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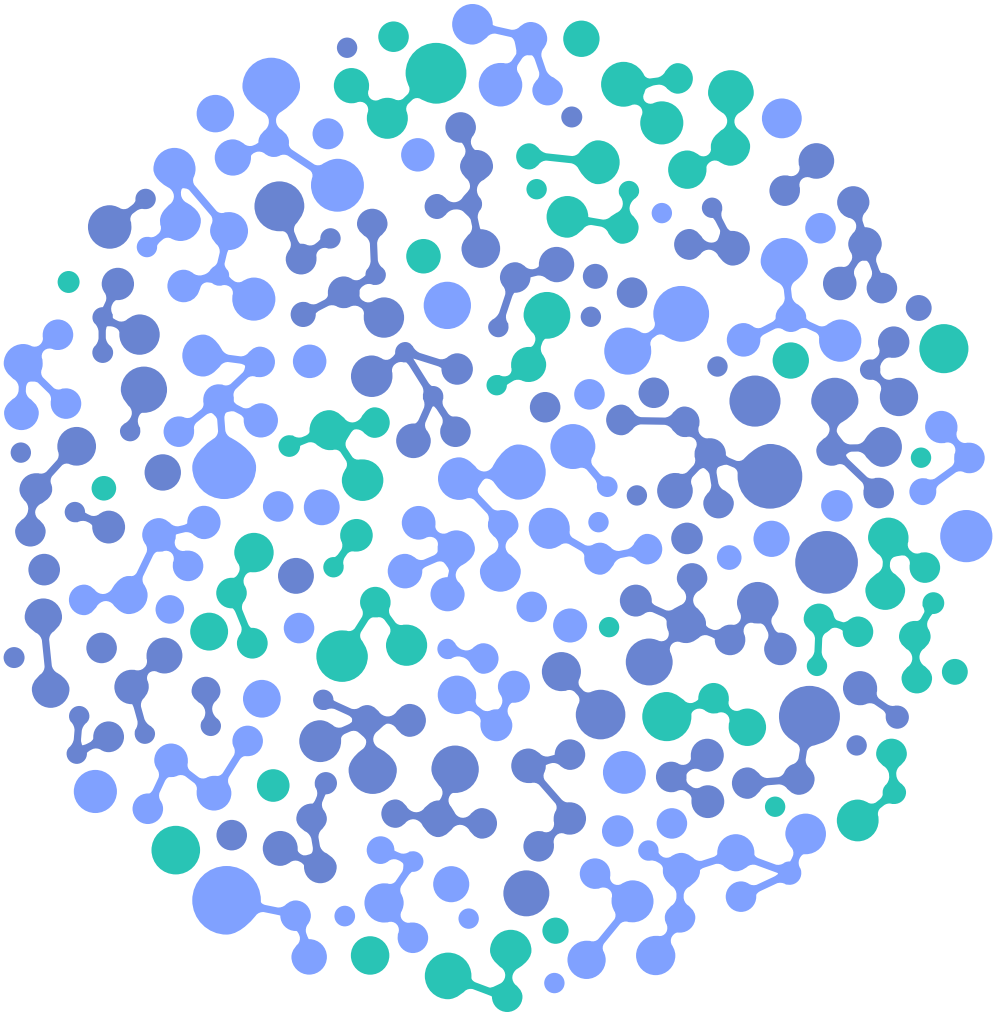

Life Sciences Industry Accounting Guide

Other Accounting and Financial Reporting Topics

March 2021

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Contracts on an Entity's Own Equity

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Current Expected Credit Losses

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Transfers and Servicing of Financial Assets

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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 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 2021 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 developments (through February 28, 2021), and key differences between U.S. GAAP and IFRS® Standards. In addition, this Guide discusses accounting and financial reporting considerations associated with the coronavirus disease 2019 ("COVID-19") pandemic that apply specifically to the life sciences industry.

Appendix B lists the titles of standards and other literature we cited, and Appendix C defines the abbreviations we used.

We hope this 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 13 — Other Accounting and Financial Reporting Topics

13.1 Government Assistance

13.1.1 Considerations Related to COVID-19

In response to the COVID-19 pandemic, domestic and international governments are considering, or may have implemented, legislation to help entities that have experienced financial difficulty associated with it. One such example is the CARES Act, which provides assistance in the form of loans, grants, tax credits, or other forms of government aid. 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 or other forms of government assistance that is 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.

13.1.1.1 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 to an entity or a 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 is adapted from ASC 958-605-15-5A and 15-6 (as amended by ASU 2018-08).

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.

(Table continued)

An Exchange Transaction May Not Exist if:	An Exchange Transaction May Exist if:
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

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).

13.1.1.2 Government Grants

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

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

In the absence of explicit guidance in U.S. GAAP for 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 Standards. As discussed further below, we understand that there may be diversity in practice.

[1] See ASC 958-605-15-6(d).

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 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 we believe that 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 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.

13.1.1.3 IAS 20 Accounting Framework

An entity that elects an IAS 20 framework to account for government grants should consider that such 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 the government grant 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).

13.1.1.3.1 Capital Grants

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

13.1.1.3.2 Income Grants

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

Connecting the Dots

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

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

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

13.1.1.4 Statement of Cash Flows

When an entity receives a capital grant, the timing of the cash payment it receives from the government for long-lived assets could affect the cash flow classification. If the entity receives the cash after it has incurred the capital costs, it would be appropriate to present the cash inflow from the government in the same category (i.e., investing) as the original payment for those long-lived assets. However, if the government provides the funds before the expenditures have been incurred, it would be appropriate for the entity to present that cash inflow as a financing activity because receiving the cash before incurring the related cost would be similar to receiving a refundable loan advance. In addition, when the entity incurs the costs in accordance with the conditions of the government grant, it should disclose the existence of a noncash financing activity resulting from the fulfillment of the grant requirements.

Similarly, if an entity receives an income grant as reimbursement for qualifying operating expenses, the grant would be presented in the statement of cash flows as an operating activity if it was received after the operating expenses were incurred. However, some entities may believe that in cases in which cash is received before the qualifying operating expenses are incurred, it would be appropriate to present the cash inflow as a financing activity for the advance (e.g., forgivable loans) in a manner consistent with the guidance above. Alternatively, others may believe that it is acceptable to present the cash inflow as an operating activity if the entity expects to comply with the terms of the grant (e.g., an advance on future payroll taxes credit) so that both the inflow and outflow are presented in the operating category.

13.1.1.5 Disclosures

Currently, there is no authoritative guidance in U.S. GAAP on disclosure requirements for government grants received by business entities, although the FASB in November 2015 issued a proposed ASU describing various disclosures that the Board considered relevant and useful to stakeholders (see Section 13.1.2 below for discussion of the proposed ASU). In the absence of authoritative guidance, we believe that it is critical for an entity to disclose its accounting policy for government grants if the amounts are material to its financial statements.

For more information and financial reporting considerations related to government assistance associated with the CARES Act, see the following Deloitte publications:

- *Financial Reporting Alert*, "Financial Reporting Considerations Related to COVID-19 and an Economic Downturn."
- *Heads Up*, "Highlights of the CARES Act."
- *Heads Up*, "Accounting and Reporting Considerations for Forgivable Loans Received by Business Entities Under the CARES Act's Paycheck Protection Program."

13.1.2 On the Horizon — Proposed ASU on Disclosures by Business Entities About Government Assistance

As noted above, in November 2015, the FASB issued a proposed ASU on disclosures about government assistance received by entities. As explained in the proposed ASU, the proposal's objective is "to increase transparency about government assistance arrangements including (1) the types of arrangements, (2) the accounting for government assistance, and (3) their effect on an entity's financial statements." Comments were due by February 10, 2016, and the Board received approximately 40 comment letters.

13.1.2.1 Background

There is no explicit guidance under current U.S. GAAP on the recognition, measurement, or disclosure of government assistance. As a result, there is diversity in practice related to how business entities account for, and disclose information about, government assistance arrangements.

The proposed ASU would apply to all entities, other than NFPs within the scope of ASC 958, that enter into a "legally enforceable agreement with a government to receive value." However, the proposed ASU states that it would not apply to transactions in which the government is either (1) "[l]egally required to provide a nondiscretionary level of assistance to an entity simply because the entity meets the applicable eligibility requirements that are broadly available without specific agreement between the entity and the government" or (2) "[s]olely a customer" of the entity.

13.1.2.2 Key Provisions

Under the proposal, entities would be required to disclose in their annual financial statements information about the nature of the assistance, related accounting policies, and the effect on the financial statements, including:

- A "general description of the significant categories (for example, grants, loans, or tax incentives) and the form in which the assistance has been received (for example, as a reduction of an expense, a refund of taxes paid, free resources, or a cash grant)."
- "The accounting policy used to account for government assistance (for example, whether assistance is recognized immediately into income or recognized over the life of a related asset)."
- The financial statement line items "affected by government assistance (for example, whether the assistance has been deducted from the carrying value of an asset or presented as a performance obligation liability) and the amounts applicable to each line item."
- "Unless impracticable, the amount of government assistance received but not recognized directly in the financial statements."

The proposed ASU would also require entities to disclose the significant terms and conditions of the agreement, including its duration or period, the tax rate or interest rate provided in the agreement, the commitments made by each party, the provisions (if any) for recapturing government assistance, and any other contingencies.

13.1.2.3 Redeliberations and Next Steps

After the comment period closed, the FASB began redeliberations on the basis of stakeholder feedback. The FASB staff plans to focus on scope, disclosure requirements for amounts not recognized directly in the financial statements, restrictions, transition and effective date, private-company considerations, and overall costs and benefits of the disclosures.

At the FASB's February 27, 2019, meeting, the Board continued its redeliberations, which involved discussion of (1) comments received from an external review of the FASB staff's draft of a final ASU and (2) next steps. As stated in the FASB's tentative Board decisions, the Board "directed the staff to conduct outreach to gain additional information about the expected costs and the expected benefits of the staff draft of a final Update." While the project continues to be listed on the FASB's active agenda, there is no scheduled date for further redeliberations.

Connecting the Dots

Entities in the life sciences industry have historically benefited domestically and internationally from a wide variety of government assistance programs. Although the scope of the FASB's project related to government assistance is limited to disclosures, the final ASU that is ultimately issued may still require significant effort to track a vast array of arrangements and provide the appropriate level of disclosure. Life sciences entities should continue to monitor the progress of the project and consider whether systems or other changes will be needed to gather the required information.

13.2 Inventory

13.2.1 On the Horizon — Proposed ASU on Disclosure Requirements for Inventory

13.2.1.1 Background

In January 2017, the FASB issued a proposed ASU that would modify or eliminate certain disclosure requirements related to inventory as well as establish new requirements. Comments on the proposed ASU were due by March 13, 2017.

The proposal is part of the FASB's disclosure framework project, which, as explained on the Board's related Project Update page, is intended "to improve the effectiveness of disclosures in notes to financial statements by facilitating clear communication of the information required by generally accepted accounting principles (GAAP) that is most important to users of each entity's financial statements."

In March 2014, the FASB issued a proposed Concepts Statement on Chapter 8 of its conceptual framework for financial reporting.[2] The Board later decided to test the proposed Concepts Statement by considering the effectiveness of financial statement disclosures related to inventory, income taxes, fair value measurements, and defined benefit pension and other postretirement plans. The proposed ASU is the result of the application of the proposed Concepts Statement to inventory. For more information about the proposed ASU, see Deloitte's January 12, 2017, *Heads Up*.

The proposed ASU notes that the objective of the inventory disclosures in ASC 330 is to give financial statement users information that would help them assess how future cash flows may be affected by:

- Different types of inventory.
- The use of differing methods to measure inventory balances.
- Transactions, events, and circumstances that are outside the entity's normal course of business.

[2] The proposed Concepts Statement was finalized in August 2018.

13.2.1.2 Key Provisions

13.2.1.2.1 Materiality

The proposed ASU notes that entities would not be required to provide inventory disclosures if such disclosures are immaterial.

13.2.1.2.2 Disclosure of Changes in Inventory

The Board considered several approaches for disclosing changes in inventory, including (1) a detailed rollforward of the inventory balance in tabular format; (2) disclosure of significant changes in the balance that are not attributable to the purchase, manufacture, and sale of inventory in the normal course of business; and (3) a hybrid approach that would combine both methods depending on the significance of an entity's inventory. Because the Board believes that the rollforward and hybrid approaches would most likely be too costly and difficult for entities to implement, the proposed ASU would require all entities to disclose significant changes in inventory resulting from transactions or events other than the purchase, manufacture, or sale of inventory in the normal course of business.

The following are examples of such changes:

- "Atypical losses from the subsequent measurement of inventory or shrinkage, spoilage, or damage and a description of the facts and circumstances leading to those losses."
- "Balance sheet reclassifications."
- "Inventory obtained through a business combination" or "disposed of through a divestiture."
- "Unrealized gains and losses for inventories recorded above cost or at selling prices."

The proposed ASU includes an illustrative example of how an entity would disclose changes in inventory.

13.2.1.2.2.1 Composition of Inventory

In addition to total inventory, the proposed ASU would require all entities to disclose the inventory's major components. That is, entities would disclose the composition of inventory such as raw materials, work in process, finished goods, and supplies. Under the proposed ASU's amendments, an entity would also be required to (1) provide "a qualitative description of the types of costs it capitalizes into inventory" and (2) the basis it uses to measure its inventory as well as the amount recorded under each basis.

Further, an entity that reports inventory on a last in, first out (LIFO) basis would be excluded from the requirement if it were to conclude that it is impracticable to allocate the LIFO reserve to inventory components. That is, an entity would be permitted to disclose inventory components under another cost basis — such as first in, first out (FIFO) — and reconcile such components to the ending aggregate LIFO inventory balance with the aggregate LIFO reserve.

13.2.1.2.2.2 Inventory Reported Under the LIFO Cost Flow Assumption

Besides adding the measurement alternative discussed above, the proposed ASU would codify LIFO-related disclosures that SEC registrants are currently required to provide. In addition, paragraph BC49 of the proposal notes that other entities include similar disclosures in their financial statements on the basis of recommendations in a 1984 AICPA Issues Paper.[3] Consequently, the Board proposes to add ASC 330-10-50-13, which would require all entities that apply the LIFO method to disclose (1) the excess of replacement cost or current cost over the reported inventory amount and (2) the effect on net income of the liquidation of a portion of an entity's LIFO inventory.

[3] AICPA Issues Paper, *Identification and Discussion of Certain Financial Accounting and Reporting Issues Concerning LIFO Inventories.*

Connecting the Dots

In the proposed ASU's Background Information, Basis for Conclusions, and Alternative Views, the FASB observed that the cost of implementing the guidance should be minimal because many entities reporting inventory under LIFO are likely to be providing the proposed disclosures already.

13.2.1.2.2.3 Other Inventory Disclosures

For entities that use standard costs to measure inventory, the proposed ASU would update ASC 330-10-30-12 to eliminate the requirement to describe the relationship between standard costs and costs computed under another recognizable inventory measurement basis. This disclosure was seen as redundant because as long as standard costs are updated at reasonable intervals, the revised standard costs should approximate another acceptable inventory measurement basis, such as FIFO or average costs.

13.2.1.2.2.4 Segment Disclosures for PBEs

For PBEs, the proposed ASU would amend ASC 280-10-50-25 to add (1) inventory disclosures by reportable segment and (2) a reference to a related example (Example 4) that would be codified in ASC 280-10-55-53 and 55-54. Specifically, if inventory balances are included in (1) the determination of segment assets that the chief operating decision maker (CODM) reviews or (2) information that the CODM regularly reviews (even if such balances are not included in the determination of segment assets), PBEs would be required to disclose the following by reportable segment:

- Total inventory.
- A disaggregation of inventory by major component (such as raw materials, work in process, finished goods, and supplies).

In addition, inventory or a major component of inventory that has not been allocated to a reportable segment would be classified as unallocated.

A PBE would also be required to provide similar disclosures in its interim financial statements if the criteria in ASC 280-10-50-25 are met (i.e., inventory balances are included in the determination of segment assets, or the CODM reviews information that includes inventory balances).

Connecting the Dots

Only the information reviewed by the CODM would need to be disclosed on an interim basis. As illustrated in Example 4 of the proposed ASU (specifically, in ASC 280-10-55-54 as proposed), if the CODM reviews inventory by segment in total but does not regularly review information about inventory for each component by segment, an entity would be required to disclose only total inventory by segment in its interim financial statements.

13.2.1.3 Scope, Transition, and Effective Date

The proposed ASU would affect only inventory disclosures under ASC 330 for all entities (i.e., the proposal would not affect disclosures related to cost of goods sold). The guidance would be applied prospectively, and the Board will determine an effective date and whether to permit early adoption after it considers feedback from stakeholders on the proposal.

Connecting the Dots

On June 21, 2017, the Board held a meeting to discuss a summary of the comments received on the proposed ASU. No decisions were made during the meeting. The Board directed the staff to conduct additional outreach and research on the proposed disclosure requirements related to changes to the inventory balance. The Board asked the staff to consider (1) the application of those proposed disclosures to companies engaged in manufacturing and wholesale businesses and (2) the needs of financial statement users in such industries. The Board also asked the staff to present a plan for redeliberations collectively with the other disclosure framework projects at a future meeting.

13.3 Common-Control Transactions

As life sciences entities seek to balance their portfolio and potentially prepare for public offerings, they may engage in 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 parent's financial statements.

For more information and interpretive guidance on common-control transactions, see Appendix B of Deloitte's *A Roadmap to Accounting for Business Combinations*.

13.4 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 a business or product line, questions often arise about whether the divested group of assets should be reported as a discontinued operation. An entity will need to use judgment when making this determination. The entity's conclusion will be based on whether the disposition represents a strategic shift to the entity and whether the disposal will have a major effect on the entity's operations and financial results.

For more information about discontinued-operations reporting, including interpretations of the accounting guidance on the topic, see Deloitte's *A Roadmap to Impairments and Disposals of Long-Lived Assets and Discontinued Operations*.

13.5 Carve-Outs

Carve-out financial statements are commonly prepared for divestments of businesses in transactions involving life sciences entities. A carve-out occurs when a parent entity segregates a portion of its operations and prepares a distinct set of financial information in preparation for a sale, spin-off, or divestiture of the "carve-out entity." 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 of those financial statements may vary, however, depending on the situation. 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. Another 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[4] 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,[5,6] would need to be available within 75 days post-closing.

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

13.5.1 Management Considerations

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

13.5.1.1 Assembling the Right Team

Involving the appropriate personnel is an integral step in planning for carve-out transactions. Management should evaluate which employees could help provide the information needed to prepare accurate and complete financial statements. Such employees may include those outside accounting (e.g., in operations or human resources). In addition, management may need to engage external specialists (e.g., tax or valuation specialists).

13.5.1.2 Materiality and Evaluating Misstatements

Because the materiality thresholds related to the carve-out financial statements will most likely be lower than those of the consolidated parent entity, management may need to assess accounts and balances of the carve-out entity more closely than it had as part of preparing the financial statements of the parent. Passed misstatements and disclosures previously considered immaterial to the parent's financial statements that are related to the carve-out entity would need to be reconsidered on the basis of materiality thresholds applicable to the carve-out financial statements. Further, the effects of transition

[4] A Form 10 is the spin-off equivalent of a Form S-1 filed by new registrants in connection with an IPO.

[5] On May 20, 2020, the SEC issued a final rule that amends the financial statement requirements for acquisitions and dispositions of businesses and related pro forma financial information. The final rule is effective for fiscal years beginning after December 31, 2020; however, early application is permitted. For an overview of reporting considerations under the new requirements for SEC registrants that enter into business acquisitions, see Appendix D of Deloitte's *A Roadmap to Accounting for Business Combinations*. For considerations related to the requirements before adoption of the final rule, see the 2020 edition of Deloitte's *A Roadmap to SEC Reporting Considerations for Business Combinations*. For additional information and interpretive guidance on SEC rules regarding business acquisitions and other SEC requirements related to business acquisitions, see Deloitte's June 2, 2020, *Heads Up*.

[6] Public buyers have to comply with SEC Regulation S-X, Rule 3-05, which requires them to provide financial statements for significant acquisitions. 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 one audited period (and potentially up to two such periods if the results of any of the tests exceed a threshold of 40 percent) will be required.

adjustments related to the adoption of new accounting standards that may have been immaterial in the parent entity's financial statements may be material in the carve-out entity's financial statements.

13.5.1.3 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 (1) modify such controls to accommodate process changes related to preparing the carve-out financial statements and (2) ensure that any other controls related to preparing the parent company financial statements are sufficiently direct and precise.

In addition to controls related to the carve-out entity, management may need to consider controls for its future status as either a public or a private company. Typically, consideration of such future controls affords management an opportunity to reevaluate the control structure to ensure that it is most efficient and effective for the new company going forward or that it aligns with the controls of a purchaser.

13.5.1.4 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 selling, general, and administrative expenses).

Management may choose to use existing accounting systems as much as possible when preparing carve-out financial statements. The use of existing accounting systems may be limited, however, 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. Multiple periods of carve-out financial statements may be required throughout the registration statement process given that financial statements may become stale. Historical periods may include additional complexities for documentation and support depending on whether historical acquisitions occurred during those periods.

13.5.1.5 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 the preparation of the carve-out financial statements. 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. Typically, the audit scope could widen and the number of audit procedures could increase if controls over the carve-out financial statements cannot be relied upon.

13.5.2 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 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.

13.5.3 "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."

The parent entity is required under ASC 205-20 to evaluate whether the effect of a disposal resulting from a carve-out transaction is to be presented as a discontinued operation. Depending on the form of the carve-out transaction, this evaluation may occur when (1) the carve-out entity meets the criteria in ASC 205-20-45-1E to be classified as held for sale, (2) the carve-out entity is disposed of by sale, or (3) the carve-out entity 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 for the parent entity to report it as a discontinued operation, 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 13.4 of this Guide and Deloitte's *A Roadmap to 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 *A Roadmap to the Preparation of the Statement of Cash Flows* for further discussion.

13.5.4 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 following carve-out financial statements may be prepared:

- *Public entity financial statements* — When carve-out financial statements are required for a registrant and its predecessor in an initial registration statement filed with the SEC as well as in Forms 10-K and 10-Q filed after the initial registration statement, such financial statements must comply with the general financial statement requirements in SEC Regulation S-X, Rules 3-01 through 3-04. Such carve-out financial statements may also be used for a significant acquired or to be acquired business in accordance with SEC Regulation S-X, Rule 3-05, in certain SEC filings.

  Abbreviated financial information may be provided for significant acquired or to be acquired businesses in accordance with Rule 3-05 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).
- *Nonpublic-entity financial statements* — Certain U.S. GAAP presentation and disclosure requirements are not applicable to nonpublic entities. In addition, nonpublic entities may elect to apply reporting alternatives developed by the Private Company Council (PCC) and subsequently endorsed by the FASB. Nonpublic-entity carve-out financial statements in which PCC accounting alternatives have been elected may be appropriate when the financial statements are not 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. Reissuance of the carve-out financial statements may require the auditor 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 financial information of the carve-out entity 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 *A Roadmap to Accounting and Financial Reporting for Carve-Out Transactions*.

13.6 Cost of Doing Business

13.6.1 Introduction

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

13.6.2 Branded Prescription Drug Fee

13.6.2.1 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.

ASU 2010-27 (codified in ASC 720-50) provides 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, the IRS issued final regulations[7] related to the BPD fee that contain a new term, "covered entity status" (see 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. Further, the 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.

13.6.2.2 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

[7] TD 9684, *Branded Prescription Drug Fee*.

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.

13.6.3 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.

13.7 Going Concern

13.7.1 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 how to determine when and how to disclose going-concern uncertainties in the financial statements. It requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable).[8] 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."

[8] 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").

13.7.2 Disclosure Threshold

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

ASC 205-40 — Glossary

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

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

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

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

a. Negative financial trends, for example, recurring operating losses, working capital deficiencies, negative cash flows from operating activities, and other adverse key financial ratios

b. Other indications of possible financial difficulties, for example, default on loans or similar agreements, arrearages in dividends, denial of usual trade credit from suppliers, a need to restructure debt to avoid default, noncompliance with statutory capital requirements, and a need to seek new sources or methods of financing or to dispose of substantial assets

c. Internal matters, for example, work stoppages or other labor difficulties, substantial dependence on the success of a particular project, uneconomic long-term commitments, and a need to significantly revise operations

d. External matters, for example, legal proceedings, legislation, or similar matters that might jeopardize the entity's ability to operate; loss of a key franchise, license, or patent; loss of a principal customer or supplier; and an uninsured or underinsured catastrophe such as a hurricane, tornado, earthquake, or flood.

13.7.3 Time Horizon

In each reporting period (including interim periods), an entity is required to assess its ability to meet its obligations as they become due for one year after the date the financial statements are issued or available to be issued.[9]

[9] See footnote 8.

13.7.4 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
• Principal conditions or events. • Management's evaluation. • Management's plans.	• Principal conditions or events. • Management's evaluation. • Management's plans. • Statement that there is "substantial doubt about the entity's ability to continue as a going concern."

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

a. It is probable that management's plans will be effectively implemented within one year after the date that the financial statements are issued.

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

13.8 Health Tech

The health tech marketplace is 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. These companies 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, 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. Health care incumbents are working to bend the cost curve and improve care quality. Many incumbents have identified consumers and the adoption of advanced technologies offered by health tech companies as part of future strategies, but there are many challenges and barriers to implementing these strategies. The gap between what health care incumbents offer today and what is likely to be required in the future has created an opening for these health tech companies.

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.

13.8.1 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. In addition, a growing number of processes are managed through the use of automated solutions. As a result of such innovations, health tech companies are incurring increasing amounts of software costs as they develop on-premise software products to be sold or marketed, or software solutions to be provided over the Internet (e.g., cloud computing or software as a service (SaaS)).

The accounting for software costs will vary depending on whether the software involved is (1) obtained or developed for internal use ("internal-use software," which includes software that will be used to provide a service), (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, an entity (i.e., the purchaser of such service) should consider the guidance in ASC 350-40-15-4A, which, before the adoption of ASU 2018-15,[10] states:

  > The guidance in 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 capitalized 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.,

[10] Because ASU 2018-15 adds guidance to ASC 350-40 on a customer's accounting for implementation costs incurred in a cloud computing arrangement that is a service contract, it amends the opening phrase of ASC 350-40-15-4A to read, "The guidance in **the General Subsections of** this Subtopic" (emphasis added). For PBEs, the ASU is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. For all other entities, the ASU is effective for annual reporting periods beginning after December 15, 2020, and interim periods within annual periods beginning after December 15, 2021. Early adoption is permitted.

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).

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 consider the guidance on capitalizing internal-use software costs.

13.8.2 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 migrating to SaaS as their preferred customer delivery mechanism as they digitize current service offerings and update current software offerings. Health tech companies often develop a SaaS platform on which they provide their services to customers via access to a digital 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 can significantly affect the timing and amount of revenue to be recognized. Entities should also consider the interpretive guidance developed by the AICPA's Software Entities Revenue Recognition Task Force, which was one of 16 AICPA industry task forces that helped develop the AICPA Audit and Accounting Guide *Revenue Recognition* (the "AICPA Revenue Guide"). The AICPA Revenue Guide contains guidelines on how entities in various industries should apply the new revenue standard. See the AICPA's Web site for status updates and further information about the software entities task force.

Example 13-1

Health tech entities may enter into revenue arrangements to develop and commercialize digital therapies that treat a specific health concern. For example, certain digital therapies may function via the collection of patient data on a mobile application (the "app"). A health tech entity hosts the data received from the app, allowing the patient's doctor to review and analyze results based on the data.

Under this type of arrangement, a health tech entity may be obligated to provide its customer with the following:

- A license to the IP necessary to commercialize the digital therapy.
- Technical development (e.g., development of the app and an online platform).
- Software hosting and support.
- Joint steering committee participation.

As discussed in Section 2.4, entities must determine whether a promise or multiple promises represent one or more performance obligations to the customer. In this type of arrangement, there can be a high degree of complexity and judgment in the determination of whether the promises are distinct and, therefore, separate performance obligations. Depending on the facts and circumstances, the license and promised services may be considered highly interrelated inputs that together provide the customer with the desired solution, which is a comprehensive digital therapy.

Identifying performance obligations in these fact patterns could be challenging. Accordingly, entities may conclude that consultation with their accounting advisers is warranted.

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. That is, an entity must determine whether it is acting as a principal or as an agent. Among the many situations in which third parties may be involved are those in which insurance claims are processed on behalf of payers or health care providers, prescriptions or other medical data are exchanged between health care providers and pharmacies, and coupons or vouchers are transferred to patients on behalf of pharmaceutical manufacturers. For an entity to determine the nature of its promise to a customer, 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. 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.

13.8.3 Costs of Obtaining a Contract

Growing 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 costs, such as travel and legal expenses, may be incurred regardless of whether a contract is obtained while other costs, such as commissions, may be incurred only when a contract is obtained. Accordingly, ASC 340-40 introduces comprehensive guidance on accounting for costs of obtaining a contract within the scope of ASC 606.

For additional information about the technical accounting topics discussed above, 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.

13.9 PCAOB Changes to the Auditor's Report — Critical Audit Matters

In June 2017, the PCAOB adopted a new auditing standard on the auditor's report (the "standard" or "release"). While retaining the current "pass/fail" opinion of the existing auditor's report, the standard includes several significant modifications, including the introduction of critical audit matters (CAMs), all of which are intended to increase the informational value, usefulness, and relevance of the auditor's report.

13.9.1 Critical Audit Matters

A CAM is defined in the standard 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."

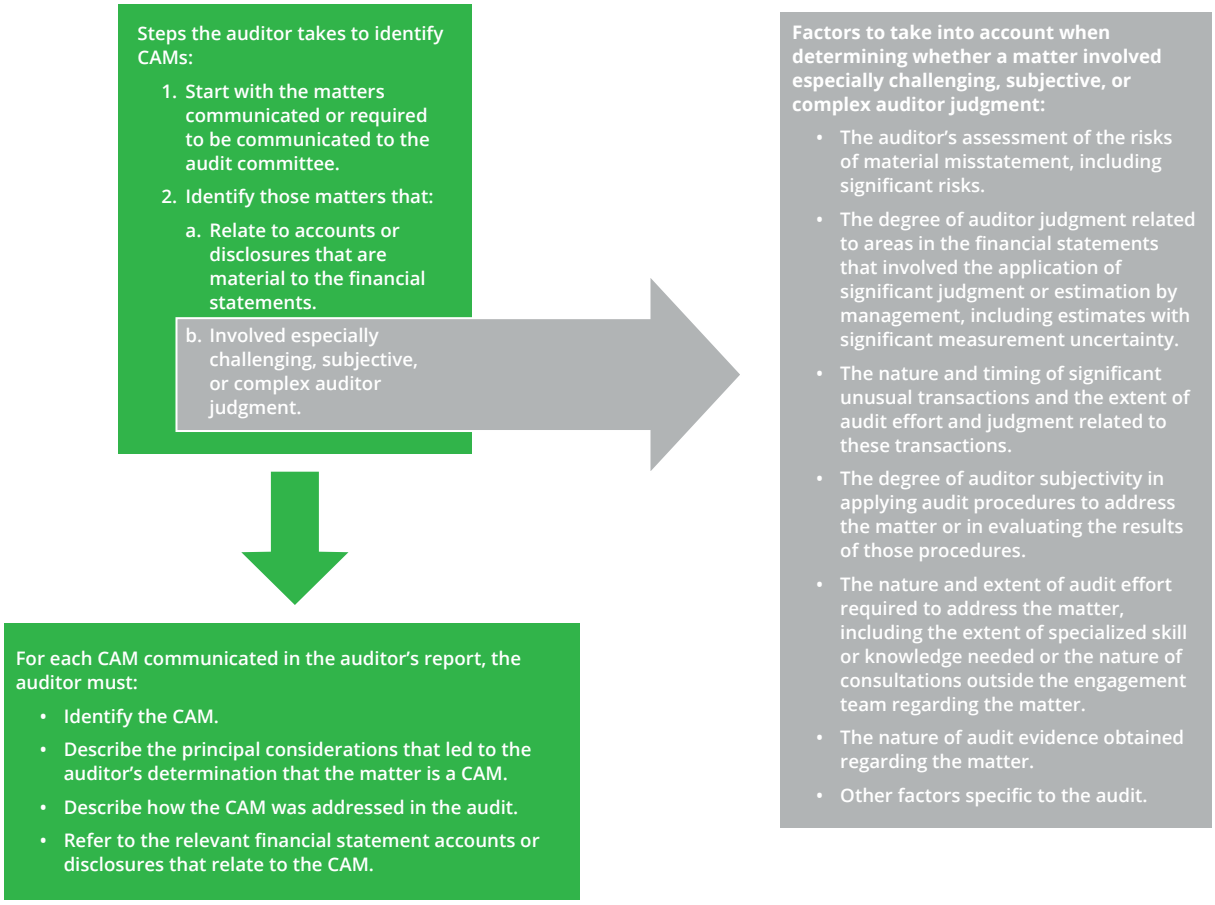
The standard includes a nonexclusive list of factors for the auditor to take into account, alone or in combination, in determining whether a matter involved especially challenging, subjective, or complex auditor judgment.

CAMs will be identified and described in a separate section in the auditor's report titled "Critical Audit Matters." Specific language will precede 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. The release states that for each CAM communicated in the auditor's report, the auditor will be 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]."

The release also states that 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 (see applicability information below), the auditor would identify at least one CAM. If no CAMs are identified, the auditor would be required to make a statement to that effect in the auditor's report.

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



13.9.2 Effective Date

The effective date for CAMs is as follows:

- *Audits of large accelerated filers (as defined by the SEC)* — Fiscal years ending on or after June 30, 2019.
- *Audits of all other companies* — Fiscal years ending on or after December 15, 2020.

However, the release states that auditors may elect to comply with the standard before its effective date.

Communication of CAMs is not required for audits of emerging growth companies as defined in Section 3(a)(80) of the Exchange Act. However, the standard permits voluntary inclusion of CAMs in the auditor's report for such entities.

13.9.3 Considerations for Auditors, Management, and Audit Committees

Auditors are encouraged to engage with management and the audit committee in advance of the related effective dates to discuss the types of matters that may be communicated as CAMs in future audit reports.

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 will the timing of auditor communications with management and the audit committee accommodate the discussion of CAMs?
- 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?
- Does management have a communications and investor relations strategy to discuss CAMs with external stakeholders?
- Is the investor relations function prepared for questions it may receive about CAMs?
- Is the company engaged in dialogue with investor analysts about the upcoming reporting of CAMs?

13.9.4 Looking Ahead

In October 2020, the PCAOB issued an interim analysis report, *Evidence on the Initial Impact of Critical Audit Matter Requirements*, which evaluates the overall effect of the CAM requirements on stakeholders in the audit process. Key findings of the report include the following:

- "Audit firms made significant investments to support initial implementation of the CAM requirements."
- "Investor awareness of CAMs communicated in the auditor's report is still developing, but some investors are reading CAMs and find the information beneficial."
- "The staff has not found evidence of significant unintended consequences from auditors' implementation of the CAM requirements for audits of [large accelerated filers] in the initial year."

The interim analysis report was accompanied by two white papers:

- *Stakeholder Outreach on the Initial Implementation of CAM Requirements*.
- *Econometric Analysis on the Initial Implementation of CAM Requirements*.

See the PCAOB's Web site for more information.

13.10 Structured Trade Payable Arrangements

To manage working capital more efficiently, life sciences companies may 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, structured trade payable arrangements offer the parties various potential benefits, such as:

- *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 agree to extended payment terms with 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 relation 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 30 days or 2/10 net 30), for instance, the intermediary may offer the 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 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 favorable 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 an amount borrowed from the intermediary may affect the appropriate cash flow classification.

In speeches at the 2003 and 2004 AICPA Conferences on Current SEC and PCAOB Developments, Robert Comerford, then professional accounting fellow in the SEC's Office of the Chief Accountant (OCA), discussed the SEC staff's views about the presentation of certain trade payable arrangements involving an intermediary as trade payables or short-term borrowings. In his 2004 speech, 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.

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.

(Table continued)

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

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

13.10.1 Disclosure Considerations

On the basis of our discussions with the SEC staff in the context of registrant preclearance processes, we understand that the staff expects an issuer to consider disclosing the following information, if material, related to trade payable arrangements involving an intermediary:

- A description of the arrangement and why the entity entered into the arrangement.
- A description of the benefits to the entity and to the entity's suppliers.
- The amount that is eligible for factoring and the amount that has been factored (if known).
- Any risks the arrangement exposes the entity to and how those risks are mitigated.

In recent comment letters to registrants, the SEC staff has expressed interest in better understanding the quantitative and qualitative characteristics of such arrangements, such as:

- The dollar amounts settled under the arrangement and the balance representative of amounts owed to the financial institution or intermediary.
- The analysis supporting classification of amounts settled under the arrangement as trade payables or bank financing, including classification and noncash disclosure considerations required by ASC 230.

- The arrangement's impact on an entity's payment terms to its suppliers, days payable outstanding, liquidity, and risk factors.

For more information, see Section 14.3.1.3 of Deloitte's *A Roadmap to the Issuer's Accounting for Debt*.

13.11 Foreign Currency Accounting Considerations

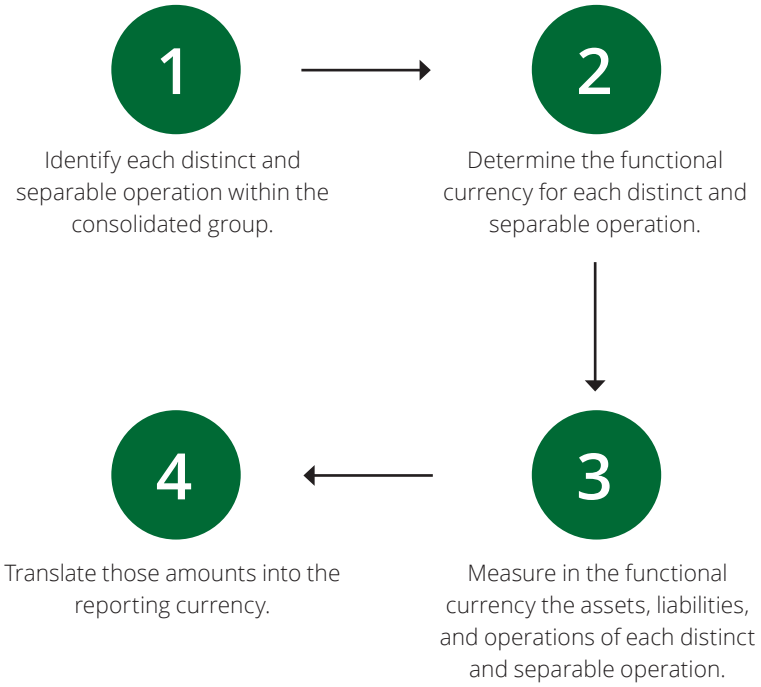
13.11.1 Overview

Since the issuance of FASB Statement 52 (codified in ASC 830) in 1981, domestic and international economies have become increasingly 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 its 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 do four things:

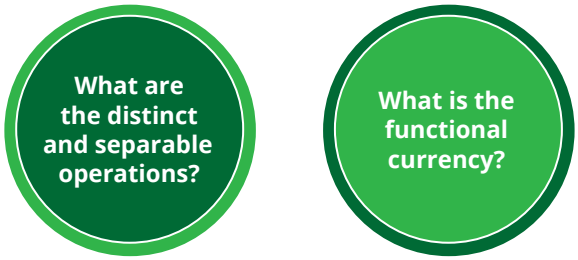


Because the functional-currency approach requires an entity to measure the assets, liabilities, and operations in the functional currency, an entity that enters into transactions in currencies other than its functional currency must first remeasure those amounts in its functional currency before they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

13.11.1.1 Decision Points



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

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

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

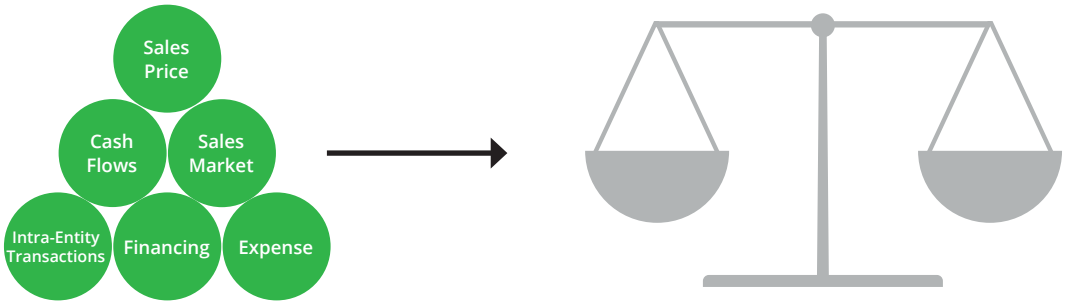
Connecting the Dots

ASC 830-10-45-5 clarifies that an entity should consider each distinct and separable operation of the reporting entity a separate "entity" when applying the requirements of ASC 830. Therefore, throughout this Guide's discussion of foreign currency accounting considerations, the terms "distinct and separable operation" and "entity" are used interchangeably.

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

13.11.2 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 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 geographical location. Therefore, an entity that is domiciled in the United States may meet the definition of a foreign entity under ASC 830. Similarly, an entity that is domiciled in a foreign country may not meet the definition of a foreign entity under ASC 830. Therefore, the reporting entity must determine the functional currency of each distinct and separable operation 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.

13.11.2.1 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 difference 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:

- An 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 *A Roadmap to Foreign Currency Transactions and Translations*.

13.11.2.2 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.

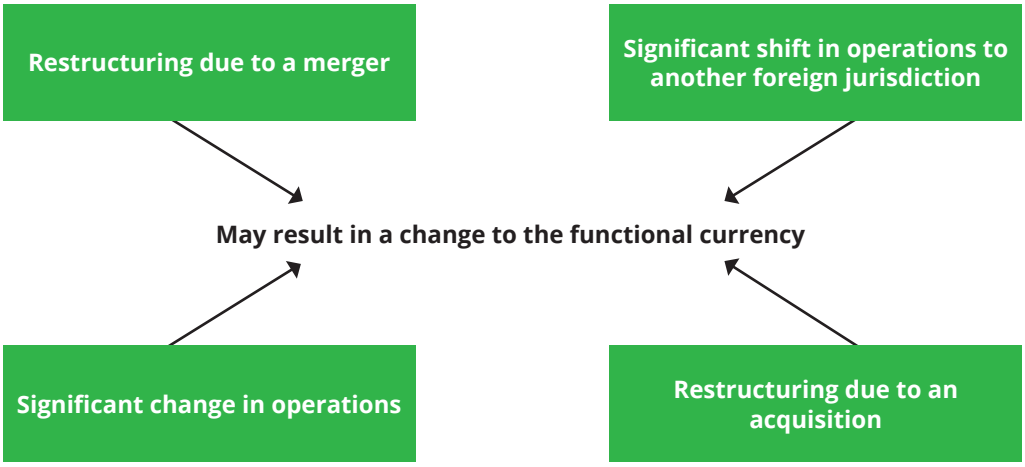
13.11.3 Change in Functional Currency

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 generally expected to be rare.

Life sciences entities that conduct business globally may have operations in highly inflationary economies. For accounting and disclosure considerations related to highly inflationary economies, see Chapter 7 and Section 9.2.3 of Deloitte's *A Roadmap to Foreign Currency Transactions and Translations*.

Connecting the Dots

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."

13.11.3.1 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.

13.11.3.2 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 *A Roadmap to Foreign Currency Transactions and Translations*.

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

Audit and Accounting Guide

Revenue Recognition

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"

Issues Papers

Identification and Discussion of Certain Financial Accounting and Reporting Issues Concerning LIFO Inventories

86-2, *Accounting for Options*

Other

AICPA Technical Q&A Section 2260.03, "Other Assets; Legal Expenses Incurred to Defend Patent Infringement Suit"

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 and Equity 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*

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Appendix C — Abbreviations

Abbreviation	Description
AETR	annual effective tax rate
AFS	available for sale
AICPA	American Institute of Certified Public Accountants
AMT	alternative minimum tax
API	active pharmaceutical ingredient
APIC	additional paid-in capital
ASC	FASB Accounting Standards Codification
ASR	accelerated share repurchase
ASU	FASB Accounting Standards Update
BCF	beneficial conversion feature
BEAT	base erosion anti-abuse tax
BEMTA	base erosion minimum tax amount
BPD	branded prescription drug
CAM	critical audit matter
CCF	cash conversion feature
CECL	current expected credit loss
CFC	controlled foreign corporation
CFR	Code of Federal Regulations
CMO	contract manufacturing organization
CODM	chief operating decision maker
CRO	contract research organization
DTA	deferred tax asset
DTL	deferred tax liability
EBITDA	earnings before interest, taxes, depreciation, and amortization
ED	exposure draft

Abbreviation	Description
EDGAR	SEC electronic data gathering, analysis, and retrieval system
EGC	emerging growth company
EITF	Emerging Issues Task Force
EPS	earnings per share
ESPP	employee stock purchase plan
EU	European Union
EUR	euros
FASB	Financial Accounting Standards Board
FDA	Food and Drug Administration
FDII	foreign derived intangible income
FIFO	first in, first out
FIN	FASB Interpretation
FOB	free on board
FRM	SEC Division of Corporation Finance Financial Reporting Manual
FVTOCI	fair value through other comprehensive income
GAAP	generally accepted accounting principles
GILTI	global intangible low-taxed income
GPO	group purchasing organization
HFI	held for investment
HFS	held for sale
IAS	International Accounting Standard
IASB	International Accounting Standards Board
IBNR	incurred but not reported

Abbreviation	Description
IFRS	International Financial Reporting Standard
IIR	investigator-initiated research
IP	intellectual property
IPO	initial public offering
IPR&D	in-process research and development
IRC	Internal Revenue Code
IRS	Internal Revenue Service
ISO	incentive stock option
IT	information technology
LCD	liquid-crystal display
LIBOR	London Interbank Offered Rate
LIFO	last in, first out
M&A	merger and acquisition
MD&A	Management's Discussion & Analysis
MSL	medical science liaison
NFP	not-for-profit entity
NOL	net operating loss
NQSO	nonqualified stock option
NSO	nonstatutory option
OCA	SEC's Office of the Chief Accountant
OCI	other comprehensive income
OECD	Organisation for Economic Co-operation and Development
OEM	original equipment manufacturer
PBE	public business entity
PCAOB	Public Company Accounting Oversight Board

Abbreviation	Description
PCC	Private Company Council
PP&E	property, plant, and equipment
PRV	priority review voucher
PTRS	probability of technical and regulatory success
Q&A	question and answer
QIP	qualified improvement property
R&D	research and development
R&E	research and experimentation
REMS	risk evaluation and mitigation strategy
ROU	right of use
SaaS	software as a service
SAB	Staff Accounting Bulletin
SEC	Securities and Exchange Commission
SME	small to medium-sized entity
SPAC	special-purpose acquisition company
SPPI	solely payments of principal and interest
SRC	smaller reporting entity
S&P 500	Standard & Poor's 500 Index
TD	Treasury Decision
TRG	transition resource group
USD	U.S. dollars
UTB	unrecognized tax benefit
VIE	variable interest entity
VWAP	volume-weighted average daily market price

The following is a list of short references for the Acts mentioned in this Guide:

Abbreviation	Act
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
Exchange Act	Securities Exchange Act of 1934
FAST Act	Fixing America's Surface Transportation Act
JOBS Act	Jumpstart Our Business Startups Act
Securities Act	Securities Act of 1933
2017 Act	Tax Cuts and Jobs Act of 2017