "Management, with the relevant authority, implicitly or explicitly authorizes and commits to funding a computer software project."
- "It is probable that the project will be completed and the software will be used to perform the function intended (referred to as the probable-to-complete recognition threshold)."

¹⁷ ASC 985-20-15-5(a) and ASC 350-40-15-4A(a).

¹⁸ ASC 985-20-15-5(b) and ASC 350-40-15-4A(b).

Under the proposed ASU, the probable-to-complete recognition threshold would not be met when there is “significant uncertainty associated with the development activities of the software (referred to as significant development uncertainty).” The proposed guidance provides the following factors that may be indicative of significant development uncertainty:

- “The computer software being developed has novel, unique, unproven functions and features or technological innovations.”
- “The significant performance requirements of the computer software have not been identified, or the significant performance requirements continue to be substantially revised.”

For more information about the proposed ASU, see Deloitte’s November 5, 2024, [Heads Up](#).

12.13 Segment Reporting

12.13.1 Introduction

In November 2023, the FASB issued [ASU 2023-07](#), which amends ASC 280 to improve the information that a public entity discloses about its reportable segments and to address investor requests for more information about reportable segment expenses by requiring incremental disclosures for segment reporting.

The amendments in ASU 2023-07 apply to all public entities and are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024.

ASU 2023-07 does not change any of the requirements in ASC 280 related to how a public entity identifies its chief operating decision maker (CODM), identifies and aggregates its operating segments, or applies the quantitative thresholds to determine its reportable segments.

In accordance with ASC 350-20-35-33, “[t]he provisions of Topic 280 shall be used to determine the reporting units of an entity.” The process for identifying reporting units, which is relevant to both public and private entities, is also unchanged by ASU 2023-07. For considerations related to the identification of reporting units, see [Section 2.6](#) of Deloitte’s Roadmap [Goodwill and Intangible Assets](#).

12.13.2 The Fundamentals of Segment Reporting

In applying the segment reporting guidance in ASC 280, an entity should perform each of the following key steps:



These steps are further discussed below.

12.13.2.1 Step 1: Identification of Operating Segments

An entity's first step is to identify its operating segments. It performs such identification by using the management approach. As indicated in ASC 280-10-50-1, "[a]n operating segment is a component of a public entity that has all of the following characteristics:

- a. It engages in business activities from which it may recognize revenues and incur expenses
- b. Its operating results are regularly reviewed by the public entity's chief operating decision maker to make decisions about resources to be allocated to the segment and assess its performance.
- c. Its discrete financial information is available."

An entity may need to use judgment when evaluating whether a component has all the characteristics of an operating segment.

For more information, see [Chapter 2](#) of Deloitte's Roadmap [Segment Reporting](#).

12.13.2.2 Step 2: Aggregation Into a Single Operating Segment

Once an entity has identified its operating segments, it determines which of them to report.

Two or more operating segments may be aggregated into a single operating segment if the following three criteria are met:

- Aggregation is consistent with the objectives and basic principles of ASC 280.
- The segments have similar economic characteristics.
- The segments are similar with respect to **all** of the qualitative characteristics.

An entity is not required to aggregate operating segments. Because ASC 280 does not define the term "similar" or provide extensive guidance on the aggregation criteria, the determination that two or more operating segments are similar depends on facts and circumstances and is subject to judgment.

For more information, see [Section 3.2](#) of Deloitte's Roadmap [Segment Reporting](#).

12.13.2.3 Step 3: Identification of Reportable Segments

Once an entity determines which of its operating segments may be aggregated, it must apply the quantitative threshold guidance (i.e., the 10 percent tests that are based on revenue, profit or loss, and assets) in ASC 280 to determine which segments to report separately. An operating segment needs to meet only one of the 10 percent tests in ASC 280 to be a reportable segment, although it may meet more than one.

After identifying which operating segments meet the quantitative threshold requirements or are otherwise qualitatively material and must be reported separately, the entity can apply the guidance in ASC 280-10-50-13, which permits the combination of any remaining segments to produce a reportable segment if all of the following criteria are met:

- "[A]ggregation is consistent with the objective and basic principles" of ASC 280.
- The "segments have similar economic characteristics."
- The "segments share a **majority** of [qualitative] aggregation criteria" outlined in ASC 280 (emphasis added).

An entity is not required to aggregate operating segments and is encouraged to consider whether to separately report information on them irrespective of whether the segments meet the quantitative requirements for separate disclosure. The total external revenue disclosed by the reportable segments should constitute greater than 75 percent of total consolidated revenue.

Because aggregation is a high hurdle, the SEC staff may ask a registrant to provide an analysis on how it determined that its aggregation of operating segments complies with both the quantitative and qualitative requirements of ASC 280.

For more information, see [Chapter 3](#) of Deloitte's Roadmap *Segment Reporting*.

12.13.2.4 Step 4: Segment Disclosures

After an entity has identified its reportable segments, it must provide the following types of quantitative and qualitative disclosures for each of them, generally for each period presented:

- General information.
- Information about segment profit or loss and assets.
- Reconciliations to consolidated amounts.

For more information, see [Chapter 4](#) of Deloitte's Roadmap *Segment Reporting*.

12.13.2.5 Step 5: Entity-Wide Disclosures

Entities are required to disclose information about products and services, geographical operations, and major customers on an entity-wide basis regardless of how the entity is organized.

These disclosures are intended to ensure some level of comparability across entities, irrespective of how the entities are managed or resources are allocated. Accordingly, an entity should carefully consider the objectives and principles of ASC 280 when evaluating the disclosure requirements.

For more information, see [Chapter 5](#) of Deloitte's Roadmap *Segment Reporting*.

12.13.2.6 Key Changes in ASU 2023-07

The table below summarizes the main provisions of ASU 2023-07.

Change	Overview and When Disclosure Is Required
Significant segment expenses	On both an annual and an interim basis, significant segment expenses by reportable segment are required to be disclosed if they are regularly provided to the CODM and included in each reported measure of segment profit or loss.
Other segment items	On both an annual and an interim basis, other segment items by reportable segment are required to be disclosed. Such a disclosure would constitute the difference between reported segment revenues and the significant segment expenses (disclosed) less reported segment profit or loss. Disclosures are required on both an annual and an interim basis.
Interim disclosure changes	On an interim basis, all existing annual disclosures about segment profit or loss must be provided in addition to disclosure of significant segment expenses and other segment items as noted above.

(Table continued)

Change	Overview and When Disclosure Is Required
Multiple measures of a segment's profit or loss	On both an annual and an interim basis, entities may disclose more than one measure of segment profit or loss used by the CODM, provided that at least one of the reported measures includes the segment profit or loss measure that is most consistent with GAAP measurement principles.
CODM-related disclosures	On an annual basis, the CODM's title and position are required to be disclosed, as well as an explanation of how the CODM uses the reported measure(s) and other disclosures.
Entities with a single reportable segment	Entities with a single reportable segment must apply all of the disclosure requirements of ASU 2023-07, as well as all existing segment disclosure and reconciliation requirements in ASC 280, on both an annual and an interim basis.
Recasting of prior-period segment information to conform to current-period segment information	Recasting is required if segment information regularly provided to the CODM is changed in a manner that causes the identification of significant segment expenses to change.

12.13.3 Scope

All public entities that are subject to the segment reporting requirements of ASC 280 are within the scope of ASU 2023-07. As expressly provided in ASU 2023-07, the scope of ASC 280 includes public entities that have a single reportable segment. In addition, public entities include those that are preparing for the sale of securities in a public market, such as in an IPO.

Although an entity may not currently be profitable or have commercial revenue streams, an entity that engages in business activities will still need to comply with the requirements of ASC 280 to report segment information, including those related to the disclosure of significant segment expenses and other incremental disclosures introduced by ASU 2023-07.

Example 12-4

Company A is a public biotechnology company with one reportable segment and one operating segment. Currently in the R&D phase, A has not yet achieved commercialization and has not yet generated external revenue. Because A is a public entity, it is required to comply with ASC 280 when preparing financial statements under U.S. GAAP, including the disclosure requirements of ASU 2023-07.

Under ASU 2023-07, entities must apply all the current annual disclosure requirements in ASC 280 on an interim basis, except for entity-wide disclosures, in addition to the new requirements added by the ASU. This means that public entities must disclose significant segment expenses and other segment items, as well as all existing segment information about profit or loss, on an annual and interim basis.

12.13.4 Entities With a Single Reportable Segment

12.13.4.1 Single Reportable Segment — Disclosure Requirements

Some life sciences entities, particularly EGCs, have a single reportable segment. Entities with a single reportable segment are required to comply with all disclosure requirements in ASC 280 (see [Section 12.13.3](#)). The table below summarizes the disclosure requirements for entities with a single reportable segment before and after adoption of ASU 2023-07.

Disclosure Requirements for Entities With a Single Reportable Segment Before Adoption of ASU 2023-07

General information:

- Factors used to identify the public entity's reportable segment, including the basis of organization.
- Types of products and services from which the entity derives revenue.

Entity-wide disclosures:

- Products and services (see [Section 5.4](#) of Deloitte's Roadmap [Segment Reporting](#)).
- Geographical areas (see [Section 5.5](#) of Deloitte's Roadmap [Segment Reporting](#)).
- Major customers (see [Section 5.7](#) of Deloitte's Roadmap [Segment Reporting](#)).

Disclosure Requirements for Entities With a Single Reportable Segment After Adoption of ASU 2023-07

General information:

- Factors used to identify the public entity's reportable segment, including the basis of organization.
- Types of products and services from which the entity derives revenue.
- CODM-related disclosures, including disclosure of the CODM's title and position, as well as an explanation of how the CODM uses the reported measure(s) and other disclosures (see [Section 2.3.1](#) of Deloitte's Roadmap [Segment Reporting](#)).

Information about profit or loss and assets for the reportable segment:

- Segment performance measure.
- Reconciliation of segment performance measure to consolidated income.
- Segment assets.*
- Interest revenue and expense.**
- Depreciation and amortization.**
- Unusual items.**
- Equity in the income of equity method investees.**
- Income tax expense or benefit.**
- Other significant noncash items.**
- Investment in equity method investees.**
- Expenditures for long-lived assets.*
- Significant expense categories and amounts.
- Other segment items.

Entity-wide disclosures:

- Product and services (see [Section 5.4](#) of Deloitte's Roadmap [Segment Reporting](#)).
- Geographical areas (see [Section 5.5](#) of Deloitte's Roadmap [Segment Reporting](#)).
- Major customers (see [Section 5.7](#) of Deloitte's Roadmap [Segment Reporting](#)).

* Segment asset disclosure is only required if such information is provided to the CODM.

** To the extent that such information would be required for the entity on an annual basis.

12.13.4.2 Segment Performance Measure for Single Reportable Segments

The SEC staff expects that the required measure for entities managed on a consolidated basis would be consolidated net income since ASC 280 requires disclosure of the measure closest to GAAP (i.e., the measure most consistent with how amounts are measured in the financial statements). An entity may voluntarily disclose additional measures of segment profit or loss.

Entities that have a single reportable segment and a single operating segment are considered to be managed on a consolidated basis.

The evaluation of whether an entity is managed on a consolidated basis may be necessary in circumstances in which the entity is aggregating multiple operating segments into a single reportable segment. Although our discussions with the SEC staff did not address this, we would not object that it would be reasonable for an entity that aggregates multiple operating segments into a single reportable segment to use a segment performance measure other than consolidated net income. This is because ASC 280-10-50-11 permits, but does not require, an entity to aggregate operating segments into a reportable segment if their economic and qualitative characteristics are similar. In other words, if an entity elected not to aggregate operating segments, it would have multiple operating and reportable segments and could apply the multiple-segment reporting concepts discussed in [Sections 12.13.2.6](#) and [12.13.5](#).

12.13.4.3 Significant Segment Expenses Match the Consolidated Income Statement

When the regularly provided significant segment expense information is the same as that included in the consolidated income statement, entities that have a single reportable segment and are managed on a consolidated basis would have a choice of either of the following:

- Disclose those expenses as significant segment expenses in the segment footnote.
- Include a statement indicating that the CODM is regularly provided with only the consolidated expenses as noted on the face of the income statement (rather than disclosing a detailed reconciliation of significant expenses and other expenses as required by ASU 2023-07). This approach is consistent with paragraph BC32 of the ASU, which states, in part, that “[w]hile duplication is not prohibited, the Board believes that duplication of the entire consolidated income statement in the segment footnote is unnecessary; rather, a public entity may choose to reference the primary financial statements in the segment footnote.”

12.13.5 Use of Multiple Segment Performance Measures

An entity is not precluded from reporting additional measures of a segment’s profit or loss that are used by the CODM, provided that the entity presents at least one measure of segment profit or loss that, as stated in ASU 2023-07, “is determined in accordance with the measurement principles most consistent with those used in measuring the corresponding amounts in a public entity’s consolidated financial statements” (“basis consistent with GAAP”).

In accordance with ASC 280-10-50-28C (added by ASU 2023-07), if multiple measures of a segment’s profit or loss are disclosed, an entity must reconcile each total reportable segment measure to the consolidated financial statements. The guidance in the ASU on significant segment expenses and other segment items also applies to each of these additional measures.

12.13.5.1 Non-GAAP Considerations

Since disclosure of additional measures is voluntary (i.e., ASU 2023-07 permits, but does not require, the disclosure of additional segment performance measures), each additional measure that is not computed on a basis consistent with GAAP is considered to be a non-GAAP segment measure (“non-GAAP performance measure”) and is required to comply with the SEC’s requirements for non-GAAP performance measures. Discussed below are the requirements of SEC Regulation G and SEC Regulation S-K, Item 10(e), for each additional non-GAAP performance measure that an entity voluntarily discloses.

Regulation G provides that:

- Non-GAAP financial measures must not be misleading.
- The most directly comparable GAAP measure must be presented.
- A quantitative reconciliation of the non-GAAP financial measure to the most comparable GAAP measure must be presented for a non-GAAP measure.

Regulation S-K, Item 10(e), expands on Regulation G to require a registrant to:

- Present the most directly comparable GAAP measure with prominence equal to or greater than that of the non-GAAP measure.
- Include a statement indicating the reasons why the registrant believes that the non-GAAP measure provides useful information to investors about the registrant's financial condition and results of operations.
- Provide, to the extent material, a statement disclosing the additional purposes, if any, for which the registrant uses the non-GAAP measure.

The SEC staff's C&DIs on non-GAAP financial measures provide further guidance to registrants on how to apply the requirements of Regulation G and Regulation S-K, Item 10(e). Specifically, [C&DI Question 100.01](#) provides guidance on non-GAAP measures that could mislead investors. See also [Chapter 4](#) of Deloitte's Roadmap *Non-GAAP Financial Measures and Metrics*.

In our informal discussions with the SEC staff, the staff indicated that the disclosures under Regulation G and Regulation S-K, Item 10(e), do not need to be included in the financial statements and could be elsewhere in the filing. This approach is consistent with how entities reporting non-GAAP measures in their filings historically have complied with the SEC's disclosure requirements.

When a company voluntarily elects to show additional non-GAAP performance measures in the segment footnote, there are two separate reconciliations that are required: (1) the reconciliation of the segment performance measures (including non-GAAP performance measures) to consolidated income before tax (if the performance measures are pretax measures) or consolidated income after tax (if the performance measures are post-tax measures), as required by ASC 280; and (2) the reconciliation of the non-GAAP performance measure to the comparable GAAP measure (e.g., the required segment performance measure), as required by Regulation G. Possible alternatives for presenting both reconciliations may include:

1. Presentation of the ASC 280 reconciliation in the segment footnote with the Regulation G reconciliation presented in MD&A.
2. Separate presentation of the reconciliations required by ASC 280 and Regulation G in the segment footnote.
3. A combined presentation of the reconciliations required by ASC 280 and Regulation G in the segment footnote.

If an entity voluntarily includes additional non-GAAP performance measures, our firm's preference would be for the entity to include, or continue to include, these Regulation G and Regulation S-K, Item 10(e), disclosures in MD&A rather than in the segment footnote, in a manner consistent with historical practice and in light of the complexities of the SEC rules and regulations. However, entities should make their own determination after discussing their specific facts and circumstances with their SEC counsel.

Note that in accordance with Regulation S-K, the financial statement footnotes should not include a cross-reference to other parts of a filing that contain such Regulation G and Regulation S-K, Item 10(e), disclosures.

Illustrative Example

Background

The CODM of Company X regularly reviews GAAP segment profit and segment EBITDA to assess segment performance and allocate resources for X's two reportable segments. Company X has identified GAAP segment profit as the required measure of segment profit and loss since it is the measure of segment performance that is most consistent with GAAP measurement principles. Company X has voluntarily elected to also disclose segment EBITDA as an additional measure of segment performance, which constitutes a non-GAAP performance measure. Company X has determined that segment EBITDA (1) is not considered to be misleading and (2) complies with the C&DIs on non-GAAP performance measures as well as with SEC rules and regulations.

Company X must include, among other SEC and GAAP disclosures, ASC 280 reconciliations for both the GAAP segment profit and segment EBITDA performance measures and a Regulation G reconciliation for segment EBITDA.

Below is an option for preparing the reconciliations, under which the ASC 280 reconciliation is presented in the segment footnote and the Regulation G reconciliation is presented in MD&A. Note that the example only illustrates the required reconciliation for the segment EBITDA performance measure that is voluntarily presented. Company X would still need to disclose its ASC 280 reconciliation of segment profit (i.e., the required measure of segment profit or loss) to profit before tax and provide all other disclosures required by ASC 280, as amended by ASU 2023-07, for both the GAAP segment profit and segment EBITDA.

Illustrative Disclosure

In the manner shown below, X prepares its ASC 280 reconciliation in the segment footnote and prepares the Regulation G reconciliation in MD&A.

ASC 280 reconciliation in segment footnote:

	Reportable Segment A	Reportable Segment B	Total
Segment EBITDA	530	1,060	1,590
Unallocated corporate expenses			(100)
Depreciation and amortization			(60)
Interest			(30)
Profit before tax			1,400

This reconciles segment EBITDA to profit before tax as required by ASC 280.

Regulation G reconciliation in MD&A:

	Reportable Segment A	Reportable Segment B
GAAP segment profit	500	1,000
Depreciation and amortization	20	40
Interest	10	20
Segment EBITDA	530	1,060

This reconciles GAAP segment profit (the comparable GAAP measure) to segment EBITDA as required by Regulation G.

See Deloitte’s Roadmap [Segment Reporting](#) for additional considerations related to the use of multiple performance measures.

12.13.6 Significant Segment Expenses

For each reportable segment, ASU 2023-07 requires entities to disclose, on an interim and annual basis, those expenses that are (1) considered significant, including categories of expense and amounts; (2) regularly provided to the CODM; and (3) included in each reported measure of segment profit or loss.



ASU 2023-07 defines significant segment expenses as expenses that are regularly provided to the CODM and included within each reported measure of segment profit or loss, collectively referred to as the “significant expense principle.” For each reportable segment, entities are required to disclose, on an annual and interim basis, the significant expense categories and amounts for such expenses. The ASU focuses on the disclosure of information that is regularly provided to the CODM, even if it is not regularly reviewed by the CODM.

In a manner consistent with ASC 280, the identification of segment expenses by reportable segment is based on the management approach and, therefore, requires that the segment expenses be regularly provided to the CODM. Significant segment expense amounts will not necessarily tie to or be the same as the expense amounts and captions identified on the face of the income statement in accordance with U.S. GAAP.

12.13.6.1 Significance Threshold and Regularly Provided Information

ASU 2023-07 does not define the terms “significant” and “regularly provided” or specify how entities may interpret their meaning. We believe that entities should use judgment when determining whether certain segment items and amounts provided to the CODM should be disclosed. In doing so, they should keep in mind the principle that if an expense is important to the understanding of segment performance or would change an investor or financial statement user’s decision about that segment or the entity as a whole, the expense should generally be disclosed.

As indicated in ASC 280-10-50-26A (added by ASU 2023-07), an entity should “consider relevant qualitative and quantitative factors when determining whether segment expense categories and amounts are significant.”

Further, we generally believe that for most public entities, a regular review would be held at least quarterly; similarly, we believe that information provided at least quarterly would be considered regularly provided. Entities should consider their own facts and circumstances in determining which segment expenses are regularly provided to the CODM.

For more information, see [Sections 6.2](#) and [C.4](#) of Deloitte’s Roadmap [Segment Reporting](#).

12.13.6.2 Information Provided in More Than One Way

Given the management approach used in applying ASC 280, an entity may have more than one way to provide segment expense information to the CODM. In the life sciences industry, there are various cases in which an entity's CODM receives segment expense information in more than one way, specifically as related to R&D expenses. In those instances, an entity may need to use additional judgment to determine what segment expense information is relevant under the significant expense principle, particularly when more than one measure of segment performance is included in the financial statements.

Example 12-5

Company A, a public pharmaceutical company with one reportable segment, discloses R&D expense by program in its MD&A. The CODM package includes R&D expense by nature. Because the MD&A and the CODM package are both considered to be regularly provided to the CODM, the CODM is regularly provided with information about R&D expense in more than one way: by program and by nature. Company A must use judgment to determine which of the two sets of segment expense information is more relevant.

Company A determines that the CODM uses R&D expense by program to allocate resources and make financing decisions. Therefore, A concludes that R&D expense by program is more relevant for segment disclosure purposes.

We believe that when R&D expense is provided to the CODM in more than one way, R&D expense by program would generally be the most relevant for segment disclosure purposes.

12.14 Disaggregation of Income Statement Expenses

In November 2024, the FASB issued [ASU 2024-03](#), which provides for the disaggregation of income statement expenses for PBEs, including entities that file or furnish financial statements with the SEC. There is currently limited guidance in ASC 220 on the presentation of expenses in the income statement and disaggregation of expense captions. Presentation of certain income statement expense captions may be driven by SEC presentation requirements and industry-specific guidance, or triggered when a specific event occurs. Certain other types of expenses are required to be disclosed in the footnotes to the financial statements. The stated objective of ASU 2024-03 is to “address requests from investors for more detailed information about the types of expenses . . . in commonly presented expense captions (such as cost of sales, SG&A, and research and development).” As the ASU explains, investors advised the FASB that “disclosure of disaggregated information about expenses is critically important in understanding an entity's performance, assessing an entity's prospects for future cash flows, and comparing an entity's performance over time and with that of other entities.”

ASU 2024-03 requires entities to disaggregate any relevant expense caption presented on the face of the income statement within continuing operations into the following required natural expense categories, as applicable: “(a) purchases of inventory, (b) employee compensation, (c) depreciation, (d) intangible asset amortization, and (e) depreciation, depletion, and amortization recognized as part of oil- and gas-producing activities” or other depletion expenses. The tabular disclosure would also include certain other expenses, when applicable. The ASU does not change or remove existing expense disclosure requirements; however, it may affect where that information appears in the footnotes to the financial statements.

The ASU also provides the following clarifications regarding the identification of relevant expense captions:

- A relevant expense caption may include an “expense caption [that] is presented as a natural expense classification on the face of the income statement” (e.g., depreciation and amortization). If that natural expense classification “includes more than one of the required expense categories,” further disaggregation is required. For example, an expense caption consisting of depreciation and intangible asset amortization would need to be further disaggregated to separately disclose depreciation and intangible asset amortization in the footnotes.
- An expense caption that consists entirely of one of the required natural expense categories will not be subject to the new disaggregation guidance. For example, an expense caption consisting entirely of depreciation expense on the face of the income statement would not need to be further disaggregated.

Certain expenses and gains or losses that may require disclosure under existing U.S. GAAP, and that are recorded in a relevant expense caption, should be presented in the same tabular disclosure on an annual and, when applicable, interim basis, for each relevant expense caption in which the expense is recorded. For life sciences entities, such expenses may include, but are not limited to, (1) the amount of R&D assets acquired in a transaction other than a business combination and written off and (2) recognized intangible asset impairment losses.

Certain other expenses and gains or losses require disclosure only if those amounts are included entirely in one expense caption and not over multiple expense captions. For example, if (1) cost of sales was a relevant expense caption and (2) warranty expense was recognized entirely in the cost of sales rather than in multiple expense captions presented on the face of the income statement, warranty expense would need to be included as a separate category in the tabular disclosure for cost of sales. However, in that same example, if the warranty expense was disaggregated across multiple expense captions (e.g., also included in SG&A), separate disaggregation would not be required.

ASU 2024-03 requires entities to disclose the amount, and a qualitative description of the composition, of other items remaining in relevant expense captions that are not separately disaggregated. The ASU notes that the “detail provided in those qualitative disclosures should be commensurate with the significance of the amounts being described.”

ASU 2024-03 requires an entity to present a separate total of its selling expenses in a manner similar to the presentation of R&D and advertising expenses. The ASU does not define selling expenses. Rather, entities will make their own determination of the composition of selling expenses and disclose the definition on an annual basis. Selling expenses should include only items that are presented as expenses in the income statement. If that definition changes during an interim period, disclosure of such change is required in that interim period.

ASU 2024-03 requires disclosure of expense reimbursement amounts included in relevant expense captions that are related to a cost-sharing or cost-reimbursement arrangement. Such amounts should be provided in the tabular format disclosure. An entity that includes amounts net of expense reimbursements from another entity within a relevant expense caption may elect one of the following alternatives, which should be applied consistently once elected:

- Disclose separately the amount of the expense reimbursement.
- Disclose the amounts of the required expense categories that are included in the relevant expense caption net of any reimbursement effects.

Further, the ASU requires entities to disclose “how expense reimbursements related to a cost-sharing or cost-reimbursement arrangement are included in the tabular format disclosure.”



Connecting the Dots

R&D expense is generally expected to represent a relevant expense caption for many life sciences entities. In accordance with ASU 2024-03, such expense caption would require further disaggregation into specific natural expense categories such as employee compensation, depreciation of equipment used in R&D, and other R&D, as applicable. Further, R&D cost-sharing arrangements (e.g., collaborative arrangements) are common in the life sciences industry, and the amount of expense reimbursements presented net within R&D expense will be subject to the disclosure requirements of the ASU.

ASU 2024-03 is effective for all PBEs for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027.¹⁹ Early adoption is permitted. PBEs are required to adopt the ASU prospectively. However, PBEs are permitted to apply the amendments in the ASU retrospectively. The FASB has provided a delayed implementation timeline to give issuers additional time to prepare for the impacts of adoption, including the potential need for issuers to modify their existing financial reporting systems and processes to compile and present the required information.

For more information about ASU 2024-03, see Deloitte’s November 8, 2024 (updated January 21, 2025), [Heads Up](#).

¹⁹ In January 2025, the FASB issued [ASU 2025-01](#), which clarifies the effective date of ASU 2024-03 with respect to interim periods. The rationale for the Board’s clarification is that non-calendar-year-end entities could have concluded that initial adoption of ASU 2024-03’s amendments would have been required in an interim reporting period rather than in an annual reporting period.

Appendix B — Titles of Standards and Other Literature

AICPA Literature

Accounting and Valuation Guides

Assets Acquired to Be Used in Research and Development Activities

Valuation of Privately-Held-Company Equity Securities Issued as Compensation

Clarified Statements on Auditing Standards

AU-C Section 501, "Audit Evidence — Specific Considerations for Selected Items"

AU-C Section 620, "Using the Work of an Auditor's Specialist"

FASB Literature

ASC Topics

ASC 105, *Generally Accepted Accounting Principles*

ASC 205, *Presentation of Financial Statements*

ASC 210, *Balance Sheet*

ASC 220, *Income Statement — Reporting Comprehensive Income*

ASC 230, *Statement of Cash Flows*

ASC 235, *Notes to Financial Statements*

ASC 250, *Accounting Changes and Error Corrections*

ASC 260, *Earnings per Share*

ASC 270, *Interim Reporting*

ASC 275, *Risks and Uncertainties*

ASC 280, *Segment Reporting*

ASC 310, *Receivables*

ASC 320, *Investments — Debt Securities*

ASC 321, *Investments — Equity Securities*

ASC 323, *Investments — Equity Method and Joint Ventures*

ASC 326, *Financial Instruments — Credit Losses*

ASC 330, *Inventory*

ASC 340, *Other Assets and Deferred Costs*

ASC 350, *Intangibles — Goodwill and Other*

ASC 360, *Property, Plant, and Equipment*

ASC 405, *Liabilities*

ASC 410, *Asset Retirement and Environmental Obligations*

ASC 420, *Exit or Disposal Cost Obligations*

ASC 440, *Commitments*

ASC 450, *Contingencies*

ASC 460, *Guarantees*

ASC 470, *Debt*

ASC 480, *Distinguishing Liabilities From Equity*

ASC 505, *Equity*

ASC 605, *Revenue Recognition*

ASC 606, *Revenue From Contracts With Customers*

ASC 610, *Other Income*

ASC 705, *Cost of Sales and Services*

ASC 710, *Compensation — General*

ASC 712, *Compensation — Nonretirement Postemployment Benefits*

ASC 715, *Compensation — Retirement Benefits*

ASC 718, *Compensation — Stock Compensation*

ASC 720, *Other Expenses*

ASC 730, *Research and Development*

ASC 740, *Income Taxes*

ASC 805, *Business Combinations*

ASC 808, *Collaborative Arrangements*

ASC 810, *Consolidation*

ASC 815, *Derivatives and Hedging*

ASC 820, *Fair Value Measurement*

ASC 825, *Financial Instruments*

ASC 830, *Foreign Currency Matters*

ASC 832, *Government Assistance*

ASC 835, *Interest*
 ASC 840, *Leases*
 ASC 842, *Leases*
 ASC 845, *Nonmonetary Transactions*
 ASC 848, *Reference Rate Reform*
 ASC 852, *Reorganizations*
 ASC 855, *Subsequent Events*
 ASC 860, *Transfers and Servicing*
 ASC 905, *Agriculture*
 ASC 915, *Development Stage Entities*
 ASC 930, *Extractive Activities — Mining*
 ASC 944, *Financial Services — Insurance*
 ASC 946, *Financial Services — Investment Companies*
 ASC 954, *Health Care Entities*
 ASC 958, *Not-for-Profit Entities*
 ASC 960, *Plan Accounting — Defined Benefit Pension Plans*
 ASC 970, *Real Estate — General*
 ASC 985, *Software*

ASUs

ASU 2010-27, *Other Expenses (Topic 720): Fees Paid to the Federal Government by Pharmaceutical Manufacturers* — a consensus of the FASB Emerging Issues Task Force

ASU 2011-06, *Other Expenses (Topic 720): Fees Paid to the Federal Government by Health Insurers* — a consensus of the FASB Emerging Issues Task Force

ASU 2014-09, *Revenue From Contracts With Customers (Topic 606)*

ASU 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*

ASU 2014-15, *Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern*

ASU 2014-16, *Derivatives and Hedging (Topic 815): Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity* — a consensus of the FASB Emerging Issues Task Force

ASU 2015-16, *Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments*

ASU 2016-01, *Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*

ASU 2016-02, *Leases (Topic 842)*

ASU 2016-10, *Revenue From Contracts With Customers (Topic 606): Identifying Performance Obligations and Licensing*

ASU 2016-12, *Revenue From Contracts With Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*

ASU 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*

ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* — a consensus of the FASB Emerging Issues Task Force

ASU 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory*

ASU 2016-17, *Consolidation (Topic 810): Interests Held Through Related Parties That Are Under Common Control*

ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* — a consensus of the FASB Emerging Issues Task Force

ASU 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue From Contracts With Customers*

ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*

ASU 2017-04, *Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*

ASU 2017-11, *Earnings per Share (Topic 260); Distinguishing Liabilities From Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments With Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests With a Scope Exception*

ASU 2017-12, *Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities*

ASU 2018-08, *Not-for-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*

ASU 2018-10, *Codification Improvements to Topic 842, Leases*

ASU 2018-11, *Leases (Topic 842): Targeted Improvements*

ASU 2018-17, *Consolidation (Topic 810): Targeted Improvements to Related Party Guidance for Variable Interest Entities*

ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*

ASU 2019-01, *Leases (Topic 842): Codification Improvements*

ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments — Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*

ASU 2019-05, *Financial Instruments — Credit Losses (Topic 326): Targeted Transition Relief*

ASU 2019-10, *Financial Instruments — Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*

ASU 2019-11, *Codification Improvements to Topic 326, Financial Instruments — Credit Losses*

ASU 2020-01, *Investments — Equity Securities (Topic 321), Investments — Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815): Clarifying the Interactions Between Topic 321, Topic 323, and Topic 815* — a consensus of the FASB Emerging Issues Task Force

ASU 2020-02, *Financial Instruments — Credit Losses (Topic 326) and Leases (Topic 842): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02, Leases (Topic 842)*

ASU 2020-03, *Codification Improvements to Financial Instruments*

ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*

ASU 2020-05, *Revenue From Contracts With Customers (Topic 606) and Leases (Topic 842): Effective Dates for Certain Entities*

ASU 2020-06, *Debt — Debt With Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*

ASU 2021-01, *Reference Rate Reform (Topic 848): Scope*

ASU 2021-04, *Earnings per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options* — a consensus of the FASB Emerging Issues Task Force

ASU 2021-05, *Leases (Topic 842): Lessors — Certain Leases With Variable Lease Payments*

ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities From Contracts With Customers*

ASU 2021-09, *Leases (Topic 842): Discount Rate for Lessees That Are Not Public Business Entities*

ASU 2022-01, *Derivatives and Hedging (Topic 815): Fair Value Hedging — Portfolio Layer Method*

ASU 2022-02, *Financial Instruments — Credit Losses (Topic 326): Troubled Debt Restructurings and Vintage Disclosures*

ASU 2022-03, *Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*

ASU 2022-06, *Reference Rate Reform (Topic 848): Deferral of the Sunset Date of Topic 848*

ASU 2023-01, *Leases (Topic 842): Common Control Arrangements*

ASU 2023-05, *Business Combinations — Joint Venture Formations (Subtopic 805-60): Recognition and Initial Measurement*

ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*

ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*

ASU 2024-02, *Codification Improvements — Amendments to Remove References to the Concepts Statements*

ASU 2024-03, *Income Statement — Reporting Comprehensive Income — Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*

ASU 2025-01, *Income Statement — Reporting Comprehensive Income — Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date*

Concepts Statements

No. 5, *Recognition and Measurement in Financial Statements of Business Enterprises*

No. 8, *Conceptual Framework for Financial Reporting — Chapter 4, Elements of Financial Statements*

Invitations to Comment

No. 2021-004, *Agenda Consultation*

No. 2025-ITC100, *Agenda Consultation*

Proposed ASUs

No. 2017-280, *Consolidation (Topic 812): Reorganization*

No. 2019-790, *Derivatives and Hedging (Topic 815): Codification Improvements to Hedge Accounting*

No. 2019-800, *Codification Improvements*

No. 2024-ED100, *Derivatives and Hedging (Topic 815) and Revenue From Contracts With Customers (Topic 606): Derivatives Scope Refinements and Scope Clarification for a Share-Based Payment From a Customer in a Revenue Contract*

No. 2024-ED200, *Derivatives and Hedging (Topic 815): Hedge Accounting Improvements*

No. 2024-ED400, *Intangibles — Goodwill and Other — Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software*

No. 2024-ED700, *Government Grants (Topic 832): Accounting for Government Grants by Business Entities*

No. 2024-ED910, *Environmental Credits and Environmental Credit Obligations (Topic 818)*

Other

FASB Staff *Revenue Recognition Implementation Q&As*

IFRS Literature

IFRS 2, *Share-Based Payment*

IFRS 3, *Business Combinations*

IFRS 9, *Financial Instruments*

IFRS 10, *Consolidated Financial Statements*

IFRS 11, *Joint Arrangements*

IFRS 12, *Disclosure of Interests in Other Entities*

IFRS 15, *Revenue From Contracts With Customers*

IFRS 16, *Leases*

IAS 1, *Presentation of Financial Statements*

IAS 7, *Statement of Cash Flows*

IAS 10, *Events After the Reporting Period*

IAS 12, *Income Taxes*

IAS 17, *Leases*

IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*

IAS 21, *The Effects of Changes in Foreign Exchange Rates*

IAS 27, *Separate Financial Statements*

IAS 32, *Financial Instruments: Presentation*

IAS 37, *Provisions, Contingent Liabilities and Contingent Assets*

IAS 38, *Intangible Assets*

IAS 40, *Investment Property*

Lease Liability in a Sale and Leaseback: Amendments to IFRS 16

IRC

Section 78, "Gross Up for Deemed Paid Foreign Tax Credit"

Section 162(a), "Trade or Business Expenses; General"

Section 163(j), "Interest; Limitation on Business Interest"

Section 174, "Amortization of Research and Experimental Expenditures"

Section 197, "Amortization of Goodwill and Certain Other Intangibles"

Section 382, "Limitation on Net Operating Loss Carryforwards and Certain Built-In Losses Following Ownership Change"

Section 409A, "Inclusion in Gross Income of Deferred Compensation Under Nonqualified Deferred Compensation Plans"

Section 422, "Incentive Stock Options"

Section 423, "Employee Stock Purchase Plans"

PCAOB Literature

Auditing Standard 3101, *The Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion*

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SEC Literature

Final Rule Releases

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No. 33-11126, *Listing Standards for Recovery of Erroneously Awarded Compensation*

No. 33-11265, *Special Purpose Acquisition Companies, Shell Companies, and Projections*

No. 33-11275, *The Enhancement and Standardization of Climate-Related Disclosures for Investors* [stayed]

No. 34-95607, *Pay Versus Performance*

FRM

Topic 1, "Registrant's Financial Statements"

Topic 2, "Other Financial Statements Required"

Topic 3, "Pro Forma Financial Information"

Topic 5, "Smaller Reporting Companies"

Topic 7, "Related Party Matters"

Topic 10, "Emerging Growth Companies"

Topic 12, "Reverse Acquisitions and Reverse Recapitalizations"

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Regulation S-K

Item 10(e), "General: Use of Non-GAAP Financial Measures in Commission Filings"

Item 101, "Description of Business"

Item 103, "Legal Proceedings"

Item 201, "Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters"

Item 302, "Supplementary Financial Information"

Item 303, "Management's Discussion and Analysis of Financial Condition and Results of Operations"

Item 305, "Quantitative and Qualitative Disclosures About Market Risk"

Item 308, "Internal Control Over Financial Reporting"

Item 402, "Executive Compensation"

Item 404, "Transactions With Related Persons, Promoters and Certain Control Persons"

Item 407, "Corporate Governance"

Item 503, "Prospectus Summary"

Regulation S-X

Rule 1-02(w), "Definitions of Terms Used in Regulation S-X (17 CFR part 210); Significant Subsidiary"

Article 2, "Qualifications and Reports of Accountants"

Rule 3-01, "Consolidated Balance Sheet"

Rule 3-02, "Consolidated Statements of Comprehensive Income and Cash Flows"

Rule 3-03, "Instructions to Statement of Comprehensive Income Requirements"

Rule 3-04, "Changes in Stockholders' Equity and Noncontrolling Interests"

Rule 3-05, "Financial Statements of Businesses Acquired or to Be Acquired"

Rule 3-09, "Separate Financial Statements of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons"

Rule 3-10, "Financial Statements of Guarantors and Issuers of Guaranteed Securities Registered or Being Registered"

Rule 3-12, "Age of Financial Statements at Effective Date of Registration Statement or at Mailing Date of Proxy Statement"

Rule 3-13, "Filing of Other Financial Statements in Certain Cases"

Rule 3-14, "Special Instructions for Financial Statements of Real Estate Operations Acquired or to Be Acquired"

Rule 3-16, "Financial Statements of Affiliates Whose Securities Collateralize an Issue Registered or Being Registered"

Rule 4-08(g), "General Notes to Financial Statements; Summarized Financial Information of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons"

Rule 4-08(n), "General Notes to Financial Statements; Accounting Policies for Certain Derivative Instruments"

Rule 5-02, "Commercial and Industrial Companies; Balance Sheets"

Rule 5-03, "Commercial and Industrial Companies; Statements of Comprehensive Income"

Article 8, "Financial Statements of Smaller Reporting Companies"

Rule 10-01(b), "Interim Financial Statements; Other Instructions as to Content"

Article 11, "Pro Forma Financial Information"

Rule 11-01 "Presentation Requirements"

Rule 11-02(a), "Preparation Requirements; Form and Content"

Article 15, "Acquisitions of Businesses by a Shell Company (Other Than a Business Combination Related Shell Company)"

SAB Topics

No. 1.B.3, "Financial Statements; Allocation of Expenses and Related Disclosure in Financial Statements of Subsidiaries, Divisions or Lesser Business Components of Another Entity: Other Matters"

No. 1.M, "Financial Statements; Materiality"

No. 5.A, "Miscellaneous Accounting; Expenses of Offering"

No. 5.Y, "Miscellaneous Accounting; Accounting and Disclosures Relating to Loss Contingencies"

No. 14, "Share-Based Payment"

- No. 14.B, "Transition From Nonpublic to Public Entity Status"
- No. 14.D, "Certain Assumptions Used in Valuation Methods"
 - No. 14.D.1, "Expected Volatility"
 - No. 14.D.2, "Expected Term"

Securities Act of 1933

Rule 144, “Persons Deemed Not to Be Engaged in a Distribution and Therefore Not Underwriters — General Guidance”

Rule 405, “Definitions of Terms”

Section 6(e), “Commissions, Allowances, Discounts, and Other Fees”

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Rule 17a-5, “Reports to Be Made by Certain Brokers and Dealers”

Section 3(a)(80), “Definitions and Application of Title; Emerging Growth Company”

Section 13(a), “Periodical and Other Reports”

Section 15(d), “Supplementary and Periodic Information”

TRG Agenda Papers

TRG Agenda Paper 6, *Customer Options for Additional Goods and Services and Nonrefundable Upfront Fees*

TRG Agenda Paper 11, *October 2014 Meeting — Summary of Issues Discussed and Next Steps*

TRG Agenda Paper 41, *Measuring Progress When Multiple Goods or Services Are Included in a Single Performance Obligation*

TRG Agenda Paper 44, *July 2015 Meeting — Summary of Issues Discussed and Next Steps*

TRG Agenda Paper 48, *Customer Options for Additional Goods and Services*

TRG Agenda Paper 54, *Considering Class of Customer When Evaluating Whether a Customer Option Gives Rise to a Material Right*

TRG Agenda Paper 55, *April 2016 Meeting — Summary of Issues Discussed and Next Steps*

Superseded Literature

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AIN-APB 25, *Accounting for Stock Issued to Employees: Accounting Interpretations of APB Opinion No. 25*

AICPA Accounting Statement of Position

96-1, *Environmental Remediation Liabilities*

EITF Abstracts

Issue No. 00-21, “Revenue Arrangements With Multiple Deliverables”

Issue No. 01-9, “Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor’s Products)”

Issue No. 01-10, “Accounting for the Impact of the Terrorist Attacks of September 11, 2001”

Issue No. 03-17, “Subsequent Accounting for Executory Contracts That Have Been Recognized on an Entity’s Balance Sheet”

Issue No. 08-6, “Equity Method Investment Accounting Considerations”

Issue No. 09-2, “Research and Development Assets Acquired in an Asset Acquisition”

Issue No. 09-4, “Seller Accounting for Contingent Consideration”

FASB Concepts Statement

No. 6, *Elements of Financial Statements* — a replacement of FASB Concepts Statement No. 3 (incorporating an amendment of FASB Concepts Statement No. 2)

FASB Interpretation

No. 14, *Reasonable Estimation of the Amount of a Loss* — an interpretation of FASB Statement No. 5

FASB Statements

No. 5, *Accounting for Contingencies*

No. 52, *Foreign Currency Translation*

No. 95, *Statement of Cash Flows*

No. 114, *Accounting by Creditors for Impairment of a Loan* — an amendment of FASB Statements No. 5 and 15

No. 123(R), *Share-Based Payment*

No. 133, *Accounting for Derivative Instruments and Hedging Activities*

No. 141, *Business Combinations*

No. 141(R), *Business Combinations*

No. 160, *Noncontrolling Interests in Consolidated Financial Statements* — an amendment of ARB No. 51

Other

California Climate Legislation

AB-1305, *Voluntary Carbon Market Disclosures*

SB-219, *Greenhouse Gases: Climate Corporate Accountability: Climate-Related Financial Risk*

SB-253, *Climate Corporate Data Accountability Act*

SB-261, *Greenhouse Gases: Climate-Related Financial Risk*

European Sustainability Reporting Standards (ESRS)

Regulation (EU) 2023/2772 of 31 July 2023 Supplementing Directive 2013/34/EU of the European Parliament and of the Council as Regards Sustainability Reporting Standards

- ESRS 1, *General Requirements*
- ESRS 2, *General Disclosures*

E.U. Corporate Sustainability Reporting Directive (CSRD)

Directive 2022/2464/EU of the European Parliament and of the Council of 14 December 2022 Amending Regulation (EU) No 537/2014, Directive 2004/109/EC, Directive 2006/43/EC and Directive 2013/34/EU, as Regards Corporate Sustainability Reporting

EU Taxonomy Regulation

Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the Establishment of a Framework to Facilitate Sustainable Investment, and Amending Regulation (EU) 2019/2088

IFRS Sustainability Disclosure Standards

IFRS S1, General Requirements for Disclosure of Sustainability-Related Financial Information

IFRS S2, Climate-Related Disclosures

Non-Financial Reporting Directive (NFRD)

Directive 2014/95/EU of the European Parliament and of the Council of 22 October 2014 Amending Directive 2013/34/EU as Regards Disclosure of Non-Financial and Diversity Information by Certain Large Undertakings and Groups

Proposed European Commission Literature

Omnibus I — COM(2025) 80, Proposal for a Directive of the European Parliament and of the Council Amending Directives (EU) 2022/2464 and (EU) 2024/1760 as Regards the Dates From Which Member States Are to Apply Certain Corporate Sustainability Reporting and Due Diligence Requirements

Omnibus I — COM(2025) 81, Proposal for a Directive of the European Parliament and of the Council Amending Directives 2006/43/EC, 2013/34/EU, (EU) 2022/2464 and (EU) 2024/1760 as Regards Certain Corporate Sustainability Reporting and Due Diligence Requirements

Appendix C — Abbreviations

Abbreviation	Description
AETR	annual effective tax rate
AFS	available for sale
AFSI	adjusted financial statement income
AI	artificial intelligence
AICPA	American Institute of Certified Public Accountants
AIN	AICPA Accounting Interpretation of an APB Opinion
AMT	alternative minimum tax
ANDA	abbreviated new drug application
APB	Accounting Principles Board
API	active pharmaceutical ingredient
ARO	asset retirement obligation
ASC	FASB Accounting Standards Codification
ASR	accelerated share repurchase
ASU	FASB Accounting Standards Update
AUD	Australian dollar(s)
BC	Basis for Conclusions
BEAT	base erosion anti-abuse tax
BEMTA	base erosion minimum tax amount
BPD	branded prescription drug
C&DI	Compliance and Disclosure Interpretation
CAM	critical audit matter
CAQ	Center for Audit Quality
CARB	California Air Resources Board
CARES Act	Coronavirus Aid, Relief, and Economic Security Act

Abbreviation	Description
CECL	current expected credit loss
CFC	controlled foreign corporation
CIMA	Chartered Institute of Management Accountants
CMO	contract manufacturing organization
CODM	chief operating decision maker
CPU	central processing unit
CRO	contract research organization
CSRD	Corporate Sustainability Reporting Directive
DTA	deferred tax asset
DTL	deferred tax liability
EBITDA	earnings before interest, taxes, depreciation, and amortization
EC	European Commission
ED	exposure draft
EDGAR	SEC electronic data gathering, analysis, and retrieval system
EFRAG	European Financial Reporting Advisory Group
EGC	emerging growth company
EITF	Emerging Issues Task Force
ELOC	equity line of credit
EPS	earnings per share
ESA	energy service agreement
ESG	environmental, social, and governance
ESPP	employee stock purchase plan
ESRS	European Sustainability Reporting Standards

Abbreviation	Description
E.U.	European Union
EUR	euros
Exchange Act	Securities Exchange Act of 1934
FAQ	frequently asked question
FASB	Financial Accounting Standards Board
FAST Act	Fixing America's Surface Transportation Act
FDA	U.S. Food and Drug Administration
FDII	foreign-derived intangible income
FOB	free on board
FPI	foreign private issuer
FRM	SEC Division of Corporation Finance Financial Reporting Manual
FVO	fair value option
FVTOCI	fair value through other comprehensive income
GAAP	generally accepted accounting principles
GDP	gross domestic product
GHG	greenhouse gas
GILTI	global intangible low-taxed income
GloBE	Global anti-Base Erosion
GPO	group purchasing organization
GPU	graphics processing unit
HAFWP	how and for what purpose
HFI	held for investment
HFS	held for sale
HVAC	heating, ventilation, and air conditioning
IAS	International Accounting Standard
IASB	International Accounting Standards Board
ICFR	internal control over financial reporting
IFRS	International Financial Reporting Standard
IIR	investigator-initiated research

Abbreviation	Description
IOSCO	International Organization of Securities Commissions
IP	intellectual property
IPO	initial public offering
IPR&D	in-process research and development
IRA	Inflation Reduction Act of 2022
IRC	Internal Revenue Code
IRS	Internal Revenue Service
ISO	incentive stock option
ISSB	International Sustainability Standards Board
IT	information technology
ITC	invitation to comment
JOBS Act	Jumpstart Our Business Startups Act
LCD	liquid-crystal display
LIBOR	London Interbank Offered Rate
LIFO	last in, first out
LLM	large language model
M&A	merger and acquisition
MD&A	Management's Discussion & Analysis
MNE	multinational enterprise
MSL	medical science liaison
NDA	new drug application
NFP	not-for-profit (entity)
NFRD	Non-Financial Reporting Directive
NIH	National Institutes of Health
NLP	natural language processing
NOL	net operating loss
NOPA	notice of proposed adjustment
NQSO or NSO	nonqualified stock option
OCA	SEC Office of the Chief Accountant
OCI	other comprehensive income

Abbreviation	Description
OECD	Organisation for Economic Co-operation and Development
OEM	original equipment manufacturer
PBE	public business entity
PCAOB	Public Company Accounting Oversight Board
PCC	Private Company Council
PIPE	private investment in public equity
PP&E	property, plant, and equipment
PRV	priority review voucher
PTRS	probability of technical and regulatory success
Q&A	question and answer
QIP	qualified improvement property
R&D	research and development
R&E	research and experimental
RAM	random-access memory
REMS	risk evaluation and mitigation strategy
RIM	retail inventory method
ROU	right-of-use
SaaS	software as a service
SAB	SEC Staff Accounting Bulletin
SAFE	simple agreement for future equity
SEC	U.S. Securities and Exchange Commission

Abbreviation	Description
Securities Act	Securities Act of 1933
SEPA	standby equity purchase agreement
SG&A	selling, general, and administrative
SOX	Sarbanes-Oxley Act of 2002
SPAC	special-purpose acquisition company
SPPI	solely payments of principal and interest
SRC	smaller reporting company
S&P 500	Standard & Poor's 500 Index
TCFD	Task Force on Climate-related Financial Disclosures
TD	Treasury Decision
TDR	troubled debt restructuring
TRG	transition resource group
TSA	transition services agreement
USD	U.S. dollar(s)
UTB	unrecognized tax benefit
VCO	voluntary carbon offset
VIE	variable interest entity
VWAP	volume-weighted average daily market price
XBRL	eXtensible Business Reporting Language

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