



## **Life Sciences Industry Accounting Guide** Other Accounting and Financial Reporting Topics

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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 2026 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, legislative, and rulemaking developments (through March 6, 2026); and key differences between U.S. GAAP and IFRS<sup>®</sup> 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 2025 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 provides.

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 — Before the Adoption of ASU 2025-10**

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.<sup>1</sup> 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

<sup>1</sup> 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 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).

#### 12.1.1.2.2 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."

### 12.1.1.2.3 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.

### 12.1.1.2.4 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.

### 12.1.1.2.5 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

##### **Nature of the Assistance, Related Accounting Policies, and Effect on Financial Statement Amounts**

**50-3** An entity shall disclose the following about transactions with a government within the scope of this Topic:

- 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.

##### **Significant Terms and Conditions**

**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:

- 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.

### **12.1.1.3 Government Grants — After the Adoption of ASU 2025-10**

In December 2025, the FASB issued [ASU 2025-10](#), which adds guidance to ASC 832 on the recognition, measurement, and presentation of government grants. In the absence of such guidance, many for-profit entities historically have analogized to other GAAP, including IAS 20 or ASC 958-605, when accounting for government grants. In developing the ASU's recognition and measurement framework, the FASB largely leveraged the guidance in IAS 20.

#### **12.1.1.3.1 Scope of ASU 2025-10**

ASU 2025-10 defines a government grant as “[a] transfer of a monetary asset or a tangible nonmonetary asset, other than in an exchange transaction (including an exchange transaction that may be at a significant discount to fair value), from a government to an entity except for a not-for-profit entity and an employee benefit plan within the scope of Topics 960, 962, and 965 on plan accounting.” All business entities other than NFPs or certain employee benefit plans will be subject to the guidance in the ASU, but the new guidance will not apply to the following transaction types:

- “Transactions within the scope of Topic 740 on income taxes (for example, nonrefundable, nontransferable income tax credits).”
- “The benefit of below-market interest rate loans.”
- “Government guarantees.”

- “The transfer of an intangible asset or provision of a service.”
- “A reduction of an entity’s liabilities (for example, sales, property, payroll, or other tax abatement).”
- “Government participation in the ownership of an entity.”
- “A contribution to a business entity from a nongovernmental source within the scope of Subtopic 958-605 on not-for-profit entities — revenue recognition.”
- “A transaction within the scope of Topic 606 on revenue from contracts with customers or Subtopic 610-20 on other income — gains and losses from the derecognition of nonfinancial assets.”

The scope of ASU 2025-10 is consistent with that of the [exposure draft](#) (ED) issued in November 2024. In providing feedback on the ED, stakeholders asked the FASB to clarify whether transferable tax credits and leases would be specifically excluded from the final ASU. Paragraph BC29 of ASU 2025-10 states, in part, that “the Board decided not to expand the scope of the amendments in this Update to include intangible assets or a subset of intangible assets such as nonrefundable, transferable tax credits.”



### Connecting the Dots

In the absence of authoritative guidance, business entities that generate transferable tax credits have established various practices. These credits may be transferred to an unrelated third party in an exchange transaction, and business entities may have already made an accounting policy election to account for such credits under ASC 740 or other GAAP. An entity generating the credits does not need taxable income to obtain an economic benefit from them. Many entities that elect to account for the transferable tax credits outside the scope of ASC 740 currently apply IAS 20 by analogy because the receiving entity is obtaining an asset (i.e., a transferable tax credit) from the government. This is similar to the manner in which entities account for refundable tax credits (which are effectively a monetary grant from the government). ASC 832-10-55-4 (added by ASU 2025-10) states, in part, that a “refundable tax credit that is not within the scope of Topic 740 on income taxes” should be accounted for as a government grant.

As noted above, the FASB decided not to expand the scope of ASU 2025-10 to include any intangible assets, including nonrefundable, transferable tax credits. Therefore, entities that account for nonrefundable, transferable tax credits outside the scope of ASC 740 will need to consider the appropriateness of their accounting policy upon adopting the ASU. We believe that upon adopting the ASU, entities may analogize to ASC 832 when accounting for nonrefundable, transferable tax credits. Entities should consider consulting with their accounting advisers if they currently analogize to IAS 20 or ASC 958-605 to account for nonrefundable, transferable tax credits. See the [Connecting the Dots](#) discussion below that refers to paragraph BC63 of the ASU.

#### 12.1.1.3.2 Recognition, Measurement, and Presentation

Under ASU 2025-10, the recognition, measurement, and presentation of a government grant depends on whether the grant is related to an asset or to income. The ASU defines a grant related to an asset and a grant related to income as follows:

- *Grant related to an asset* — “A government grant, or part of a government grant, that is conditioned on the purchase, construction, or acquisition of an asset (for example, a long-lived asset or inventory). 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, or part of a government grant, other than a grant related to an asset (for example, a grant that reimburses an entity for operating expenses).”

Regardless of whether a government grant is related to an asset or to income, an entity will not be able to recognize the grant until it is probable that both of the following criteria in ASC 832-10-25-1(a) (added by the ASU) will be met:

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

In addition to the above, the ASU provides that an entity should not recognize on its balance sheet a grant related to an asset (e.g., as a receivable) until it “incurs the related costs for which the grant is intended to compensate” (see [Section 12.1.1.3.2.1](#) for a discussion of subsequent measurement). A grant of a nonmonetary asset is subject to the same recognition and subsequent measurement principles as a grant of a monetary asset. The ASU further provides that “[a] grant related to 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 grant is intended to compensate.”



### Connecting the Dots

ASU 2025-10 clarifies that receipt of the grant does not, by itself, indicate that the recognition criteria are met. For example, the ASU includes within its scope forgivable loans issued by the government. Some entities currently account for forgivable loans from the government under ASC 470 and therefore recognize income related to the forgiveness of a loan only when the liability is extinguished in accordance with ASC 470-50. However, after the ASU is adopted, ASC 832 will apply to forgivable loans issued by the government. To recognize a forgivable loan as a government grant after adoption of the ASU, an entity will have to conclude that it is probable that the loan will be forgiven (i.e., it is probable that the entity will meet the conditions required for the loan to be forgiven). The entity will thus need to consider the conditions associated with the forgivable loan in determining the timing of recognition of the government grant in the income statement.

#### 12.1.1.3.2.1 Grant Related to an Asset

ASC 832-10-25-4 (added by ASU 2025-10) allows 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 will recognize deferred income (liability) as a separate financial statement line item on the balance sheet. For a monetary grant, the deferred income initially recognized will be the amount of the monetary asset received or expected to be received on the date the grant meets the recognition criteria in ASC 832-10-25-1(a), which are discussed above. For a nonmonetary grant of a tangible asset (e.g., equipment or land), deferred income will be initially measured at the fair value of the asset received as of the date the grant meets the same recognition criteria in ASC 832-10-25-1(a). As stated in the ASU, 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.” If the grant that is being recognized under the deferred income approach is related to a nondepreciable asset (e.g., land), the grant “shall be subsequently recognized in earnings on a systematic and rational basis over the periods in which the entity incurs the costs to which the grant relates.” Regardless of the specific type of asset, the grant should be presented “as part of earnings either (1) separately under a general heading such as other income or (2) deducted from the related expense.”



### Connecting the Dots

ASC 832, as amended by ASU 2025-10, states, in part, that an entity may present a grant in earnings “[s]eparately under a general heading such as other income.” The term “other income” is not intended to convey the same meaning in ASC 832 that it does in SEC Regulation S-X, Rule 5-03, “Statements of Comprehensive Income.” Whereas “other income” as used in Rule 5-03 represents income presented outside of operating income, the term as used in ASC 832 after adoption of the ASU implies that an entity should record the income within an income account (other than revenue from contracts with customers in accordance with ASC 606). An entity may present this “other income” as a component of income from operations if it is appropriate to do so on the basis of the entity’s facts and circumstances.

- *Cost accumulation approach* — Under this approach, an entity will reflect a grant as a reduction of “the cost basis in determining the carrying amount of the asset.” For a nonmonetary grant involving the transfer of a tangible asset (e.g., equipment or land) from the government (the grantor) to a business entity (the grantee), the carrying value of the asset received will be the cost to the entity, if any. In the case of a monetary grant, an entity should initially 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 criteria for recognizing the grant are met (see [Example 12-1](#) for an illustration of this concept). In accordance with this approach, recognition of a monetary asset grant reduces the carrying value of the asset, and since the grant will not be separately identifiable (i.e., it forms part of the carrying value of the related asset), no separate subsequent measurement or presentation guidance will apply (i.e., the entity would depreciate the asset net of the grant). Application of the subsequent measurement and presentation guidance will depend on the nature of the asset. In other words, the cost basis (net of the grant) will be subject to depreciation, impairment, or other subsequent measurement and presentation guidance (e.g., ASC 360-10 or ASC 330) depending on the asset’s nature.



### Connecting the Dots

In paragraph BC63 of ASU 2025-10, the Board clarifies that “a business entity must choose an accounting policy to be applied consistently for similar types of grants.” Entities must carefully consider what accounting policy to elect for each type of grant since the adoption of the ASU will allow them to change or modify their current policy (e.g., their accounting policy for types of grants when analogizing to IAS 20). Once an entity makes an accounting policy election, it must maintain that accounting policy in accordance with ASC 250 and cannot change the policy unless doing so is preferable in accordance with ASC 250-10-45-2(b).

We believe that an entity that currently analogizes to IAS 20 or ASC 958-605 when accounting for government grants, including transfers from a government that may not be within the scope of ASC 832, as amended by ASU 2025-10 (e.g., nonrefundable, transferable tax credits), could apply the transition guidance in the ASU and make an accounting policy election if it plans to analogize to the new guidance in ASC 832. The entity may reasonably conclude that ASC 832, as amended by the ASU, is the most applicable U.S. GAAP to which to analogize when accounting for transfers from a government that are not specifically included within the scope of amended ASC 832 or any other U.S. GAAP. Therefore, the entity may adopt a new accounting policy upon the adoption of the ASU.

The example below illustrates the application of the guidance in ASU 2025-10 to a grant related to an asset.

### Example 12-1

Entity A applied for a monetary grant that was approved by a federal governmental agency. The grant will be for \$20 million, which A must use to build a manufacturing facility that is capable of producing 5 million vaccines and making them available for purchase by third parties. Entity A and the federal governmental agency have not entered into any agreements related to the agency's purchase of vaccines or any minimum capacity of vaccines that must be reserved for such agency. In addition, A has concluded that the grant does not represent an exchange transaction because A does not have a contract under ASC 606 or ASC 610-20 with the governmental agency. None of the other scope exceptions in ASU 2025-10 apply, and A concludes that the grant is within the scope of the guidance in ASC 832, as amended by the ASU. Entity A has elected to apply the cost accumulation approach to account for grants related to an asset and will reflect the grant as an adjustment to the cost basis of the constructed asset.

On January 1, 20X0, A receives the \$20 million from the federal governmental agency. At this time, A has not engaged a construction company to build the manufacturing facility and has not obtained any of the requisite permits from the local authorities. When the cash is received, A does not believe that it is probable that it will comply with the government grant's conditions since it does not believe that it is probable that the local government will approve the project. As a result, A recognizes cash with a corresponding liability representing A's contingent obligation to repay the federal government \$20 million because the recognition criteria in amended ASC 832 have not been met.

As of June 30, 20X0, A has entered into a contract with a construction company to build the manufacturing facility and has incurred \$15 million in costs. While the construction is not complete, all necessary permits have been acquired and the construction company has a history of completing similar projects. On June 30, 20X0, A believes that it is probable that it will comply with the conditions attached to the grant, and the grant has already been received. Under the cost accumulation approach, A should recognize the asset at its cost incurred to date (i.e., \$15 million) less \$15 million (i.e., the portion of the grant recognized) since the grant should be recognized when, and to the extent that, the costs are incurred. This results in no net asset being recorded on the balance sheet as of June 30, 20X0. Because not enough costs have been incurred to recognize the entirety of the grant, we believe that A should continue to present \$5 million as a liability on the balance sheet.

As of December 31, 20X0, the construction is complete, and the manufacturing facility is ready to be placed into service. Entity A has incurred a cumulative \$50 million cost related to the construction of the facility. After the grant is accounted for under the cost accumulation approach, the carrying value of the manufacturing facility is \$30 million as of December 31, 20X0. Note that for simplicity, the manufacturing facility is treated as a single asset even though such a facility typically consists of several assets, including the land, building, machinery, and equipment. We believe that an entity may use a reasonable approach to allocate the grant among the different assets, or it may conclude that the grant is related to a primary asset (e.g., the building) and allocate it to that single asset.

The manufacturing facility will be subject to the guidance in ASC 360-10 on subsequent measurement, including depreciation and impairment. In A's application of that guidance, the initial carrying amount of the manufacturing facility will be \$30 million.

#### 12.1.1.3.2.2 *Grant Related to Income*

As previously noted, a grant related to income will 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 grant is intended to compensate." If an entity receives a grant related to income before it incurs the expenses associated with the grant, the entity will recognize a deferred credit liability that will be reduced as the grant is recognized ("on a systematic and rational basis over the periods in which the entity recognizes as expenses the related costs for which the grant is intended to compensate"). Alternatively, if an entity receives a grant related to income after it incurs the expenses or losses associated with the grant, the entity will recognize the grant in earnings in the period in which the recognition criteria in ASC 832-10-25-1(a) are met, which may be earlier than when the grant is received.

In a manner similar to how a grant related to an asset is accounted for under the deferred income approach, the earnings impact of a grant related to income will be either (1) recorded “separately under a general heading such as other income” or (2) “deducted from the related expense.”

The example below illustrates the application of the guidance in ASU 2025-10 to a grant related to income.

#### Example 12-2

Entity B manufactures medical devices and is developing a new product that uses cutting-edge technology to aid in patient sample collection (e.g., blood and tissue samples). In 20X1, B applies for a grant from the government. If B obtains the grant, the government will reimburse B for expenses incurred in its R&D efforts related to getting this product to market.

On December 1, 20X1, B is approved for a \$1 million government grant that requires B to submit its qualifying R&D expenses to the government in exchange for subsequent reimbursement on a cost-reimbursement basis. Entity B forecasts that it will incur costs of \$1.5 million that would be considered qualifying R&D expenses. On the date of the grant (December 1, 20X1), B determines that it is probable that the conditions for the grant will be met and that the grant will be received as long as qualifying expenses are incurred. However, on December 1, 20X1, B does not record anything related to the grant. This is because the grant has not been received and no qualifying expenses have been incurred.

During 20X2, B incurs \$1.5 million of qualifying R&D expenses. Entity B receives all of the \$1 million grant on December 15, 20X2. Entity B recognizes the grant systematically throughout the period in which the expenses were incurred, up to the \$1 million, and elects to record the grant related to income in earnings as a deduction in reporting the related expense. This results in \$500,000 ( $\$1.5 \text{ million incurred} - \$1 \text{ million grant} = \$500,000$  earnings impact) of R&D expenses associated with the recognition of the project in earnings during 20X2.

#### 12.1.1.3.2.3 *Statement of Cash Flows Presentation*

Rather than providing prescriptive guidance on the appropriate presentation of government grants in the statement of cash flows, ASU 2025-10 refers to general principles of ASC 230. The Board clarifies in paragraph BC59 of the ASU 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 will need to apply significant judgment when determining the underlying nature of the grant and the resulting presentation in the statement of cash flows. An entity’s election of the classification of proceeds from grants represents an accounting policy that the entity should disclose and apply consistently in similar arrangements. See Section 6.2.4.3 for further discussion of the statement of cash flows presentation under ASU 2025-10.

#### 12.1.1.3.3 *Disclosure*

Under ASU 2025-10, the current disclosure requirements in ASC 832 for government assistance mostly will continue to apply to government grants. The ASU clarifies 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. Similarly, if the cost accumulation approach is used, an entity will only be required to disclose the useful life of the related depreciable or amortizable asset in the period in which the grant was recognized. Further, the ASU adds a requirement to disclose the fair value of tangible nonmonetary assets that are received as a government grant even if accounted for under the cost accumulation approach.

### 12.1.1.3.4 Other Matters Under ASU 2025-10

#### 12.1.1.3.4.1 *Repayment of Government Grants*

ASU 2025-10 provides guidance on repayments that occur after a government grant has initially been recognized.

For a grant related to income, the repayment will first be applied against any deferred income liability remaining. Any excess repayment beyond the deferred income liability will then be immediately recognized in earnings.

For a grant related to an asset, the repayment will be recognized by increasing the carrying amount of the asset (if the cost accumulation approach was used) or reducing the deferred income balance (if the deferred income approach was used) by the amount repayable. An entity will recognize in earnings the cumulative effect of additional depreciation, impairment, or gain or loss on a prior sale of the asset as of the date of the repayment.

#### 12.1.1.3.4.2 *Business Combinations*

ASU 2025-10 includes amendments to ASC 805-20 that add an exception to the recognition and measurement principles for liabilities associated with grants related to income. The acquirer must recognize deferred income in accordance with ASC 832 unless the acquiree has already fully complied with the conditions associated with the grant. The acquirer must also measure the deferred income in accordance with ASC 832.

### 12.1.1.3.5 Effective Dates and Transition for ASU 2025-10

For PBEs, ASU 2025-10 is effective for fiscal years beginning after December 15, 2028, including interim periods within those fiscal years. For non-PBEs, the ASU is effective for fiscal years beginning after December 15, 2029, including interim periods within those fiscal years. Early adoption is permitted.

Entities should apply the guidance in ASU 2025-10 by using one of the following transition methods:

- *Modified prospective approach* — Under this approach, the amendments in the ASU are applied to government grants that are not complete<sup>2</sup> as of the adoption date (i.e., the beginning of the adoption period) and to any new government grants entered into after that date. There is “no cumulative-effect adjustment to the opening balance of retained earnings” under the modified prospective approach.
- *Modified retrospective approach* — Under this approach, the amendments in the ASU are applied to “government grants that are not complete<sup>3</sup> as of the beginning of the earliest period presented” upon adoption and to any new government grants entered into after that date. Entities should record a “cumulative-effect adjustment to the opening balance of retained earnings” and restate all prior periods on the basis of their adjustments.
- *Full retrospective approach* — Under this approach, the amendments in the ASU are applied to all government grants. Entities must record a “cumulative-effect adjustment to the opening balance of retained earnings as of the beginning of the earliest period presented.”

<sup>2</sup> ASC 832-10-65-2(d)(1)(ii) (added by ASU 2025-10) states, in part, that “[a] government grant is complete when substantially all of the government grant proceeds have been recognized before the effective date of the [amendments in the ASU].”

<sup>3</sup> ASC 832-10-65-2(d)(2)(ii) (added by ASU 2025-10) states, in part, that “[a] government grant is complete when substantially all of the government grant proceeds have been recognized before the beginning of the earliest period presented in which the [amendments in the ASU are] adopted.”

## 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 12-3

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,<sup>4</sup> 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

<sup>4</sup> 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.

pool is numerous or diverse. SEC registrants are encouraged to consult with their legal advisers and independent accountants regarding these requirements.

## **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. Three examples, which are discussed below, are (1) the BPD fee under the federal Patient Protection and Affordable Care Act, (2) fees imposed on the sale of opioid-based products by various states, and (3) tariffs.

### 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](#)<sup>5</sup> 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.

<sup>5</sup> 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.

### 12.5.4 Tariffs

In 2025, the U.S. government expanded tariffs on a broad range of products via executive order under the International Emergency Economic Powers Act (IEEPA). Life sciences entities may experience increases in the cost of doing business as a result of evolving U.S. tariff and trade policies. Recent and proposed tariffs may affect a broad spectrum of raw materials, APIs, medical device components, and finished products, many of which previously benefited from duty-free entry or were subject to low tariffs. These changes could significantly increase the cost of such items, particularly imports from key trading partners. Companies will need to be cognizant of the evolving policy landscape and may need to consider compliance with laws or regulations and related controls. Inadequate processes or controls may lead to underreporting tariffs and thereby expose businesses to penalties, fines, and reputational risks.



## Changing Lanes

On February 20, 2026, the U.S. Supreme Court ruled that IEEPA does not authorize the president to impose tariffs. We believe that the ruling is akin to a change in law and therefore represents a Type 2 (nonrecognized) subsequent event under ASC 855 for reporting periods that ended before the ruling. In accordance with ASC 855-10-25-50-2, if this nonrecognized subsequent event is of such a nature that it must be disclosed to keep the financial statements from being misleading, an entity is required to disclose:

- The nature of the event.
- An estimate of the event's financial effect or a statement that such an estimate cannot be made.

For reporting periods ending after the ruling, we believe that an entity can apply the principles of the loss recovery model in ASC 410-30 by analogy to determine whether it may recognize an asset for any recovery of tariffs that were paid before the ruling. In accordance with those principles, an entity must compare the amount of the probable tariff refund proceeds with the related previously recognized tariff cost. That is, any recognized asset is limited to the amount of previously recognized tariff costs, and recovery must be probable. When assessing whether a recovery is probable, an entity applies the loss contingency model in ASC 450-20.

The ruling did not address refunds. Consequently, there is uncertainty associated with an entity's ability to obtain a refund and the process for trying to do so. In the absence of clarity related to the refund process, we believe that it may be difficult for an entity to assert that recovery is probable. If recovery is not probable, an asset cannot be recognized.

For more information, see Deloitte's February 27, 2026, [Heads Up](#).

### 12.5.4.1 Reporting Considerations Related to Tariffs

From an SEC reporting perspective, registrants have disclosed, primarily in the risk factors section of their filings, that the tariffs are likely to affect their cost structures, their profitability, and consumer demand and that they may need to make strategic adjustments to avoid potential issues with global supply chains. Further, many registrants have disclosed that the tariffs, together with related regulations and restrictions, may lead to increased volatility in operating costs and sales margins. Although we have not yet seen SEC staff comments to registrants on these disclosures, we expect such disclosures to remain an area of focus for companies and investors alike.

In addition, an entity should assess whether any of its public statements regarding investment or capital expenditure commitments to avoid tariffs or receive tariff relief would give rise to firm commitments that must be disclosed in the financial statements. We note that life sciences companies may enter into agreements, including MFN arrangements, that may include tariff relief and commitments to make certain investments in the United States. The ASC master glossary defines a firm commitment, in part, 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 . . . the 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 (e.g., "[a] commitment for plant acquisition"). In addition, ASC 440 requires disclosure of "unconditional purchase obligations," as described more fully in Section 5.2.6.4. 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.

### 12.5.4.2 **Nonfinancial Asset Impairment Considerations Related to Tariffs**

The effects of tariffs on an entity's financial reporting may be broad or may be limited to certain accounts, transactions, or disclosures. Some of those effects may be related to nonfinancial assets and their potential impairment. Entities may consider how tariffs affect (1) inventory valuation; (2) recoverability of long-lived assets; and (3) indefinite-lived intangible assets, including goodwill.

For more information, see Deloitte's August 13, 2025, [Accounting Spotlight](#).

## 12.5.5 **BIOSECURE Act Considerations**

In December 2025, President Trump signed the BIOSECURE Act into law as part of the National Defense Authorization Act for Fiscal Year 2026. The BIOSECURE Act reflects a significant policy shift intended to strengthen U.S. national security with respect to biotechnology products, research, and supply chains. The legislation restricts federal agencies and entities that receive federal funding — including through grants, contracts, or cooperative agreements — from procuring or using specified biotechnology equipment, software, or services from certain designated “biotechnology companies of concern.” In addition, the BIOSECURE Act directs the Office of Management and Budget to publish a list of entities that constitute biotechnology companies of concern no later than December 2026.

The BIOSECURE Act restrictions apply primarily to federal agencies, recipients of federal funds, and their contractors and subcontractors, but broader market impacts may be felt as supply-chain partners implement the law's requirements. Companies not engaged in federally funded work are not directly covered by the BIOSECURE Act but may nevertheless encounter downstream effects as a result of changes in customer or supplier requirements.

With regulations and detailed compliance requirements still forthcoming, the full scope and practical application of the BIOSECURE Act remain uncertain. While it is clear that prohibited new procurement from listed vendors will not be permissible for federally funded endeavors going forward, questions remain about the treatment of previously acquired inventory and equipment, as well as the handling of existing licensing, collaboration, and revenue arrangements with affected entities. Companies may have a transition period of several years in which to assess their current compliance, phase out the use of covered products and relationships, and adapt operations accordingly. However, the precise contours of transition rules, grandfathering provisions, and effective dates will be determined by future regulatory updates, including likely amendments to the Federal Acquisition Regulation and agency-level directives.

Given this evolving landscape, companies in the life sciences industry should closely monitor it for new regulatory developments and begin cataloging and evaluating exposure within inventories, equipment, technology assets, existing agreements, and investment holdings. In addition, they should maintain thorough documentation of acquisition dates and contractual arrangements involving vendors that may become barred under the BIOSECURE Act. While detailed actions regarding contract terminations, asset write-downs, or investment disposals are not yet known, companies should remain agile since forthcoming guidance may require operational and accounting adjustments within the compliance window.

From a financial reporting and disclosure perspective, given the uncertainty about implementation, timing, and compliance details, companies may consider the need for enhanced risk disclosures, including both SEC reporting obligations and disclosures about risks and uncertainties under ASC 275. Companies may consider early disclosure if there is a reasonable possibility that the BIOSECURE Act could result in a material impact to their financial statements in areas such as asset impairment, contractual modifications, increased compliance costs, and disruption to business models.

## 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 on which the financial statements are available to be issued when applicable).<sup>6</sup> 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

<sup>6</sup> 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").

- 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 on which the financial statements are issued or available to be issued.<sup>7</sup>

### 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"> <li>• Principal conditions or events.</li> <li>• Management's evaluation.</li> <li>• Management's plans.</li> </ul>	<ul style="list-style-type: none"> <li>• Principal conditions or events.</li> <li>• Management's evaluation.</li> <li>• Management's plans.</li> <li>• Statement that there is "substantial doubt about the entity's ability to continue as a going concern."</li> </ul>

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.

<sup>7</sup> See footnote 6.

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.

### **12.6.6 Impact of Tariffs on Going-Concern Evaluation**

As a result of the evolving nature of tariffs and their potential effect on an entity's operations and forecasted future cash flows, entities may need to reevaluate whether they have the ability to continue as a going concern within one year after the date on which the interim or annual financial statements are issued (or available to be issued, when applicable). Management is required to provide comprehensive disclosures in its annual and interim financial statements when events and conditions are identified that raise substantial doubt about the entity's ability to continue as a going concern, even when management's plans alleviate such doubt.

## **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 [2026 US Health Care Outlook](#), "[m]ore than half of surveyed health plan executives (53%) intend to invest in initiatives that expand the use of digital tools for member engagement and behavior change, and 50% of health system executives plan investments in tech-enabled patient engagement and monitoring tools."

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.



### Connecting the Dots

In September 2025, the FASB issued [ASU 2025-06](#), which amends certain aspects of the accounting for and disclosure of software costs under ASC 350-40. The ASU makes targeted improvements to ASC 350-40 but does not fully align the framework for accounting for internally developed software costs that are subject to ASC 350-40 with the framework applied to software to be sold or marketed externally that is subject to ASC 985-20. The ASU also does not amend the guidance on costs of software licenses that are within the scope of ASC 985-20. The amendments supersede the guidance on Web site development costs in ASC 350-50 and relocate that guidance, along with the recognition requirements for development costs specific to Web sites, to ASC 350-40.

For more information, see [Section 12.12.3.1](#) and Deloitte's September 18, 2025, [Heads Up](#).

## 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 are applying SaaS delivery models 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 12-4

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.

**Example 12-4 (continued)**

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."

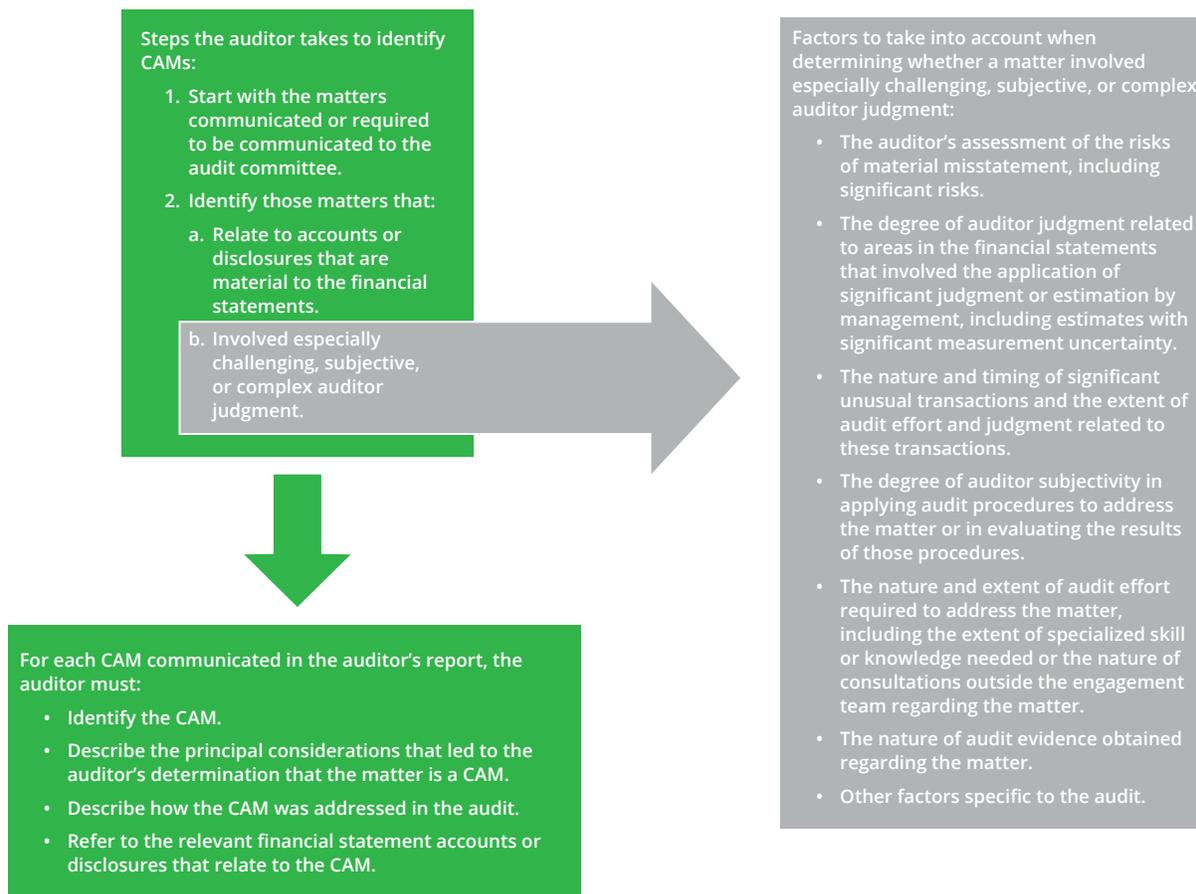
The standard includes a nonexclusive list of factors for the auditor to take into account, alone or in combination, in determining whether a matter involved especially challenging, subjective, or complex auditor judgment.

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 can 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 can 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 can 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, then OCA Professional Accounting Fellow Robert Comerford 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).
“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.

(Table continued)

SEC Staff Consideration Point	Related SEC Staff Observations	Deloitte Observations
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 6.2.8 for a discussion of those implications.

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 14.3.1.3](#) of Deloitte’s Roadmap *Issuer’s Accounting for Debt*.

## 12.10 Foreign Currency Accounting Considerations

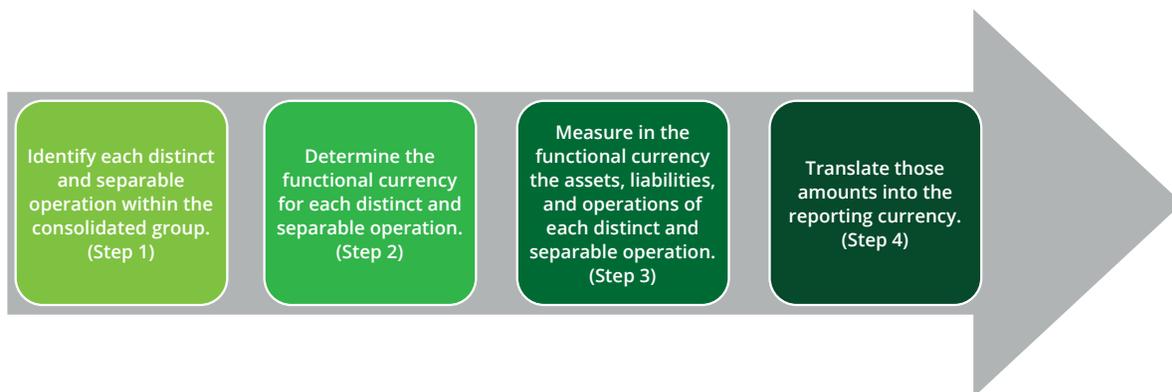
### 12.10.1 Overview

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:

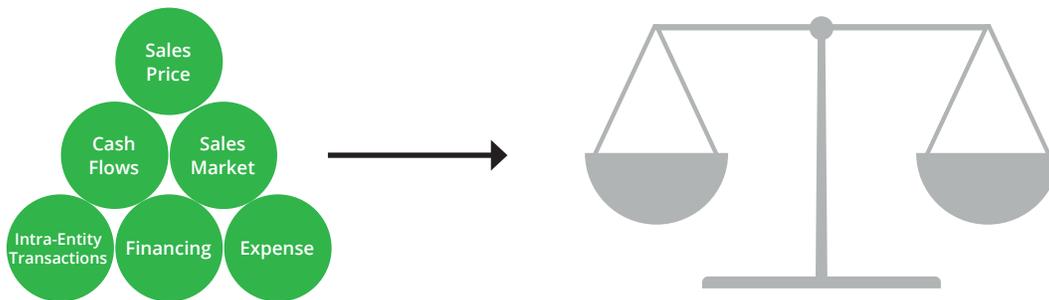
An entity might have more than one distinct and separable operation, such as a division or branch, in which case each operation may be considered a separate entity. If those operations are conducted in different economic environments, they might have different functional currencies.

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.

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.



### 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.

## 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.

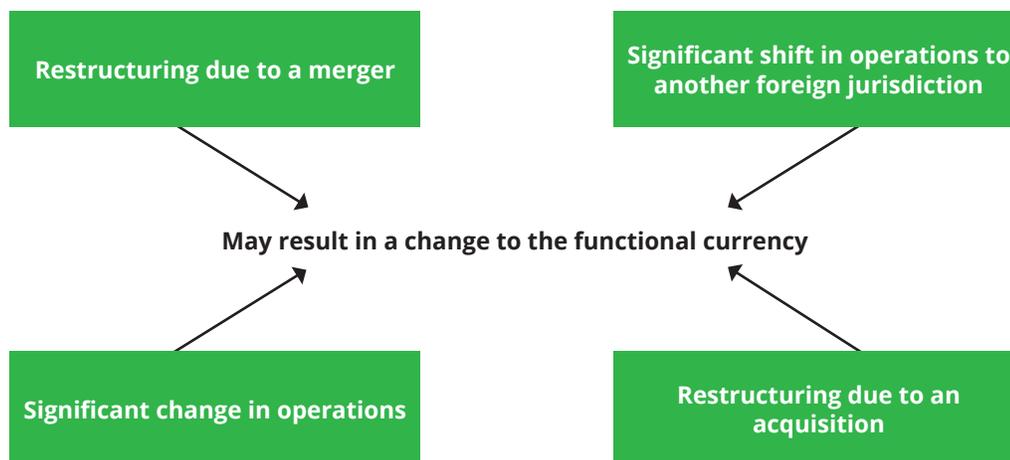
It should be noted that ASC 830 does not address how the economic factors in ASC 830-10-55(a)-(f) should be applied (e.g., weightings or hierarchy may differ for certain factors). Rather, ASC 830-10-55-5 states that these "factors, and possibly others, should be considered both individually and collectively 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 have been increasing requirements for entities to provide sustainability reporting. Until recently, entities have been using sustainability reporting frameworks or standards to report on a voluntary basis. However, sustainability reporting for certain U.S. companies 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](#) (the “CSRD”) and [European Sustainability Reporting Standards](#) (ESRS), (2) the International Sustainability Standards Board (ISSB) within the IFRS Foundation, and (3) the state of California in the United States.

Currently, the state of California is the only jurisdiction in the United States with mandatory sustainability-related reporting requirements. In March 2025, the SEC announced that it was ending its defense of its [final rule](#) on climate-related disclosures, which was issued in March 2024 and voluntarily stayed shortly thereafter pending judicial review by the U.S. Court of Appeals for the Eighth Circuit of petitions challenging the final rule. In September 2025, the court ordered the petitions for review to be held in abeyance until the SEC determines whether the final rule “will be rescinded, modified, or defended in litigation.” The SEC has yet to make that determination.

Although the trajectory of the SEC's final rule on climate-related disclosures has changed, SEC registrants should still consider climate-related matters and their impact on current operations, or potential impact on future operations, when evaluating MD&A disclosure requirements. Specifically, registrants are required to disclose climate-related matters in MD&A if those matters meet the criteria of SEC Regulation S-K, Item 303(b)(2)(ii). For more information, see Deloitte's Roadmap [SEC Comment Letter Considerations, Including Industry Insights](#).

In addition, the FASB, SEC, and CAQ have all provided public information<sup>8</sup> for both preparers of financial statements and auditors regarding the importance of considering sustainability-related matters. Given the increased interest in sustainability-related 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 sustainability landscape, they will need to incorporate sustainability-related 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 The European Union's 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.

The CSRD has affected 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. It required certain European public filers to begin publishing sustainability reports for periods ended December 31, 2024, and will require nonpublic entities in Europe to provide sustainability reporting in the following years. Entities within the scope of the CSRD will need to report under the ESRS and meet the requirements related to the [EU Taxonomy for Sustainable Activities](#) (the "EU Taxonomy"), as discussed below.



#### Changing Lanes

On February 26, 2025, in response to significant stakeholder feedback on the CSRD's broad scope and the effort required to comply with its granular provisions, the European Commission (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. Since February 2025, the EC, the European Council, and the European Parliament have taken numerous steps to advance the proposed amendments.

The European Parliament voted to approve COM(2025) 80 (commonly known as the "Stop-the-Clock" proposal), which was adopted by the Council of the European Union as [Directive \(EU\) 2025/794](#) (the "Stop-the-Clock" directive). Member states were required to transpose the legal text by December 31, 2025, to be effective for the 2025 reporting period. The Stop-the-Clock directive postpones by two years the application of the existing reporting requirements for certain entities under the current CSRD, including EU Taxonomy disclosures required by the CSRD. We would expect most U.S.-based entities to be subject to the two-year postponement of the existing reporting requirements under the Stop-the-Clock directive.

<sup>8</sup> 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](#).

COM(2025) 81 (commonly known as the “Content Proposal”) was proposed to modify the scope and certain other provisions of the CSRD and EU Taxonomy, including amending the employee and turnover (i.e., revenue) thresholds used to determine applicability. While the Content Proposal addressed the criteria for determining which entities are required to comply with the CSRD, it also included revision and simplification of the ESRS that establish the sustainability reporting required for companies complying with the CSRD. The commitment in the Content Proposal was aimed at substantially reducing the number of data points that entities are required to report, revising unclear provisions, improving consistency with other pieces of legislation, improving the interoperability with other sustainability-related standards and frameworks, and clarifying the instructions for applying the double materiality principle. On December 9, 2025, the European Council and European Parliament reached an informal provisional agreement related to the Content Proposal. On December 16, 2025, the European Parliament approved the final text of the provisional agreement. On February 24, 2026 the provisional agreement was adopted by the Council of the European Union as [Directive \(EU\) 2026/470](#) (the “February 2026 Directive”), which was published in the *Official Journal of the European Union* on February 26, 2026. The February 2026 Directive will enter into force 20 days after publication. Member states are required to transpose the February 2026 Directive’s provisions related to the CSRD by March 19, 2027, and those related to the European Union’s Corporate Sustainability Due Diligence Directive by July 26, 2028.

Under the February 2026 Directive, E.U. entities will be within the scope of the CSRD if they have a net turnover exceeding €450 million and an average of more than 1,000 employees during the financial year. The same threshold will apply for non-E.U. entities that are listed on an E.U.-regulated market. When the text of the February 2026 Directive is transposed into member state law, these entities (other than “Wave 1”<sup>9</sup> entities, which are already reporting under the CSRD) will have reporting obligations for financial years beginning with financial year 2027. Wave 1 entities will still have reporting obligations for financial years 2025 and 2026 unless they benefit from a member state option transposed into national law that exempts such entities that do not meet the thresholds of more than 1,000 employees and more than €450 million in net turnover from their reporting obligations. In addition, enterprise-level reporting for financial years beginning with financial year 2028 will be required for E.U. subsidiaries or branches with a non-E.U. parent for which the group both (1) generates net turnover in the European Union exceeding €450 million at the group level for each of the last two consecutive financial years and (2) has at least one E.U. subsidiary or branch that generated more than €200 million in net turnover in the preceding financial year.

For more information about the proposed updates to the CSRD requirements that were ultimately adopted as the February 2026 Directive, see Deloitte’s January 14, 2026, [Heads Up](#).

### 12.11.2.1.2 European Sustainability Reporting Standards

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

<sup>9</sup> Large public interest entities (PIEs) and issuers on an E.U.-regulated market with more than 500 employees; such entities are generally already within the scope of the Non-Financial Reporting Directive. Wave 1 includes (1) large U.S. companies that are listed on an E.U.-regulated market and have more than 500 employees and (2) large E.U.-based subsidiaries that are PIEs or are listed on a regulated market and have more than 500 employees.

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.



### Changing Lanes

The Content Proposal included a commitment to revise the ESRS that were issued through a delegated act in December 2023. In July 2025, EFRAG published EDs containing proposed revisions to those standards. While retaining the overall architecture of the ESRS framework, including the cross-cutting standards (ESRS 1 and ESRS 2) and sector-agnostic topical standards, EFRAG has recommended significant simplifications to improve readability, proportionality, and decision-usefulness. In December 2025, EFRAG submitted to the EC its final [technical advice](#) (alternatively referred to below as “draft simplified ESRS”), which includes various changes to the July 2025 EDs. The EC will consider EFRAG’s technical advice when adopting the delegated act that amends the ESRS and may adopt revised ESRS that differ from the technical advice.

For more information about the proposed ESRS revisions, see Deloitte’s [August 21, 2025](#), and [January 14, 2026](#), *Heads Up* newsletters

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.”



### Changing Lanes

Draft simplified ESRS 1 would maintain the double materiality assessment and the concepts of impact materiality and financial materiality. For editorial purposes, it would amend the definitions of impact materiality and financial materiality, respectively, but the overall understanding of those concepts would remain consistent. In addition, draft simplified ESRS 1 would highlight simplifications to the process itself, including placing more emphasis on the materiality of information as an overarching principle (all data points are subject to materiality), flexibility in the reporting level, and simplification of the topics to be assessed for materiality.

Collectively, the draft simplified ESRS would introduce practical considerations in the execution of the double materiality assessment to reduce the overall complexity of the process and the extent of unnecessary scoring. Further, they would clarify that either a top-down or a bottom-up approach may be used to perform the double materiality assessment.

For more information about the proposed ESRS revisions, including simplification of the double materiality assessment, see Deloitte’s [August 21, 2025](#), and [January 14, 2026](#), *Heads Up* newsletters.

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.



### Changing Lanes

The draft simplified ESRS would highlight that all data points, including those in ESRS 2, are subject to an entity's double materiality assessment. However, while draft simplified ESRS 2 would still require an entity to disclose the basis for its conclusion that climate change is not material, it would require much less detail than the current ESRS 2.

For more information about the proposed ESRS revisions, including simplification of the general disclosure requirements, see Deloitte's [August 21, 2025](#), and [January 14, 2026](#), *Heads Up* newsletters.

#### 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 table below outlines the scope and reporting requirements stipulated in the February 2026 Directive from the perspective of a U.S.-based company, exclusive of Wave 1 reporters already within the scope of the CSRD.

		Enterprise Level	
		Reporting for Calendar-Year-End Filers	
		2027 (Reporting in 2028)	2028 (Reporting in 2029)
Scope	Companies that have more than 1,000 employees on average and generated a net turnover exceeding €450 million during the financial year, including (1) U.S. companies listed on an E.U.-regulated market and (2) E.U. subsidiaries of U.S. companies.	All U.S. companies* that (1) generated net turnover in the European Union of more than €450 million in each of the last two financial years at the group level and (2) have at least one E.U. subsidiary or branch with net turnover exceeding €200 million in the preceding financial year.	
Required standards	Revised ESRS** (or equivalent standards***)	Revised ESRS** (or equivalent standards***) or alternative standards for non-E.U. entities to be developed†	
Reporting level	Stand-alone subsidiary, unless included in the parent's report prepared under the ESRS or equivalent standards for a non-E.U. parent (i.e., consolidated group level)	Consolidated group	

\* The reporting obligation resides with the E.U. subsidiary or branch. The reporting is published by the E.U. subsidiary or branch at the consolidated non-E.U. ultimate parent, or enterprise, level.

\*\* Revised ESRS to be developed under a future delegated act. The EC is currently reviewing technical advice and revised ESRS submitted by EFRAG on December 3, 2025 (see additional information below).

\*\*\* "Equivalent standards" are only applicable to U.S. (non-E.U.) company-level reporting. E.U. subsidiaries and groups must report in accordance with the revised ESRS. What may be deemed "equivalent" is yet to be determined by the EC.

† Standards for non-E.U. entities will not be adopted by the EC before October 1, 2027.

For more information about the proposed changes to the requirements of the CSRD that were ultimately adopted as the February 2026 Directive, see Deloitte's January 14, 2026, [Heads Up](#).

### 12.11.2.1.5 CSRD Reporting Insights — Wave 1 Reporters

Financial year 2024 was the first financial year on which Wave 1 entities were required to report under the CSRD. In August 2025, Deloitte released [Beyond Compliance: Enhancing Trust Through Reporting — Observations on Practices Following Wave 1 of CSRD Reporting](#) (the "2025 Wave 1 Report") which discusses key observations related to Wave 1 reporters, including reporters in the life sciences and health care industry. The publication analyzes 16 reporting entities in that industry, noting that they "disclose[d] a range of sustainability matters, including ethical R&D, healthcare equity, sustainable manufacturing, and human rights in supply chains. The industry also highlight[ed] efforts to improve post-consumer product stewardship and to expand access to healthcare in underserved regions." All 16 of those reporting entities identified material topics related to climate change (ESRS E1), own workforce (ESRS S1), and business conduct (ESRS G1) as part of their double materiality assessment.

For more information about Wave 1 reporting entities, including life sciences and health care entities, see the full 2025 Wave 1 Report.

### 12.11.2.1.6 Additional Information

Various Deloitte resources provide additional information on the following topics:

- *Current CSRD and ESRS requirements* — See Deloitte's August 17, 2023 (updated February 23, 2024), [Heads Up](#).
- *Double materiality assessment* — See Deloitte's June 27, 2024, [Heads Up](#).
- *Omnibus proposals to revise the CSRD and ESRS (including those related to the July 2025 EDs and the simplification process)* — See Deloitte's August 21, 2025, [Heads Up](#).
- *Omnibus legislative developments since August 2025* — See Deloitte's January 14, 2026, [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-related and other sustainability-related topics. In June 2023, the ISSB issued its first two standards: [IFRS S1](#) (general requirements for disclosure of sustainability-related financial information) and [IFRS S2](#) (climate-related disclosures). These standards are intended to serve as the global baseline of sustainability disclosures, focused on material information that is useful to investors. In developing the global baseline, the ISSB seeks to reduce fragmentation of sustainability reporting requirements and thereby reduce the reporting burden for preparers.

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

Entities should be aware of jurisdictions that are adopting ISSB standards and/or incorporating ISSB standards into local reporting requirements. The IFRS Foundation [announced](#) in June 2025 that "[t]hirty-six jurisdictions have adopted or otherwise use the IFRS Sustainability Disclosure Standards (ISSB Standards) or are in the process of finalising steps towards introducing them into their regulatory frameworks." Jurisdictions that have adopted or are in the process of adopting ISSB standards include Australia, 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. In addition, the IFRS Foundation publishes [jurisdictional profiles and jurisdictional snapshots](#) that highlight helpful information about each jurisdiction.

The IFRS Foundation is committed to supporting the implementation of ISSB standards by publishing educational materials and targeted amendments to those standards.

In May 2025, the IFRS Foundation published [educational material](#) in a Q&A format about GHG emission disclosure requirements under IFRS S2. Entities applying IFRS S2 should be aware that some of these disclosure requirements differ from the disclosure requirements prescribed by the GHG Protocol, which the educational material explains. The educational material:

- Illustrates why disclosures about all three scopes of GHG emissions is required, if material.
- Clarifies the unique way that IFRS S2 refers to various GHG Protocol standards for measuring GHG emissions. IFRS S2 refers to the GHG Protocol's [Corporate Standard](#) for measurement only and refers to the GHG Protocol's [Scope 3 Standard](#) only for definitions of Scope 3 categories.
- Clarifies the minimum boundary that must be used for value chain (i.e., Scope 3) reporting. An entity applying IFRS S2 cannot limit its measurement and disclosure of Scope 3 GHG emissions on the basis of the minimum boundaries outlined in the Corporate Standard because IFRS S2 requires disclosure of material information for the entire value chain.

Similarly, in July 2025, the IFRS Foundation published [educational material](#) about using ISSB industry-based guidance when applying ISSB standards. ISSB uses the existing Sustainability Accounting Standards Board (SASB) standards for industry-specific guidance. Life sciences entities should potentially consider the guidance in the [Biotechnology & Pharmaceuticals Sustainability Accounting Standard](#) when reporting under IFRS S2, among other potentially relevant SASB standards related to health care. The educational material released by the IFRS Foundation will help entities understand how to use the relevant SASB standard when reporting under IFRS S2.

In December 2025, the IFRS Foundation published [targeted amendments](#) to GHG emission disclosure requirements in response to companies' identification of specific application challenges. The amendments to IFRS S2:

- Permit entities to exclude facilitated, as opposed to financed, emissions (e.g., emissions attributed to derivatives, emissions associated with insurance) from the Scope 3, Category 15 emissions, that are measured and disclosed.
- Provide relief from using the Global Industry Classification Standard.
- Clarify that the existing relief for an entity that is required by a jurisdictional authority or an exchange on which it is listed to use a method for measuring GHG emissions other than the GHG Protocol standards is also available when such a requirement applies only to a part of the entity (although only for the relevant part of the entity, and only for as long as the requirement is applicable).
- Extend the jurisdictional relief for measuring GHG emissions so that if an entity, in whole or in part, is required by a jurisdictional authority or an exchange on which it is listed to use global warming potential (GWP) values that are not from the latest Intergovernmental Panel on Climate Change (IPCC) assessment, the entity would be permitted to use those GWP values instead of the GWP values from the latest IPCC assessment.

#### 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](#).

#### 12.11.2.3 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 2023, two state senate bills and one state assembly bill related to climate — [SB 253](#), [SB 261](#), and [AB 1305](#) — were signed into law in California. Another state senate bill, [SB 219](#), which was signed into law in California in 2024, amends portions of Sections 38532 and 38533 of the California Health and Safety Code that were established upon the passage of SB 253 and SB 261. Although SB 219 is aimed at reducing the financial burden of complying with SB 253 and SB 261, it notably does not affect the reporting timeline established by those bills.

The California climate legislation significantly affects certain public and private companies doing business or operating in that state. Under SB 253, entities will have to report GHG emissions in accordance with the GHG Protocol standards. Under SB 261, entities will have to report climate-related financial 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 California climate legislation is enforced by the California Air Resources Board (CARB).

The table below summarizes the applicability of SB 253, SB 261, and AB 1305.

	SB 253	SB 261	AB 1305
	Climate Corporate Data Accountability Act	Greenhouse Gases: Climate-Related Financial Risk	Voluntary Carbon Market Disclosures
<b>Companies affected</b>	Public and private U.S. businesses with total annual revenues exceeding \$1 billion and that do business in California. Applicability is based on the entity's prior fiscal year of revenue.  CARB's current proposal is to determine applicability on the basis of the lesser of the entity's previous two fiscal years of revenue.	Public and private U.S. businesses with total annual revenues exceeding \$500 million and that do business in California. Applicability is based on the entity's prior fiscal year of revenue.  CARB's current proposal is to determine applicability on the basis of the lesser of the entity's previous two fiscal years of revenue.	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.

SB 253 and SB 261 direct CARB to specifically develop and adopt regulations related to GHG emission reporting (applicable to SB 253). SB 261 does not direct CARB to develop any other specific reporting regulations related to SB 261; however, CARB has released guidance to assist entities with the reporting requirements for SB 261. On February 26, 2026, CARB approved the adoption of the California Greenhouse Gas Reporting and Climate Financial Risk Disclosure Initial Regulation (the “published regulations”), which a CARB [news release](#) describes as “an initial step in meeting the regulatory requirements of SB 253 and 261.” Finalization of the published regulations is subject to potential amendments after the CARB staff works with the California Department of Insurance to evaluate GHG emission reporting requirements for insurance companies under SB 253.

To determine the applicability of SB 253 and 261, entities must understand two critical terms: “total annual revenues” and “[doing] business in California.” CARB’s published regulations define those terms as follows:

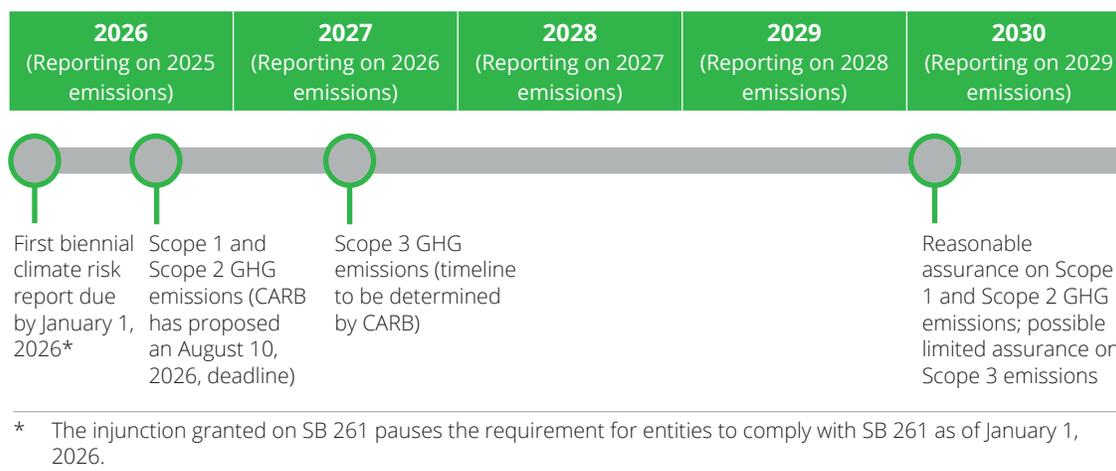
- *Total annual revenues* — This term is defined as “the gross amounts realized (the sum of money and the fair market value of other property or services received) on the sale or exchange of property, the performance of services, or the use of property or capital (including rents, royalties, interest, and dividends) in a transaction that produces business income, in which the income, gain, or loss is recognized (or would be recognized if the transaction were in the United States) under the Internal Revenue Code, as applicable for purposes of this part.” Under CARB’s published regulations, revenue is generally expected to align with gross receipts.
- *Doing business in California* — CARB’s published regulations define this term on the basis of a subset of criteria from the California Revenue and Taxation Code. Accordingly, if an entity “is actively engaging in any transaction for the purpose of financial or pecuniary gain or profit” and exceeds the sales threshold or is organized or has its main commercial office in California, it meets the definition of “doing business in California.”

In addition, CARB has tentatively exempted a number of entities from the requirements of SB 253 and SB 261. Some life sciences entities may be exempt if they are NFPs or if their presence in California is solely attributable to teleworking employees.

Entities determining the applicability of these rules should work closely with legal counsel to ensure appropriate understanding and compliance with the legislative requirements. Both SB 253 and SB 261 allow relief from subsidiary reporting requirements if the parent entity prepares a consolidated report.

### 12.11.2.3.1 Effective Date

The timeline below outlines the initial requirements for disclosure under SB 253 and SB 261. Unlike other climate disclosure regulations, such as European regulations under the CSRD, the California rules do not allow for a phase-in of applicability.



Under SB 253, entities will need to report in 2026 on prior fiscal year Scope 1 and Scope 2 GHG emissions. Under CARB’s published regulations, SB 253 reporting for the first year would be due by August 10, 2026. 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 both its Web site and CARB’s public docket 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)<sup>10</sup> 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).



#### Changing Lanes

On November 18, 2025, the U.S. Court of Appeals for the Ninth Circuit granted a temporary injunction of SB 261, which required first reporting of an entity’s climate-related financial risk report by January 1, 2026. Under the injunction, the reporting regulations for SB 261 are paused. For more information, see Deloitte’s December 4, 2025, [Sustainability Spotlight](#).

<sup>10</sup> 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.

### 12.11.2.3.2 CARB Rulemaking

The California climate legislation will be enforced by CARB, which has been tasked by the state of California with developing and adopting regulations to codify the legislative requirements. CARB did not meet the legislative deadline of July 1, 2025, for publishing such requirements and is currently working to release the regulations.

CARB's rulemaking process includes numerous stages, which typically take 16 to 24 months.<sup>11</sup> CARB is currently at the informal rulemaking proposal development stage of the rulemaking process for clarifying guidance on GHG emission reporting and assurance consideration under SB 253. It is actively engaging the public via workshops and open, public comment periods before submitting its official notice of initial formal rulemaking.

CARB has moved into the formal rulemaking stage for determination of applicability, key definitions (e.g., total annual revenues and doing business in California), fee calculation, fee payment and collection, fee enforcement, and the deadline for reporting under SB 253. For more information, see Deloitte's February 27, 2026, [news alert](#).

### 12.11.2.3.3 SB 253 Reporting Considerations

SB 253 requires entities to initially report Scope 1 and Scope 2 GHG emissions in accordance with the GHG Protocol standards and obtain limited assurance. There is no phase-in provision for obtaining limited assurance on Scope 1 and Scope 2 GHG emissions. Reporting on Scope 3 GHG emissions will be required starting in 2027. For considerations related to the accounting for GHG emissions in accordance with the GHG Protocol standards, see [Section 12.11.3](#).



#### Changing Lanes

On November 17, 2025, CARB issued an updated [FAQ document](#) addressing California's climate-related disclosure requirements. FAQ 19 of that document provides guidance on the initial year of reporting GHG emissions, which states, in part:

To support initial implementation and reduce uncertainty, CARB issued an [Enforcement Notice](#) in December 2024. In this Enforcement Notice, CARB recognizes that some reporting entities may require lead time to develop or refine their data collection processes to ensure complete and accurate reporting of Scope 1 and Scope 2 emissions. Accordingly, CARB will exercise enforcement discretion for the first report due in 2026, allowing reporting entities to submit Scope 1 and Scope 2 emissions for their prior fiscal year based on information they already have or were collecting when this Notice was issued.

### 12.11.2.3.4 SB 261 Reporting Considerations

SB 261 requires entities to report a climate-related financial risk report in accordance with TCFD guidance or any equivalent reporting standards, such as IFRS S2. For the initial year of reporting, CARB released minimum reporting requirements for SB 261, including:

- Disclosure of which voluntary framework was used to compile the report.
- The four overriding principles of TCFD (i.e., governance, strategy, risk management, and metrics and targets) must be disclosed.
- Discussion of which recommendations and disclosures have been compiled and which have not, a brief summary of the reasons why recommendations/disclosures have not been included, and discussion of any plans for future disclosures.

<sup>11</sup> CARB published a [Rulemaking 101 document](#) to help entities understand its legislative rulemaking process.



### Connecting the Dots

TCFD's recommendations rest on four pillars: governance, strategy, risk management, and metrics and targets. TCFD requires organizations to disclose how climate risks and opportunities are overseen (governance), the impact on business strategy (strategy), the processes for identifying and managing climate-related risks (risk management), and quantitative metrics and targets (including Scope 1, Scope 2, and Scope 3 GHG emissions) used to assess climate performance (metrics and targets).

CARB's minimum reporting requirements for the initial year of reporting, while grounded in the four TCFD pillars, do include some relief from the requirements of TCFD. Entities should take note of the following differences:

- Disclosure of Scope 1, Scope 2, and Scope 3 GHG emissions is not required in the initial year of reporting for SB 261 to the extent that an entity does not readily have the information available, even if GHG emissions are used as a quantitative metric and/or target for assessing climate-related performance.
- TCFD requires entities to use a climate-related scenario analysis when reporting under the strategy pillar. However, CARB has not required the use of a climate-related scenario analysis for the initial year of reporting.
- TCFD requires disclosure of both risks and opportunities. However, SB 261 only discusses risks (i.e., opportunities are not within the scope of the law).

Despite these notable differences between TCFD requirements and CARB's minimum reporting guidance, CARB's guidance does state that entities must disclose why they have not reported something in line with the voluntary framework (e.g., TCFD) that they have chosen. Accordingly, entities may have to reconcile their application of CARB's guidance to the requirements of TCFD.

#### 12.11.2.3.5 Additional Information

Various Deloitte resources provide additional information on the following topics:

- *SB 253, SB 261, and AB 1305* — See Deloitte's October 10, 2023 (updated December 19, 2023), [Heads Up](#).
- *SB 219's amendments to California's climate legislation* — See Deloitte's October 1, 2024, [Heads Up](#).
- *Status of CARB rulemaking and next steps* — See Deloitte's December 4, 2025, [Sustainability Spotlight](#) and February 27, 2026, [news alert](#).

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

### 12.11.2.4 SEC Reporting Considerations and Final Rule on Climate-Related Disclosures

#### 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 Final Rule on Climate-Related Disclosures

As previously noted in [Section 12.11.1](#), the SEC’s final rule on climate-related disclosures is currently stayed while the SEC determines whether to rescind it, modify it, or defend it in litigation before the U.S. Court of Appeals for the Eighth Circuit. Accordingly, the final rule is still not effective.

### 12.11.3 GHG Protocol Reporting Considerations

The GHG Protocol issues standards and related guidance (the “GHG Protocol standards”) 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 standards, which have been broadly applied for disclosing GHG emissions. The GHG Protocol standards provide a framework for companies and other types of organizations preparing an inventory of GHG emissions. Specifically, they address 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 standards, GHG emissions are classified into three scopes as follows:

<b>Scope 1 emissions</b>	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.
<b>Scope 2 emissions</b>	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.
<b>Scope 3 emissions</b>	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 standards 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 operations<sup>12</sup> 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*.
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.



### Changing Lanes

The GHG Protocol standards are currently undergoing a revision process. For example, because of changes in the reporting environment and the evolution of power grids and energy attribute certificate instruments, the GHG Protocol has released proposed revisions to its [Scope 2 Guidance](#), which was issued in 2015, via a [public consultation document](#) that solicits feedback from stakeholders. A key theme of the public consultation document is the continued use of the dual reporting requirement for both location-based and market-based Scope 2 emissions, with changes proposed for more precise location-based emission factors as well as for market-based emissions that are matched to market instruments on an hourly basis. The document offers measures to ease adoption of the proposed revisions, including (1) ways for entities to calculate the hourly matching requirement for market-based emissions, (2) exemption thresholds, and (3) phased implementation.

The GHG Protocol's Corporate Standard and Scope 3 Standard are also in the process of being refreshed. We expect future public consultation periods to be held for these standards.

<sup>12</sup> The GHG Protocol's 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."

Entities should continue monitoring changes to the GHG Protocol's suite of corporate standards and be aware of impacts on their current reporting processes.

### **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. 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 lower GHG emissions, it should evaluate whether there has been a triggering event<sup>13</sup> related to the

<sup>13</sup> 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.

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.

#### **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.

##### **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."<sup>14</sup>

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."

<sup>14</sup> See ASC 410-20-20, which cites the definition of promissory estoppel that is used in *Black's Law Dictionary*, seventh edition.

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.

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 12-5

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.

**ASC 440-10 (continued)****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 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. The Board is currently redeliberating its proposed guidance on the basis of comments received during the public comment period. We expect that the final ASU, which is likely to be issued in early 2026, will be largely consistent with the ED released (which is summarized below).

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 December 2025 report [2026 Life Sciences Outlook](#), generative AI in the life sciences industry is "an influential [trend that] highlights how analytics and automation are increasingly shaping research, manufacturing, and commercial operations." 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*.



### Changing Lanes

In September 2025, the FASB issued [ASU 2025-06](#) to amend certain aspects of the accounting for and disclosure of software costs under ASC 350-40. See [Section 12.12.3.1](#) for a discussion of key provisions of the ASU and examples illustrating the application of ASC 350-40 upon adoption of the ASU. Various amendments in the ASU are highlighted in other sections below as applicable.

ASU 2025-06 is effective for annual reporting periods beginning after December 15, 2027, including interim reporting periods within those annual reporting periods. Early adoption is permitted.

## 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 feasibility<sup>15</sup> 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

<sup>15</sup> Current guidance in 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. ASU 2025-06 removes from ASC 350-40 all references to the "preliminary project stage," the "application development stage," and the "postimplementation-operation stage" (collectively referred to hereinafter as "development stages"). For more information about capitalizing software costs under the new ASU, see this section's [Changing Lanes](#).

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 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.



### Changing Lanes

As previously noted, the FASB issued [ASU 2025-06](#) in September 2025 to amend certain aspects of the accounting for and disclosure of software costs under ASC 350-40. In its deliberations, the Board observed that software is not always developed in a linear manner. To clarify how the guidance applies to both linear and nonlinear software development, the ASU removes all references to development stages from ASC 350-40. Under the ASU, the following criteria in ASC 350-40-25-12(b) and (c) 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’).”

While an entity is already required to meet the above criteria under current GAAP to capitalize software development costs, the ASU provides new guidance on how to evaluate whether the probable-to-complete recognition threshold has been met. Specifically, such threshold would not be met when there is “significant uncertainty associated with the development activities of the software (referred to as ‘significant development uncertainty’).” ASC 350-40-25-12A(a) and (b) (added by the ASU) specify that if either of the following factors is present, significant development uncertainty exists:

- “The software being developed has technological innovations or novel, unique, or unproven functions or features, and the uncertainty related to those technological innovations, functions, or features, if identified, has not been resolved through coding and testing.”
- “The significant performance requirements of the software have not been identified, or the identified significant performance requirements continue to be substantially revised.”

See Deloitte’s September 18, 2025, [Heads Up](#), for more information about ASU 2025-06.

The examples below illustrate the application of ASC 350-40 to the accounting for the costs of developing software involving AI upon the adoption of ASU 2025-06.

#### Example 12-6

Entity Y offers hosted enterprise resource planning solutions to its customers as SaaS. On January 15, 20X0, Y’s CEO approved and committed to funding a project to evaluate how Y can incorporate AI into its SaaS offerings to provide a technical accounting support module. The module would be able to read customer contracts and extract key terms from the documents (the “extract functionality”) and, using generative AI technology trained on publicly available guidance, disclosures, and examples, create an output of revenue recognition considerations in the customer contract (the “write functionality”).

On January 15, 20X0, the technology necessary for providing the write functionality does not exist, and Y would need to use a combination of third-party tools and an in-house model to develop it. Entity Y has not selected the third-party tools and does not currently have the appropriate talent resources to perform the necessary in-house activities to develop the intended functionality. In addition, not all the significant performance requirements have been identified.

**Example 12-6 (continued)**

By contrast, the extract functionality is based on existing concepts and technology. Entity Y determines that it has decided what the software needs to do, and its in-house development personnel have the resources and capabilities to replicate the existing tool in the market. Accordingly, Y begins developing the extract functionality.

On February 28, 20X0, Y hired generative AI specialists to work on the write functionality and entered into a service contract to access an LLM from a reputable third party. Through June 30, 20X0, Y evaluates how the AI specialists it hired can leverage and build on its existing LLM. As of June 30, 20X0, Y determined that the tool will be limited to identifying the distinct performance obligations in the contract; however, certain novel or unproven functions still need to be developed for the software to perform this task.

As of September 30, 20X0, the AI specialists have made significant progress toward developing the model and completed the coding and testing necessary to demonstrate that the write functionality can perform the intended task in accordance with the design specifications selected by Y. Although Y has resolved the development uncertainty, the model will still need to be trained on sufficient data to achieve the desired functionality.

On December 15, 20X0, Y completes the model training necessary to demonstrate that the write functionality can perform the performance obligation assessment in accordance with the design specifications.

The appropriate accounting for the costs incurred to develop the functionality depends on Y's evaluation of the unit of account (i.e., what constitutes the "software project"). There are two acceptable views:

- *View A* — The extract and write functionality were funded as a single software project and therefore represent a single unit of account.

For each of the key dates above, Y assesses whether the internal and external costs incurred to develop the application meet the capitalization requirements in ASC 350-40-25-12 as follows:

- On January 15, 20X0, although the CEO approved the funding for the project, the capitalization criteria in ASC 350-40-25-12 are not met because of significant development uncertainties.
- As of February 28, 20X0, although Y has hired the AI specialists and entered into a service contract to access a third-party LLM in developing its tool, significant development uncertainties remain. Accordingly, as of February 28, 20X0, Y has determined that the software still does not meet the requirement in ASC 350-40-25-12(c).
- As of June 30, 20X0, Y has identified a specific accounting output that the software must be able to write and, as a result, it has identified the significant performance requirements that are known and not expected to change. However, the ultimate technology that Y intends to develop remains novel, unique, and unproven. Accordingly, as of June 30, 20X0, the company has determined that the software still does not meet the requirement in ASC 350-40-25-12(c).
- As of September 30, 20X0, the AI specialists have resolved the software development risk related to the novel portions of the project through coding and testing. On the basis of such progress, the development uncertainty associated with the novel, unique, and unproven aspects of the software development described in ASC 350-40-25-12A has been resolved through coding and testing, and Y therefore concludes that the software meets the requirements in ASC 350-40-25-12(c).

Eligible software development costs incurred after September 30, 20X0, would be capitalized, including those related to the model developed in-house and implementing the LLM model. Entity Y would capitalize the costs incurred for training the model that were necessary to establish that the write functionality can perform the performance obligation assessment in accordance with the design specifications through December 15, 20X0.

- *View B* — Because Y can provide the extract functionality even if the write functionality is not developed, each functionality represents a separate software project.

On January 15, 20X0, the CEO approved both projects. Because it is probable that the extract functionality will be completed (i.e., there is no significant development uncertainty associated with the software project), Y begins capitalizing eligible development costs allocable to such software project.

The milestones in View B for the write functionality are the same as those in View A, and costs related to the write project incurred after September 30, 20X0, are capitalized.

**Example 12-7**

Assume the same facts as in [Example 12-6](#), except that after Entity Y's technical accounting module is ready for its intended use, Y determines that there is a demand for an enhancement to its software that would provide principal-versus-agent analyses for revenue contracts.

On the basis of what it learned from its original technical accounting module project, Y believes that it can develop the new functionality with internal expertise and that although the functionality does not yet exist, the only development risk is related to systematizing the logic inherent in the accounting rules related to the guidance on principal versus agent. On January 31, 20X1, the CEO approves the software enhancement.

Entity Y determines that the desired functionality represents an upgrade to its current software; therefore, it considers the guidance in ASC 350-40-25-17A through 25-17E and concludes that (1) it is probable that the upgrade will result in additional functionality and (2) it should evaluate the upgrade as a new software project. Entity Y once again considers the guidance in ASC 350-40-25-12 and 25-12A and determines that as of January 31, 20X1, management has committed to funding the project and that the probable-to-complete recognition threshold is met. In making this determination, Y considers the factors in ASC 350-40-25-12A and notes that the performance requirements are defined for principal-versus-agent analyses and that although the upgrade will result in additional functionality, there are no significant development uncertainties associated with such functionality. Management reaches this decision on the basis of the successful release of Y's previous technical accounting module and concludes that no new technological innovations or novel, unique, unproven functions and features need to be developed for the new functionality to be created. Rather, the same logic and coding will be used to create the new module, and only routine coding, testing, and model training will be needed to create the new functionality.

Entity Y therefore begins capitalizing development costs of the new module after January 31, 20X1.

**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 350-30-25-4<sup>16</sup> 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.

#### 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.

<sup>16</sup> 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.



### 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.<sup>17</sup> 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):<sup>(18)</sup> . . .

- 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.

<sup>17</sup> 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).

<sup>18</sup> The amendments in [ASU 2025-06](#) supersede the current guidance on Web site development costs and move the current requirements for recognizing Web site-specific development costs, as amended, from ASC 350-50 to ASC 350-40. In addition, the ASU removes the parenthetical reference to ASC 350-50 in ASC 730-10-25-2. See paragraphs BC105 and BC106 of the ASU.

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.



### Changing Lanes

While ASU 2025-06 still requires the criteria in existing ASC 350-40-25-12(b) to be met for entities to begin capitalizing software costs (see ASC 350-40-25-12(b), as amended by the ASU, and ASC 350-40-25-12(c), as added by the ASU), the ASU removes all references to development stages and includes new guidance to clarify that entities should not capitalize costs if there is “significant uncertainty associated with the development activities of the software.”

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.<sup>19</sup>

### 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:<sup>20</sup>

#### 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.

<sup>19</sup> The current guidance in ASC 350-40-30-1 states that the only internal-use software costs that would be capitalized are the following:

- “External direct costs of materials and services consumed in developing or obtaining internal-use computer software” (ASC 350-40-30-1(a)).
- “Payroll 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” (ASC 350-40-30-1(b)).
- “Interest costs incurred while developing internal-use computer software” (ASC 350-40-30-1(c)).

ASU 2025-06 amends this guidance to include a fourth category: “Costs to develop or obtain software that allows for access to or conversion of old data by new systems” (ASC 350-40-30-1(d), an added subparagraph consisting of content moved from existing ASC 350-40-25-3).

<sup>20</sup> ASU 2025-06 amends the content currently in ASC 350-40-25-7 through 25-9 and moves it to added ASC 350-40-25-17A through 25-17C.

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<sup>21</sup> 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”<sup>22</sup> 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.”<sup>23</sup> 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.

<sup>21</sup> ASU 2025-06 amends the guidance currently in ASC 350-40-25-7 (and moves it to added ASC 350-40-25-17A) to clarify that costs of specified upgrades and enhancements to internal-use computer software are to be “evaluated for capitalization” in accordance with added ASC 350-40-25-17B through 25-17E (which consist of content moved from ASC 350-40-25-8 through 25-11, as amended).

<sup>22</sup> ASC 985-20-15-5(a) and ASC 350-40-15-4A(a).

<sup>23</sup> ASC 985-20-15-5(b) and ASC 350-40-15-4A(b).

## 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*.



#### Connecting the Dots

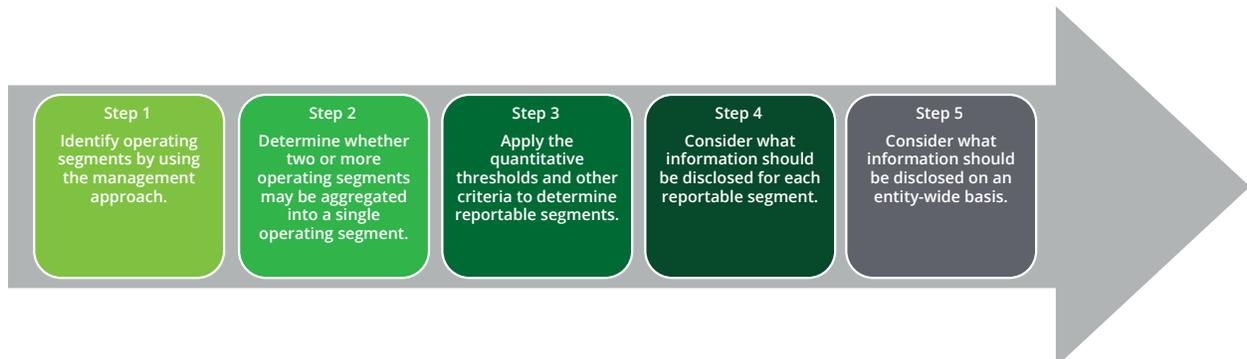
At the 2025 AICPA & CIMA Conference on Current SEC and PCAOB Developments, the SEC staff provided insight into the findings from its filing reviews related to the recent adoption of ASU 2023-07 by public entities. The staff’s discussion focused on the following topics:

- Determination of the required measure of profit and loss.
- Requirements for single reportable segments managed on a consolidated basis.
- Significant segment expenses.
- CODM-related disclosures.
- Disclosure of information not required by ASC 280.

For more information about the SEC staff’s discussion of these topics, see Deloitte’s December 12, 2025, *Heads Up*.

### 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:

- Aggregation 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.

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.

<b>Change</b>	<b>Overview and When Disclosure Is Required</b>
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 12-8

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*).
- Geographic 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*).
- Geographic 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.

**Example 12-9**

Company L is a pre-revenue life sciences company and has one operating and one reportable segment. The consolidated statement of operations includes R&D expenses, general and administrative expenses, interest expense, interest income, and income taxes. In addition to reviewing the expenses in the consolidated statement of operations, the CODM is regularly provided with R&D expenses for programs A, B, and C. Company L has concluded that the expenses on the face of the statement of operations and each program's R&D expenses are significant. Each program's R&D expenses are also disclosed in L's MD&A. Company L would need to include significant expense details of the R&D costs for programs A, B, and C and all other expenses disclosed in the statement of operations, which together reconcile to the consolidated GAAP measure of net income (loss), as shown below.

	<b>Total</b>
Revenue	\$ —
R&D expenses	
Program A	(100)
Program B	(150)
Program C	(200)
General and administrative expenses	(200)
Interest expense	(20)
Interest income	120
Income tax expense	(5)
Net income (loss)	<u>\$ (555)</u>

Company L would also need to consider all other disclosure requirements as a company with one operating segment and one reportable segment, as noted in [Section 12.13.4.1](#).

**Example 12-10**

Assume the same facts as in [Example 12-9](#), except that Company L tracks R&D expenses by nature of expense. Company L does not track R&D by program or product. The CODM is regularly provided with R&D expenses by their nature as internal research expenses, external research expenses, employee-related expenses, facilities and overhead expenses, and professional and consulting expenses. Company L has concluded that the expenses on the face of the statement of operations and each nature of R&D expenses are significant. Each nature of R&D expenses is disclosed in L's MD&A, together with a statement that R&D expenses are not tracked at a program or product level. Company L would need to include significant expense details of the R&D expenses, as noted below, and all the other expenses disclosed in the statement of operations, which together reconcile to the consolidated GAAP measure of net income (loss).

**Example 12-10 (continued)**

	<b>Total</b>
Revenue	\$ —
R&D expenses	
Internal research expenses	(100)
External research expenses	(50)
Employee-related expenses	(200)
Facilities and overhead expenses	(50)
Professional and consulting expenses	(50)
General and administrative expenses	(200)
Interest expense	(20)
Interest income	120
Income tax expense	(5)
Net income (loss)	<u>\$ (555)</u>

Company L would also need to consider all other disclosure requirements as a company with one operating segment and one reportable segment, as noted in [Section 12.13.4.1](#).

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 12-11

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.

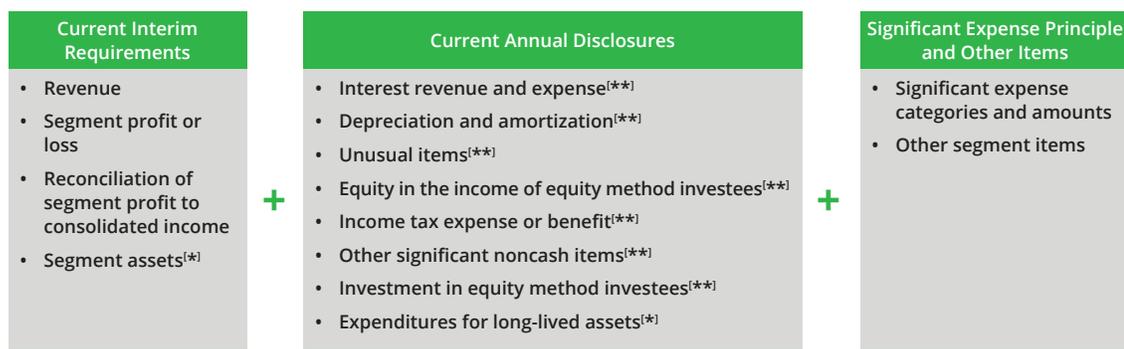
We believe that when R&D expense is provided to the CODM in more than one way, R&D expense by program would generally be the most relevant for segment disclosure purposes.

### 12.13.7 Interim Period Information

Interim disclosures are required for (1) the current quarter and year-to-date amounts for the current year and (2) the comparable quarter and year-to-date amounts for the preceding year. When issuing interim financial statements, entities are permitted to provide reduced disclosures in condensed financial statements. Entity-wide disclosures are not required for interim periods; however, if a public entity had material changes to such disclosures, including entity-wide disclosures, management should consider providing the disclosures required by ASC 280-10-50-40 through 50-42. If changes are made to any entity's reportable segments or an immaterial segment becomes material, management should consider recasting requirements.

Under ASU 2023-07, entities are required to apply the annual disclosure requirements in ASC 280 on an interim basis in addition to the new requirements introduced by the ASU. This means that public entities must disclose significant segment expenses and other required segment information about profit or loss and total assets, in a manner consistent with the measures used by the CODM, on both an annual and an interim basis. The disclosures should include information that would otherwise be required annually under ASC 280-10-50-22 through 50-26C. Interim segment disclosures must also include a reconciliation of each segment measure of profit or loss to consolidated income. Reconciliations of total segment revenues and total segment assets to consolidated amounts are permitted but not required in interim periods. Interim segment disclosures also do not have to include an explanation of how the CODM uses the measures of segment profit or loss for each reportable segment.

The chart below illustrates the segment reporting disclosures that a public entity must provide on an interim basis upon its adoption of ASU 2023-07.



\* 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 company on an annual basis.

### 12.14 Disaggregation of Income Statement Expenses (DISE)

In November 2024, the FASB issued [ASU 2024-03](#) (the "DISE standard," codified as ASC 220-40), which provides for the disaggregation of income statement expenses for PBEs, including entities that file (or furnish) financial statements with (to) the SEC (see [Section 12.14.1](#) for discussion about private companies that are in the process of going public or whose financial statements are included in another entity's SEC filing).

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 or triggered when a specific event occurs. Certain other types of expenses are required to be disclosed in the notes 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 does not change the expense captions an entity presents on the face of the income statement or the recognition and measurement principles of other GAAP standards; rather, it requires disaggregation of certain expense captions into specified categories in disclosures within the notes to the financial statements. An expense caption is considered relevant and therefore subject to disaggregation if it is presented on the face of the income statement within continuing operations and includes any of the following natural expense categories: (1) purchases of inventory; (2) employee compensation; (3) depreciation; (4) intangible asset amortization; and (5) depreciation, depletion, and amortization (DD&A) recognized as part of oil- and gas-producing activities or other types of depletion expenses. Entities will need to disaggregate relevant expense captions into these five natural expense categories (the “required expense categories”) in a tabular presentation. The tabular disclosure for each relevant expense caption would also include certain other expenses, gains, or losses that must be disclosed under existing U.S. GAAP and expense reimbursements, when applicable. The graphic below illustrates the components of the disaggregated tabular disclosures of a relevant expense caption.



The DISE standard also requires an entity to present a separate total of its selling expenses (outside of the tabular disclosure) and, in annual reporting periods, its definition of selling expenses.

ASU 2024-03 does not change or remove existing expense disclosure requirements; however, it may affect where that information appears in the notes to the financial statements because the ASU requires entities to include certain current disclosures in this tabular format. The ASU's requirements do not apply to immaterial items, and entities are allowed to use accounting estimates or other methods that reasonably approximate the required disclosure amounts.

### 12.14.1 Scope

The amendments in ASU 2024-03 apply to all PBEs, including entities that file (or furnish) financial statements with (to) the SEC, inclusive of brokers and dealers in securities and voluntary filers. While the amendments “do not apply to private companies, not-for-profit entities, and employee benefit plans,” private companies that are in the process of going public or whose financial statements are included in another entity's SEC filing (e.g., significant acquisitions under SEC Regulation S-X, Rule 3-05, or significant equity method investments under SEC Regulation S-X, Rule 3-09) meet the definition of a PBE and will be required to apply the DISE disclosures.



#### Connecting the Dots

As discussed in Chapter 11, it is common for life sciences companies to undertake an IPO or to engage in significant M&A or other investing activities. Therefore, companies in the life sciences industry should be mindful of SEC reporting requirements when they undertake an IPO or are involved in an acquisition or other investing activities. For more information about the application of these requirements, see Section 11.2.1 (Rule 3-05) and Section 11.1.1.2 (Rules 3-05 and 3-09).<sup>24</sup>

### 12.14.2 Relevant Expense Captions

As previously noted, an expense caption is considered relevant and therefore subject to disaggregation if it is presented on the face of the income statement within continuing operations and includes any of the following natural expense categories: (1) purchases of inventory; (2) employee compensation; (3) depreciation; (4) intangible asset amortization; and (5) DD&A recognized as part of oil- and gas-producing activities or other types of depletion expenses.

ASU 2024-03 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 notes to the financial statements.
- 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.

<sup>24</sup> Rule 3-09 prescribes the annual requirements for financial statements of a significant equity method investee. See Deloitte's Roadmap *SEC Reporting Considerations for Equity Method Investees* for further guidance on evaluating the significance of equity method investees.



### Connecting the Dots

Relevant expense captions for many life sciences entities may include cost of products sold, SG&A expenses, and R&D expenses, among others.

## 12.14.3 Required Expense Categories

For life sciences entities, relevant expense captions may commonly include the following required natural expense categories: (1) purchases of inventory, (2) employee compensation, (3) depreciation, and (4) intangible asset amortization.

### 12.14.3.1 Purchases of Inventory

Amounts disclosed for the purchases of inventory category should include costs of acquiring raw materials and other externally purchased inputs that are within the scope of ASC 330 and, as applicable, ASC subtopics that provide industry-specific guidance on inventory. The purchases of inventory category should exclude amounts recognized in a business combination, a joint venture formation, and an initial consolidation of a VIE that is not a business combination. It should include inventory acquired in an asset acquisition, except for acquisitions of a VIE.

ASU 2024-03 does not otherwise define purchases of inventory or include specific guidance on the presentation of all costs within the scope of ASC 330. Because purchases of material should generally include the costs of acquiring raw materials and other externally purchased inputs, not all inventoriable costs under ASC 330 may qualify as purchases of inventory. The ASU does not supersede or otherwise amend the scope, recognition, or measurement guidance in ASC 330 or other ASC topics. Therefore, entities should follow their existing accounting policies, and may sometimes need to use judgment, to determine (1) which costs are within the scope of ASC 330 and (2) which inventoriable costs under ASC 330 qualify as purchases of inventory.

Costs that are colloquially referred to as “inventory” but that are not within the scope of ASC 330 (e.g., software costs) should not be included in purchases of inventory.

An entity may need to use judgment to determine which inventoriable costs under ASC 330 qualify as purchases of inventory. Costs that are directly related to the acquisition of materials (those incurred to bring a material to its existing condition and location), such as tariffs, may be included in purchases of inventory, provided that these costs are capitalizable under ASC 330. Entities should follow their existing ASC 330 inventory capitalization policies when determining whether a cost is capitalizable. Alternative views may be acceptable. An entity should consistently apply its approach to all capitalizable acquisition costs. In addition, purchases of inventory should include only externally purchased inputs, not intercompany purchases.



### Connecting the Dots

For life sciences entities, judgment may be required to determine whether costs incurred to manufacture a product in advance of FDA approval (prelaunch inventory) should be capitalized as inventory or expensed as incurred as R&D costs. Entities should follow their existing accounting policies in making this determination and present costs within the DISE disclosure accordingly. Costs that are within the scope of ASC 330 (and qualify as purchases of inventory) are presented in the purchases of inventory category within the disaggregation of the relevant expense caption. Costs that are not within the scope of ASC 330 (e.g., expensed in accordance with ASC 730) do not qualify as purchases of inventory and should be presented in the applicable natural expense category (e.g., employee compensation, depreciation, other) within the disaggregation of the relevant expense caption (e.g., R&D expense), as applicable. See Section 2.2.3 for considerations related to the capitalization of prelaunch inventory.

In addition, life sciences entities may need to exercise judgment to determine whether arrangements involving placed equipment should be accounted for under the revenue standard or the leasing standard. Lessors typically classify leased equipment in operating lease transactions as PP&E under ASC 360 rather than as inventory under ASC 330. Entities should follow their existing accounting policies in making this determination and present costs in the DISE disclosure accordingly. Certain costs that are within the scope of ASC 330 are presented in the purchases of inventory category, whereas costs that are not within the scope of ASC 330 (e.g., costs that are capitalized and depreciated in accordance with ASC 360) are not presented in purchases of inventory but are presented in the applicable natural expense category (e.g., depreciation) within the disaggregation of the relevant expense caption, as applicable. See Section 1.2.2 for considerations related to arrangements involving placed equipment.

### **12.14.3.2 Employee Compensation**

Amounts disclosed for the employee compensation category should include costs that meet ASU 2024-03's definition of employee compensation, which refers to employees as defined in the ASU. The DISE standard's definition of an employee is aligned with that in ASC 718 and refers to full-time, part-time, temporary, or seasonal employees. Employee compensation is consistent with compensation costs in ASC 710, ASC 712, ASC 715, and ASC 718 and includes, but is not limited to, wages, bonuses, Social Security contributions, employee benefits, and stock compensation. Disclosures about employee compensation should include separate presentation of one-time employee termination benefits, when applicable, in the tabular disclosure.

### **12.14.3.3 Depreciation and Amortization (Separate Required Expense Categories)**

The amounts disclosed for the depreciation category should be consistent with the classification of amounts used to meet the disclosure requirements in ASC 360-10-50-1(a) related to total depreciation expense. The amounts disclosed for the intangible asset amortization category should be consistent with the classification of amounts used to meet the disclosure requirements in ASC 350-30-50-2(a)(2) related to total intangible asset amortization expense. Amortization of a finance lease ROU asset and of leasehold improvements that are recorded under ASC 842-20 should be included in either the depreciation category or the intangible asset amortization expense category in a manner consistent with how the entity presents amortization for similar assets.

### **12.14.4 Tabular Integration of Other Disclosures**

Certain expenses and gains and losses that may require disclosure under existing U.S. GAAP and are each recorded in a relevant expense caption should be presented in the tabular disclosure on an annual (and, when applicable, interim) basis for each relevant expense caption in which the expense is recorded. Examples of such items 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 and losses, such as warranty expense, 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 caption 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 expenses), separate disaggregation would not be required.

ASU 2024-03 provides specific lists of the expenses, gains, and losses to which these requirements apply (see ASC 220-40-50-21 and 50-22).



### Connecting the Dots

As discussed in Sections 3.2.2 and 3.2.3.6, IPR&D acquired in an asset acquisition is expensed under ASC 350-30 and ASC 730 unless the IPR&D has an alternative future use. Some life sciences entities may present this acquired IPR&D expense as a separate expense caption on the face of the income statement. When that expense caption consists exclusively of IPR&D assets acquired in an asset acquisition and written off, the expense caption is not considered relevant and therefore is not subject to disaggregation.

## 12.14.5 Expense Reimbursements

ASU 2024-03 requires disclosure of certain expense-reimbursement amounts included in relevant expense captions that are related to a cost-sharing or cost-reimbursement arrangement with another entity. Examples of these arrangements could include (1) collaborative arrangements such as codevelopment, comarketing, and copromotion arrangements and (2) R&D funding arrangements. See Sections 1.2.1 and 2.2.1 for additional information about these arrangements.

Qualifying expense reimbursements must be disaggregated in either of the following situations:

- An entity includes amounts net of expense reimbursements *from* another entity in a relevant expense caption (ASC 220-40-50-26).
- An entity includes expense reimbursement *to* another entity in a relevant expense caption (ASC 220-40-50-28).

Entities that include amounts net of expense reimbursements from another entity in 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 (ASC 220-40-50-26(a)).
- Disclose the amounts of the required expense categories that are included in the relevant expense caption net of any reimbursement effects (ASC 220-40-50-26(b)).

Further, the DISE standard requires entities to “disclose how expense reimbursements related to a cost-sharing or cost-reimbursement arrangement are included in the tabular format disclosure” (ASC 220-40-50-27).

Entities that include expense reimbursement to another entity in a relevant expense caption should provide separate disclosure of the amount of expense reimbursement in the tabular format disclosure (ASC 220-40-50-28).

An entity that elects to separately disclose the reimbursement amount from another entity under the alternative in ASC 220-40-50-26(a) or that separately discloses expense reimbursements to another entity must also provide a qualitative description of the expense categories that include the reimbursement (ASC 220-40-50-29).

The table below summarizes these requirements.

Expense Reimbursement for Cost-Sharing or Cost-Reimbursement Arrangements	Election <sup>25</sup>	Tabular Format	Disclosure <sup>26</sup>
Expense reimbursement <b>received from</b> other entities within a relevant expense caption. Entity selects alternative (a).	Election (a) — Disclose separately the amount of the expense reimbursement.	Separate disclosure in the disaggregated expense table (see the example in ASC 220-40-55-17 and 55-18).	<ul style="list-style-type: none"> <li>• Disclosure of the elected alternative related to how expense reimbursements are presented in tabular format.</li> <li>• Qualitative description of the expense categories to which the reimbursement is related.</li> </ul>
Expense reimbursement <b>received from</b> other entities within a relevant expense caption. Entity selects alternative (b).	Election (b) — Disclose the amounts of the required expense categories that are included in the relevant expense caption, net of any reimbursement effects.	Tabular disclosure, netted with the expense category discussed in ASC 220-40-50-6.	<ul style="list-style-type: none"> <li>• Disclosure of the elected alternative related to how expense reimbursements are presented in tabular format.</li> </ul>
Expense reimbursement <b>paid to</b> other entities	Not applicable.	Separate disclosure in the disaggregated expense table within the expense categories discussed in ASC 220-40-50-6.	<ul style="list-style-type: none"> <li>• Qualitative description of the expense categories related to the reimbursement.</li> </ul>



### Connecting the Dots

R&D cost-sharing arrangements (e.g., collaborative arrangements) and R&D funding arrangements are common in the life sciences industry. As described in Section 1.2.1 (collaborative arrangements) and Section 2.2.1 (R&D funding arrangements), such arrangements are often complex and may have varying terms and conditions. Participants in these arrangements will need to evaluate the appropriate accounting treatment and related income statement classification for payments between collaboration or funding partners. When payments between partners are presented in R&D expense (or another relevant expense caption), they will generally be subject to the expense-reimbursement disclosure requirements of ASU 2024-03. However, when payments between partners are reported outside of R&D expense, such as in revenue or other income, they are generally not subject to the expense-reimbursement disclosure requirements of the ASU. For example, in R&D funding arrangements, passive third-party investors often provide funds to offset some of the costs associated with an R&D program. When payments are classified as contra-R&D expense (e.g., when substantive and genuine risk transfer has occurred and the arrangement is inconsistent with the entity's ordinary activities), they will generally be subject to the disclosure requirements of the ASU. However, when the arrangement represents an obligation to repay the funding party

<sup>25</sup> Elections (a) and (b) as indicated in ASC 220-40-50-26.

<sup>26</sup> Disclosure in accordance with ASC 220-40-50-27 and ASC 220-40-50-29.

(risk transfer is not substantive and genuine) or when the contract to perform R&D services is reported outside of R&D expense (or another relevant expense caption), such as in revenue or other income, payments under the arrangement are not subject to the expense reimbursement disclosure requirements of the ASU.

### Example 12-12

Entity K has determined that R&D expense is a relevant expense caption because it contains employee compensation (one of the natural expense categories listed in ASC 220-40-50-6). In addition, K has entered into an R&D funding arrangement. Entity K recognizes an expense reimbursement from the strategic partner in R&D expenses.

Cost reimbursements received were \$7,000, \$6,000, and \$5,000 in 20X6, 20X5, and 20X4, respectively. These cost reimbursements are related to employee compensation and material costs. Specifically, cost reimbursements related to employee compensation were \$4,000, \$3,500, and \$3,000 in 20X6, 20X5, and 20X4, respectively, and cost reimbursements related to material costs were \$3,000, \$2,500, and \$2,000 in 20X6, 20X5, and 20X4, respectively. In this scenario, material costs for which R&D cost reimbursements were received are not considered inventoriable in accordance with ASC 330.

Assume that K elects to separately disclose the amount of the expense reimbursement in accordance with ASC 220-40-50-26(a). The disclosure is presented in the manner shown below.

	<b>Disaggregation of Relevant Expense Captions</b>		
	20X6	20X5	20X4
R&D expenses:			
Employee compensation	\$ 70,000	\$ 65,000	\$ 60,000
Other R&D <sup>(a)</sup>	37,000	31,000	\$ 30,000
Cost reimbursements <sup>(b)</sup>	<u>(7,000)</u>	<u>(6,000)</u>	<u>(5,000)</u>
Total R&D	<u>\$ 100,000</u>	<u>\$ 90,000</u>	<u>\$ 85,000</u>

#### Notes to table:

<sup>(a)</sup> Other R&D consists primarily of payments to third parties for professional services and licenses of IP for the years ended December 31 of 20X6, 20X5, and 20X4.

<sup>(b)</sup> Cost reimbursements consist of payments from a strategic partner for employee compensation and materials costs related to R&D that were incurred as part of an R&D funding arrangement for the years ended December 31 of 20X6, 20X5, and 20X4.

Because K elects to separately disclose the amount of expense reimbursement, it provides in note (b) a qualitative description of the natural expense categories to which the expense reimbursement is related (in accordance with ASC 220-40-50-29). Entity K also discloses the alternative elected in the notes to the financial statements.

**Example 12-13**

Assume the same facts as in [Example 12-12](#), except that Entity K elects to present the amount of the expense categories that are included in the R&D expense caption net of any reimbursement effects in accordance with ASC 220-40-50-26(b). The disclosure is presented in the manner shown below.

	<b>Disaggregation of Relevant Expense Captions</b>		
	20X6	20X5	20X4
R&D expenses:			
Employee compensation (net of cost reimbursements)	\$ 66,000	\$ 61,500	\$ 57,000
Other R&D (net of cost reimbursements) <sup>(a)</sup>	<u>34,000</u>	<u>28,500</u>	<u>28,000</u>
Total R&D	<u>\$ 100,000</u>	<u>\$ 90,000</u>	<u>\$ 85,000</u>

**Note to table:**

<sup>(a)</sup> Other R&D consists primarily of payments to third parties for professional services and licenses of IP for the years ended December 31 of 20X6, 20X5, and 20X4.

Because K elects to present the amount of the expense categories net of reimbursements, no further qualitative description is required. Material costs related to R&D expenses incurred as part of the R&D funding arrangement are presented in the other R&D expense category. Entity K also discloses the alternative elected in the notes to the financial statements.

**12.14.6 Other Items — Not Separately Disaggregated**

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 DISE standard notes that the detail of the qualitative disclosures should “be commensurate with the significance of the amounts being described.”

**12.14.7 Selling Expenses**

The DISE standard 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. If that definition changes during an interim period, disclosure of such change is required in that interim period. Selling expenses should include only items that are presented as expenses in the income statement.

**12.14.8 Effective Date and Transition**

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.<sup>27</sup> Early adoption is permitted. PBEs are required to adopt the ASU prospectively. However, PBEs are permitted to apply the amendments in the ASU retrospectively.

<sup>27</sup> 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.

### 12.14.9 Next Steps

The FASB provided an extended implementation timeline to give issuers additional time to prepare for the impacts of adopting ASU 2024-03, including the potential need for issuers to modify their existing financial reporting systems and processes to compile and present the required information. Although it will be over a year before most entities issue financial statements incorporating the new DISE disclosures, entities are encouraged not to wait to begin the implementation process. See Deloitte's March 13, 2026, [Accounting Spotlight](#), an implementation guide designed to help entities navigate the practical aspects of adopting the DISE standard.

For more information about ASU 2024-03, see Deloitte's November 8, 2024 (updated January 21, 2025), [Heads Up](#). In addition, see Deloitte's December 19, 2025, [Accounting Spotlight](#) for frequently asked questions and answers related to the DISE standard.

# 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 962, *Plan Accounting — Defined Contribution Pension Plans*

ASC 965, *Plan Accounting — Health and Welfare Benefit 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 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 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 2019-10, *Financial Instruments — Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*

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 2021-04, *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 2022-03, *Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*

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 2024-04, *Debt — Debt With Conversion and Other Options (Subtopic 470-20): Induced Conversions of Convertible Debt Instruments*

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

ASU 2025-03, *Business Combinations (Topic 805) and Consolidation (Topic 810): Determining the Accounting Acquirer in the Acquisition of a Variable Interest Entity*

ASU 2025-04, *Compensation — Stock Compensation (Topic 718) and Revenue From Contracts With Customers (Topic 606): Clarifications to Share-Based Consideration Payable to a Customer*

ASU 2025-06, *Intangibles — Goodwill and Other — Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software*

ASU 2025-07, *Derivatives and Hedging (Topic 815) and Revenue From Contracts With Customers (Topic 606): Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration From a Customer in a Revenue Contract*

ASU 2025-09, *Derivatives and Hedging (Topic 815): Hedge Accounting Improvements*

ASU 2025-10, *Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities*

## **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. 2019-790, *Derivatives and Hedging (Topic 815): Codification Improvements to Hedge Accounting*

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

No. 2025-ED300, *Equity (Topic 505): Initial Measurement of Paid-in-Kind Dividends on Equity-Classified Preferred Stock*

## 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 49, *November 2015 Meeting — Summary of Issues Discussed and Next Steps*

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

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Topic 2, “Other Financial Statements Required”

Topic 3, “Pro Forma Financial Information”

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## Appendix C — Abbreviations

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

Abbreviation	Description
<b>CFC</b>	controlled foreign corporation
<b>CIMA</b>	Chartered Institute of Management Accountants
<b>CMO</b>	contract manufacturing organization
<b>CMS</b>	Centers for Medicare & Medicaid Services
<b>CODM</b>	chief operating decision maker
<b>CPU</b>	central processing unit
<b>CRO</b>	contract research organization
<b>CSRD</b>	Corporate Sustainability Reporting Directive
<b>CYR</b>	choose-your-rate
<b>DD&amp;A</b>	depreciation, depletion, and amortization
<b>DEI</b>	deduction-eligible income
<b>DISE</b>	disaggregation of income statement expenses
<b>DTA</b>	deferred tax asset
<b>DTL</b>	deferred tax liability
<b>EBITDA</b>	earnings before interest, taxes, depreciation, and amortization
<b>EC</b>	European Commission
<b>ED</b>	exposure draft
<b>EDGAR</b>	SEC's Electronic Data Gathering, Analysis, and Retrieval system
<b>EFRAG</b>	European Financial Reporting Advisory Group
<b>EGC</b>	emerging growth company
<b>EITF</b>	Emerging Issues Task Force
<b>ELOC</b>	equity line of credit
<b>EPS</b>	earnings per share

Abbreviation	Description
<b>ESA</b>	energy service agreement
<b>ESPP</b>	employee stock purchase plan
<b>ESRS</b>	European Sustainability Reporting Standards
<b>E.U.</b>	European Union
<b>EUR</b>	euros
<b>EU Taxonomy</b>	EU Taxonomy for Sustainable Activities
<b>Exchange Act</b>	Securities Exchange Act of 1934
<b>FAQ</b>	frequently asked question
<b>FASB</b>	Financial Accounting Standards Board
<b>FAST Act</b>	Fixing America's Surface Transportation Act
<b>FDA</b>	U.S. Food and Drug Administration
<b>FDDEI</b>	foreign-derived deduction-eligible income
<b>FDII</b>	foreign-derived intangible income
<b>FinREC</b>	AICPA Financial Reporting Executive Committee
<b>FOB</b>	free on board
<b>FPI</b>	foreign private issuer
<b>FRM</b>	SEC Division of Corporation Finance Financial Reporting Manual
<b>FVO</b>	fair value option
<b>FVTOCI</b>	fair value through other comprehensive income
<b>GAAP</b>	generally accepted accounting principles
<b>GDP</b>	gross domestic product
<b>GHG</b>	greenhouse gas
<b>GILTI</b>	global intangible low-taxed income
<b>GloBE</b>	Global anti-Base Erosion
<b>GPO</b>	group purchasing organization
<b>GPU</b>	graphics processing unit
<b>GWP</b>	global warming potential
<b>HAFWP</b>	how and for what purpose
<b>HFI</b>	held for investment

Abbreviation	Description
<b>HFS</b>	held for sale
<b>HHS</b>	U.S. Department of Health and Human Services
<b>HVAC</b>	heating, ventilation, and air conditioning
<b>IAS</b>	International Accounting Standard
<b>IASB</b>	International Accounting Standards Board
<b>ICFR</b>	internal control over financial reporting
<b>IEEPA</b>	International Emergency Economic Powers Act
<b>IFRS</b>	International Financial Reporting Standard
<b>IIR</b>	investigator-initiated research
<b>IOSCO</b>	International Organization of Securities Commissions
<b>IP</b>	intellectual property
<b>IPCC</b>	Intergovernmental Panel on Climate Change
<b>IPO</b>	initial public offering
<b>IPR&amp;D</b>	in-process research and development
<b>IRA</b>	Inflation Reduction Act of 2022
<b>IRC</b>	Internal Revenue Code
<b>IRS</b>	Internal Revenue Service
<b>ISO</b>	incentive stock option
<b>ISSB</b>	International Sustainability Standards Board
<b>IT</b>	information technology
<b>ITC</b>	invitation to comment
<b>JOBS Act</b>	Jumpstart Our Business Startups Act
<b>LCD</b>	liquid-crystal display
<b>LIBOR</b>	London Interbank Offered Rate
<b>LIFO</b>	last in, first out
<b>LLM</b>	large language model
<b>M&amp;A</b>	merger and acquisition

Abbreviation	Description
<b>MD&amp;A</b>	Management's Discussion & Analysis
<b>MFN</b>	most-favored-nation
<b>MNE</b>	multinational enterprise
<b>MSL</b>	medical science liaison
<b>NCTI</b>	net CFC tested income
<b>NDA</b>	new drug application
<b>NFP</b>	not-for-profit (entity)
<b>NIH</b>	National Institutes of Health
<b>NLP</b>	natural language processing
<b>NOL</b>	net operating loss
<b>NOPA</b>	notice of proposed adjustment
<b>NQSO</b> or <b>NSO</b>	nonqualified stock option
<b>OCA</b>	SEC Office of the Chief Accountant
<b>OCI</b>	other comprehensive income
<b>OECD</b>	Organisation for Economic Co-operation and Development
<b>OEM</b>	original equipment manufacturer
<b>PBE</b>	public business entity
<b>PCAOB</b>	Public Company Accounting Oversight Board
<b>PCC</b>	Private Company Council
<b>PIE</b>	public interest entity
<b>PIK</b>	paid-in-kind
<b>PIPE</b>	private investment in public equity
<b>PP&amp;E</b>	property, plant, and equipment
<b>PRV</b>	priority review voucher
<b>PTRS</b>	probability of technical and regulatory success
<b>Q&amp;A</b>	question and answer
<b>QIP</b>	qualified improvement property
<b>R&amp;D</b>	research and development
<b>R&amp;E</b>	research and experimental

Abbreviation	Description
<b>RAM</b>	random-access memory
<b>REIT</b>	real estate investment trust
<b>REMS</b>	risk evaluation and mitigation strategy
<b>ROU</b>	right-of-use
<b>S&amp;P 500</b>	Standard & Poor's 500 Index
<b>SaaS</b>	software as a service
<b>SAB</b>	SEC Staff Accounting Bulletin
<b>SAFE</b>	simple agreement for future equity
<b>SASB</b>	Sustainability Accounting Standards Board
<b>SEC</b>	U.S. Securities and Exchange Commission
<b>Securities Act</b>	Securities Act of 1933
<b>SEPA</b>	standby equity purchase agreement
<b>SG&amp;A</b>	selling, general, and administrative
<b>SOX</b>	Sarbanes-Oxley Act of 2002
<b>SPAC</b>	special-purpose acquisition company
<b>SPPI</b>	solely payments of principal and interest
<b>SRC</b>	smaller reporting company
<b>TCFD</b>	Task Force on Climate-Related Financial Disclosures
<b>TD</b>	Treasury Decision
<b>TRG</b>	transition resource group
<b>TSA</b>	transition services agreement
<b>USD</b>	U.S. dollar(s)
<b>UTB</b>	unrecognized tax benefit
<b>VCO</b>	voluntary carbon offset
<b>VIE</b>	variable interest entity
<b>VWAP</b>	volume-weighted average daily market price



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