Life Sciences Industry Accounting Guide
Other Accounting and Financial Reporting Topics
March 2020
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- Noncontrolling Interests
- Non-GAAP Financial Measures
- Revenue Recognition
- SEC Comment Letter Considerations, Including Industry Insights
- Segment Reporting
- Share-Based Payment Awards
- Statement of Cash Flows
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About Deloitte’s Life Sciences and Health Care Practice

Deloitte and its subsidiaries have approximately 312,000 professionals with a single focus: serving our clients and helping them solve their toughest problems. Deloitte’s Life Sciences and Health Care practice is among the largest in the world, leveraging the extensive knowledge, skills, and experience of over 24,000 professionals in 90 countries. Our practice offers a distinctive menu of professional services delivered in an integrated approach that address all segments of the life sciences and health care industry. We work in four key business areas — audit, advisory, tax, and consulting — but our real strength comes from combining the talents of those groups to address clients’ needs. *Bloomberg Businessweek* and *Fortune* consistently rank our organization among the best places in which to work, which is good news for our talent and our clients alike. When the best people tackle the most compelling challenges, everyone wins.

If you have any questions about this publication or ways in which we can help your organization, please contact the following Deloitte industry specialists.

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Preface

March 2020

To our clients, colleagues, and other friends:

The life sciences ecosystem encompasses a vast array of entities that discover, develop, and manufacture health care products. Such entities include pharmaceutical manufacturers; biotechnology companies; medical device, diagnostic, and medical 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 2020 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, 2020), and key differences between U.S. GAAP and IFRS Standards. In addition, this Guide discusses the outlook for the life sciences industry in 2020. Further, while many of the key accounting and financial reporting considerations stemming from the coronavirus disease 2019 (COVID-19) outbreak are related to topics addressed in this Guide, we encourage you to review Deloitte’s March 25, 2020, Financial Reporting Alert, which discusses accounting and financial reporting considerations associated with COVID-19 that are broadly applicable as well as those 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.

This Guide is available on the Deloitte Accounting Research Tool (DART).

We hope this Guide helps you navigate the various accounting and reporting challenges you face. We encourage you to contact your Deloitte team for additional information and assistance.

Sincerely,

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Chapter 13 — Other Accounting and Financial Reporting Topics

13.1 Government Assistance

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

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.

13.1.1.1 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.

13.1.1.2 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.

13.1.1.3 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.”

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.1 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.

1 The proposed Concepts Statement was finalized in August 2018.
Connecting the Dots
Also as part of its disclosure framework project, the FASB proposed guidance in July 2016 that would amend disclosure requirements related to income taxes. See Deloitte’s July 29, 2016, Heads Up for more information. Further, in August 2018, the FASB issued ASUs 2018-13 and 2018-14, which amend the disclosure requirements related to fair value measurements and defined benefit pension and other postretirement plans, respectively. See Deloitte’s August 29 and August 31, 2018, Heads Up newsletters for more information.

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.

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. For guidance on making that determination, the proposed ASU refers entities to ASC 235-10-50-7 through 50-9, which would be added by the FASB’s proposed ASU on assessing whether disclosures are material. For additional information about the proposed ASU on materiality, see Deloitte’s September 28, 2015, Heads Up and its November 13, 2017, journal entry.

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 January 2017 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. 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.

Connecting the Dots

In the proposed ASU’s Basis for Conclusions, the FASB observed that the cost to implement 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.

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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 a variety of common-control transactions. A common-control transaction is a transfer of net assets or an exchange of equity interests between entities under the control of the same parent. Such a transaction is similar to a business combination for the entity that receives the net assets or equity interests; however, the transaction does not meet the definition of a business combination because there is no change in control over the net assets by the parent. 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 the receiving entity to 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 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 three 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\(^3\) 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,\(^4\) 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.

### 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 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.

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\(^{3}\) A Form 10 is the spin-off equivalent of a Form S-1 filed by new registrants in connection with an IPO.

\(^{4}\) 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. If the results of any of those tests exceed a threshold of 20 percent, at least one audited period (and potentially up to three such periods if the results of any of the tests exceed a threshold of 50 percent) will be required.
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 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.

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 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:

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**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.

**Analysis.** Entity A is a covered entity beginning in 2011 because it had gross receipts from branded prescription drug sales in 2011. For the 2011 fee year, Entity A does not owe a fee because the 2011 fee is based on sales data from the 2009 sales year. For the 2012 fee year, Entity A does not owe a fee because the 2012 fee is based on sales data from the 2010 sales year. Entity A continues to be a covered entity for the 2012 fee year because its branded prescription drug sales from the 2011 sales year have not yet been taken into account as described in §51.5(c) and used to calculate the adjustment amount described in §51.5(e). For the 2013 fee year, Entity A continues to be a covered entity because a portion of its branded prescription drug sales from the 2011 sales year are taken into account as described in §51.5(c) for purposes of computing the 2013 fee. For the 2013 fee year, Entity A is also liable for the adjustment amount described in §51.5(e) for the difference between its 2012 fee computed using sales data from the 2010 sales year, which is $0, and what the 2012 fee would have been using sales data from the 2011 sales year. For the 2014 fee year, Entity A continues to be a covered entity because a portion of its branded prescription drug sales for the 2011 sales year are used to calculate the adjustment amount described in §51.5(e). Therefore, for the 2014 fee year, Entity A will receive an adjustment amount for the difference between its 2013 fee computed using sales data from the 2011 sales year, and what the 2013 fee would have been using sales data from the 2012 sales year, which is $0. After the 2014 fee year, there are no remaining branded prescription drug sales to be taken into account as described in §51.5(c) or used to calculate the adjustment amount described in §51.5(e) for Entity A. Accordingly, Entity A is not a covered entity after the 2014 fee year.

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5. TD 9684, Branded Prescription Drug Fee.
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.

ASU 2014-15 (the “going-concern standard,” codified in ASC 205-40) provides guidance on how to determine when and how to disclose going-concern uncertainties in the financial statements. The going-concern standard 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). Under the standard, an entity must provide certain disclosures if conditions or events “raise substantial doubt about the entity’s ability to continue as a going concern.”

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 the going-concern standard defines as follows:

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.

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6 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 the going-concern standard’s definition of the term “financial statements are available to be issued”).
The going-concern standard 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.\(^7\)

### 13.7.4 Disclosure Content

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

<table>
<thead>
<tr>
<th>Substantial Doubt Is Raised but Is Alleviated by Management’s Plans</th>
<th>Substantial Doubt Is Raised and Is Not Alleviated</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Principal conditions or events.</td>
<td>• Principal conditions or events.</td>
</tr>
<tr>
<td>• Management’s evaluation.</td>
<td>• Management’s evaluation.</td>
</tr>
<tr>
<td>• Management’s plans.</td>
<td>• Management’s plans.</td>
</tr>
<tr>
<td></td>
<td>• Statement that there is “substantial doubt about the entity’s ability to continue as a going concern.”</td>
</tr>
</tbody>
</table>

The going-concern standard 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 going-concern standard states that 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 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.

\(^7\) See footnote 6.
Chapter 13 — Other Accounting and Financial Reporting Topics

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 stakeholders across all of the traditional sectors in the life sciences and health care industry. 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 AI, and Web-based simulation for R&D.

Health tech entities are disrupting long-standing business models and methods of health care delivery as well as sources of health information and ways to access it. The interconnectedness of that ecosystem — its strength driven in part by technology — is increasingly likely to become a key factor affecting operational and financial performance of the industry as a whole. In addition, upstarts can be expected to appear wherever there is friction in the health care ecosystem. The disruption caused by technology-driven entrants to the health care industry appears to be creating significant opportunities for incumbents to reinvent themselves, for entrepreneurs and investors to carve out new spaces in the market, and for nontraditional companies to enter the space and grow. As a result, well-funded health tech companies continue to emerge, fueled by the expanding flow of private equity, strategic, and venture capital funding.

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

Capitalized software is disaggregated by type of software as follows:

- **Internal-use** — 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.

  These considerations are also relevant to software as a service (SaaS) and could apply to hosted software. 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 states:

  The guidance in [ASC 350-40] 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 any criterion in ASC 350-40-15-4A is not met, the software is considered part of a hosting arrangement that is a service contract.

- **External-use** — 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. ASC 350-40 excludes from its scope 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 entities 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, application of the guidance on capitalization of internal-use software costs could be punitive 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.

### 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.

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.
**Example 13-1 (continued)**

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.

For additional information about the technical accounting topics discussed above, see the inaugural edition of Deloitte’s *Health Tech Industry Accounting Guide*, which is aimed at providing in-depth information on these topics for our clients and industry professionals.

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**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

The PCAOB has indicated that as the initial implementation of CAMs begins, the Board will assess stakeholders’ experiences and results and determine whether to take further action. It is imperative that auditors, management, and audit committees maintain a dialogue on the identification and communication of CAMs to ensure compliance with this significant new requirement.
Appendix B — Titles of Standards and Other Literature

The following are the titles of standards and other literature mentioned in this Guide:

**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

**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 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
Appendix B — Titles of Standards and Other Literature

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
ASC 360, Property, Plant, and Equipment
ASC 405, Liabilities
ASC 410, Asset Retirement and Environmental Obligations
ASC 420, Exit or Disposal Cost Obligations
ASC 450, Contingencies
ASC 460, Guarantees
ASC 470, Debt
ASC 480, Distinguishing Liabilities From Equity
ASC 505, Equity
ASC 605, Revenue Recognition
ASC 606, Revenue From Contracts With Customers
ASC 610, Other Income
ASC 705, Cost of Sales and Services
ASC 710, Compensation — General
ASC 712, Compensation — Nonretirement Postemployment Benefits
ASC 715, Compensation — Retirement Benefits
ASC 718, Compensation — Stock Compensation
ASC 720, Other Expenses
ASC 730, Research and Development
ASC 740, Income Taxes
ASC 805, Business Combinations
ASC 808, Collaborative Arrangements
ASC 810, Consolidation
ASC 815, Derivatives and Hedging
ASC 835, Financial Instruments
ASC 840, Leases
ASC 842, Leases
ASC 845, Nonmonetary Transactions
ASC 860, Transfers and Servicing
ASC 915, Development Stage Entities
ASC 930, Extractive Activities — Mining
ASC 942, Financial Services — Depository and Lending
ASC 944, Financial Services — Insurance
ASC 946, Financial Services — Investment Companies
ASC 948, Financial Services — Mortgage Banking
ASC 954, Health Care Entities
ASC 958, Not-for-Profit Entities
ASC 960, Plan Accounting — Defined Benefit Pension Plans
ASC 985, Software

**ASUs**

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

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

ASU 2014-02, Intangibles — Goodwill and Other (Topic 350): Accounting for Goodwill — a consensus of the Private Company Council

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

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

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

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

ASU 2015-14, Revenue From Contracts With Customers (Topic 606): Deferral of the Effective Date

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


ASU 2016-02, Leases (Topic 842)
ASU 2016-08, Revenue From Contracts With Customers (Topic 606): Principal Versus Agent Considerations (Reporting Revenue Gross Versus Net)

ASU 2016-09, Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting

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

ASU 2016-11, Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting

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

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


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

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


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

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

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

ASU 2017-05, Other Income — Gains and Losses From the Derecognition of Nonfinancial Assets (Subtopic 610-20): Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets

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

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

ASU 2017-13, Revenue Recognition (Topic 605), Revenue From Contracts With Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842): Amendments to SEC Paragraphs Pursuant to the Staff Announcement at the July 20, 2017 EITF Meeting and Rescission of Prior SEC Staff Announcements and Observer Comments (SEC Update)

ASU 2017-14, Income Statement — Reporting Comprehensive Income (Topic 220), Revenue Recognition (Topic 605), and Revenue From Contracts With Customers (Topic 606) (SEC Update)

ASU 2018-01, Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842

ASU 2018-07, Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting

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

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

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


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

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

ASU 2018-20, Leases (Topic 842): Narrow-Scope Improvements for Lessor

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

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

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

ASU 2019-08, Compensation — Stock Compensation (Topic 718) and Revenue From Contracts With Customers (Topic 606): Codification Improvements — Share-Based Consideration Payable to a Customer

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

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

ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes

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

Concepts Statements

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

No. 6, Elements of Financial Statements

No. 8, Conceptual Framework for Financial Reporting — Chapter 8, Notes to Financial Statements
Appendix B — Titles of Standards and Other Literature

**Proposed ASUs**

No. 2015-310, Notes to Financial Statements (Topic 235): Assessing Whether Disclosures Are Material

No. 2015-340, Government Assistance (Topic 832): Disclosures by Business Entities About Government Assistance

No. 2017-200, Debt (Topic 470): Simplifying the Classification of Debt in a Classified Balance Sheet (Current Versus Noncurrent)

No. 2017-210, Inventory (Topic 330): Disclosure Framework — Changes to the Disclosure Requirements for Inventory

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


No. 2019-730, Debt — Debt With Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity

No. 2019-770, Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting


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

**Other FASB Proposal**


**International Standards**

IFRS 2, Share-Based Payment

IFRS 3, Business Combinations

IFRS 5, Non-Current Assets Held for Sale and Discontinued Operations

IFRS 9, Financial Statements

IFRS 10, Consolidated Financial Statements

IFRS 11, Joint Arrangements

IFRS 12, Disclosure of Interests in Other Entities

IFRS 15, Revenue From Contracts With Customers

IFRS 16, Leases

IAS 1 (Revised 2007), Presentation of Financial Statements

IAS 7, Statement of Cash Flows

IAS 10, Events After the Reporting Period

IAS 12, Income Taxes
IAS 17, Leases
IAS 20, Accounting for Government Grants and Disclosure of Government Assistance
IAS 27 (Revised 2011), Separate Financial Statements
IAS 32, Financial Instruments: Presentation
IAS 37, Provisions, Contingent Liabilities and Contingent Assets
IAS 38, Intangible Assets
IAS 40, Investment Property

IRC
Section 78, “Gross Up for Deemed Paid Foreign Tax Credit”
Section 163(j), “Interest; Limitation on Business Interest”
Section 199, “Income Attributable to Domestic Production Activities”
Section 382, “Limitation on Net Operating Loss Carryforwards and Certain Built-In Losses Following Ownership Change”
Section 383, “Special Limitations on Certain Excess Credits, etc.”
Section 409A “Inclusion in Gross Income of Deferred Compensation Under Nonqualified Deferred Compensation Plans”
Section 422, “Incentive Stock Options”
Section 423, “Employee Stock Purchase Plans”

PCAOB Literature

SEC Literature
FRM
Topic 1, “Registrant’s Financial Information”
Topic 2, “Other Financial Statements Required”
Topic 3, “Pro Forma Financial Information”
Topic 5, “Smaller Reporting Companies”
Topic 7, “Related Party Matters”
Topic 9, “Management’s Discussion and Analysis of Financial Position and Results of Operations (MD&A)”
Topic 10, “Emerging Growth Companies”

Interpretive Release
33-10403, Updates to Commission Guidance Regarding Accounting for Sales of Vaccines and Bioterror Countermeasures to the Federal Government for Placement Into the Pediatric Vaccine Stockpile or the Strategic National Stockpile
Proposed Rule Release
No. 33-10635, *Amendments to Financial Disclosures About Acquired and Disposed Businesses*

**Regulation S-K**
Item 101, “Description of Business”
Item 103, “Business; Legal Proceedings”
Item 201, “Market Price of and Dividends on the Registrant’s Common Equity and Related Stockholder Matters”
Item 301, “Selected Financial Data”
Item 302, “Supplementary Financial Information”
Item 303, “Management’s Discussion and Analysis of Financial Condition and Results of Operations”
Item 305, “Quantitative and Qualitative Disclosures About Market Risk”
Item 402, “Executive Compensation”
Item 404, “Transactions With Related Persons, Promoters and Certain Control Persons”
Item 407, “Corporate Governance”
Item 503, “Prospectus Summary”
Item 601, “Exhibits”

**Regulation S-X**
Rule 1-02(w), “Definitions of Terms Used in Regulation S-X (17 CFR part 210); Significant Subsidiary”
Article 2, “Qualifications and Reports of Accountants”
Rule 3-02, “Consolidated Statements of Comprehensive Income and Cash Flows”
Rule 3-05, “Financial Statements of Businesses Acquired or to Be Acquired”
Rule 3-09, “Separate Financial Statements of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons”
Rule 3-10, “Financial Statements of Guarantors and Issuers of Guaranteed Securities Registered or Being Registered”
Rule 3-14, “Special Instructions for Real Estate Operations to Be Acquired”
Rule 3-16, “Financial Statements of Affiliates Whose Securities Collateralize an Issue Registered or Being Registered”
Rule 4-08(g), “General Notes to Financial Statements: Summarized Financial Information of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons”
Rule 4-08(h), “General Notes to Financial Statements: Income Tax Expense”
Rule 4-08(n), “Accounting Policies for Certain Derivative Instruments”
Article 8, “Financial Statements of Smaller Reporting Companies”
Rule 10-01(b), “Interim Financial Statements: Other Instructions as to Content”
Article 11, “Pro Forma Financial Information”
Rule 11-01 “Presentation Requirements”

**SAB Topics**
No. 1.M, “Financial Statements; Materiality”
No. 5.A, “Expenses of Offering”
No. 5.Y, “Miscellaneous Accounting; Accounting and Disclosures Relating to Loss Contingencies”
No 11.A, “Miscellaneous Disclosure; Operating-Differential Subsidies”
No. 13, “Revenue Recognition”
No. 14.B, “Share-Based Payment; Transition From Nonpublic to Public Entity Status”
No. 14.D.1, “Certain Assumptions Used in Valuation Methods; Expected Volatility”
SAB 116, “Staff Accounting Bulletin No. 116”

**SEC Securities Act of 1933 General Rules and Regulations**
Rule 144, “Persons Deemed Not to be Engaged in a Distribution and Therefore Not Underwriters — General Guidance”

**Superseded Literature**

**EITF Issues**
Issue 00-21, “Revenue Arrangements With Multiple Deliverables”
Issue 01-10, “Accounting for the Impact of the Terrorist Attacks of September 11, 2001”
Issue 02-16, “Accounting by a Customer (Including a Reseller) for Certain Consideration Received From a Vendor”
Issue 01-8, “Determining Whether an Arrangement Contains a Lease”
Issue 08-6, “Equity Method Investment Accounting Considerations”
Issue 09-2, “Research and Development Assets Acquired in an Asset Acquisition”
Issue 09-4, “Seller Accounting for Contingent Consideration”

**FASB Interpretations**
No. 47, *Accounting for Conditional Asset Retirement Obligations* — an interpretation of FASB Statement No. 143
No. 48, *Accounting for Uncertainty in Income Taxes* — an interpretation of FASB Statement No. 109
**FASB Statements**

No. 5, *Accounting for Contingencies*

No. 95, *Statement of Cash Flows*

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

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

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

No. 141, *Business Combinations*

No. 141(R), *Business Combinations*

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

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>ABO</td>
<td>accumulated benefit obligation</td>
</tr>
<tr>
<td>AFS</td>
<td>available for sale</td>
</tr>
<tr>
<td>AI</td>
<td>artificial intelligence</td>
</tr>
<tr>
<td>AICPA</td>
<td>American Institute of Certified Public Accountants</td>
</tr>
<tr>
<td>AMT</td>
<td>alternative minimum tax</td>
</tr>
<tr>
<td>API</td>
<td>active pharmaceutical ingredient</td>
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<tr>
<td>APIC</td>
<td>additional paid-in capital</td>
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<tr>
<td>ASC</td>
<td>FASB Accounting Standards Codification</td>
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<tr>
<td>ASR</td>
<td>accelerated share repurchase</td>
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<tr>
<td>ASU</td>
<td>FASB Accounting Standards Update</td>
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<tr>
<td>BCF</td>
<td>beneficial conversion feature</td>
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<td>BEAT</td>
<td>base erosion anti-abuse tax</td>
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<td>BEMTA</td>
<td>base erosion minimum tax amount</td>
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<tr>
<td>BPD</td>
<td>branded prescription drug</td>
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<tr>
<td>CAGR</td>
<td>compound annual growth rate</td>
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<tr>
<td>CAM</td>
<td>critical audit matter</td>
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<tr>
<td>CCF</td>
<td>cash conversion feature</td>
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<tr>
<td>CECL</td>
<td>current expected credit loss</td>
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<td>CFC</td>
<td>controlled foreign corporation</td>
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<td>CFR</td>
<td>Code of Federal Regulations</td>
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<tr>
<td>CMO</td>
<td>contract manufacturing organization</td>
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<tr>
<td>CODM</td>
<td>chief operating decision maker</td>
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<td>CRO</td>
<td>contract research organization</td>
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<tr>
<td>CSR</td>
<td>corporate social responsibility</td>
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<tr>
<td>DTA</td>
<td>deferred tax asset</td>
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<tr>
<td>DTL</td>
<td>deferred tax liability</td>
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<tr>
<td>EBITDA</td>
<td>earnings before interest, taxes, depreciation, and amortization</td>
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<tr>
<td>ED</td>
<td>exposure draft</td>
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<tr>
<td>EDGAR</td>
<td>SEC electronic data gathering, analysis, and retrieval system</td>
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<td>EGC</td>
<td>emerging growth company</td>
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<td>EITF</td>
<td>Emerging Issues Task Force</td>
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<td>ESPP</td>
<td>employee stock purchase plan</td>
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<td>EU</td>
<td>European Union</td>
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<tr>
<td>FASB</td>
<td>Financial Accounting Standards Board</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>FDII</td>
<td>foreign derived intangible income</td>
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<tr>
<td>FIFO</td>
<td>first in, first out</td>
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<tr>
<td>FIN</td>
<td>FASB Interpretation</td>
</tr>
<tr>
<td>FOB</td>
<td>free on board</td>
</tr>
<tr>
<td>FRM</td>
<td>SEC Division of Corporation Finance Financial Reporting Manual</td>
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<tr>
<td>FVTOCI</td>
<td>fair value through other comprehensive income</td>
</tr>
<tr>
<td>GAAP</td>
<td>generally accepted accounting principles</td>
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<tr>
<td>GILTI</td>
<td>global intangible low-taxed income</td>
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<tr>
<td>GPO</td>
<td>group purchasing organization</td>
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<td>HFI</td>
<td>held for investment</td>
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<tr>
<td>HFS</td>
<td>held for sale</td>
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<td>IAS</td>
<td>International Accounting Standard</td>
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<td>IASB</td>
<td>International Accounting Standards Board</td>
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<td>IFRIC</td>
<td>IFRS Interpretations Committee</td>
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<td>Abbreviation</td>
<td>Description</td>
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<td>--------------</td>
<td>--------------------------------------------------</td>
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<tr>
<td>IFRS</td>
<td>International Financial Reporting Standard</td>
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<tr>
<td>IIR</td>
<td>investigator-initiated research</td>
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<tr>
<td>IP</td>
<td>intellectual property</td>
</tr>
<tr>
<td>IPO</td>
<td>initial public offering</td>
</tr>
<tr>
<td>IPR&amp;D</td>
<td>in-process research and development</td>
</tr>
<tr>
<td>IRC</td>
<td>Internal Revenue Code</td>
</tr>
<tr>
<td>IRS</td>
<td>Internal Revenue Service</td>
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<tr>
<td>ISO</td>
<td>incentive stock option</td>
</tr>
<tr>
<td>IT</td>
<td>information technology</td>
</tr>
<tr>
<td>LCD</td>
<td>liquid-crystal display</td>
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<tr>
<td>LIBOR</td>
<td>London Interbank Offered Rate</td>
</tr>
<tr>
<td>LIFO</td>
<td>last in, first out</td>
</tr>
<tr>
<td>LLC</td>
<td>limited liability company</td>
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<tr>
<td>M&amp;A</td>
<td>merger and acquisition</td>
</tr>
<tr>
<td>MD&amp;A</td>
<td>Management’s Discussion &amp; Analysis</td>
</tr>
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<td>MSL</td>
<td>medical science liaison</td>
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<tr>
<td>NFP</td>
<td>not-for-profit entity</td>
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<tr>
<td>NOL</td>
<td>net operating loss</td>
</tr>
<tr>
<td>NQSO</td>
<td>non-qualified stock option</td>
</tr>
<tr>
<td>NSO</td>
<td>nonstatutory option</td>
</tr>
<tr>
<td>OCI</td>
<td>other comprehensive income</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
</tr>
<tr>
<td>OEM</td>
<td>original equipment manufacturer</td>
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<tr>
<td>PBE</td>
<td>public business entity</td>
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<tr>
<td>PBO</td>
<td>projected benefit obligation</td>
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<tr>
<td>PCAOB</td>
<td>Public Company Accounting Oversight Board</td>
</tr>
<tr>
<td>PCC</td>
<td>Private Company Council</td>
</tr>
<tr>
<td>PP&amp;E</td>
<td>property, plant, and equipment</td>
</tr>
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<td>PRV</td>
<td>priority review voucher</td>
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<tr>
<td>PRS</td>
<td>probability of technical and regulatory success</td>
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<tr>
<td>Q&amp;A</td>
<td>question and answer</td>
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<tr>
<td>R&amp;D</td>
<td>research and development</td>
</tr>
<tr>
<td>R&amp;E</td>
<td>research and experimentation</td>
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<tr>
<td>REMS</td>
<td>risk evaluation and mitigation strategy</td>
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<td>ROC</td>
<td>return on capital</td>
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<td>ROU</td>
<td>right of use</td>
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<tr>
<td>SaaS</td>
<td>software as a service</td>
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<tr>
<td>SAB</td>
<td>Staff Accounting Bulletin</td>
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<tr>
<td>SEC</td>
<td>Securities and Exchange Commission</td>
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<tr>
<td>SME</td>
<td>small to medium-sized entity</td>
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<tr>
<td>SPPI</td>
<td>solely payments of principal and interest</td>
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<tr>
<td>SRC</td>
<td>smaller reporting entity</td>
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<tr>
<td>S&amp;P 500</td>
<td>Standard &amp; Poor’s 500 Index</td>
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<tr>
<td>TD</td>
<td>Treasury Decision</td>
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<tr>
<td>TRG</td>
<td>transition resource group</td>
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<tr>
<td>UTB</td>
<td>unrecognized tax benefit</td>
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<tr>
<td>VIE</td>
<td>variable interest entity</td>
</tr>
<tr>
<td>VWAP</td>
<td>volume-weighted average daily market price</td>
</tr>
</tbody>
</table>
The following is a list of short references for the Acts mentioned in this Guide:

<table>
<thead>
<tr>
<th>Abbreviation</th>
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<tr>
<td>FAST Act</td>
<td>Fixing America's Surface Transportation Act</td>
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<td>JOBS Act</td>
<td>Jumpstart Our Business Startups Act</td>
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<tr>
<td>Securities Act</td>
<td>Securities Act of 1933</td>
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<td>TCJA</td>
<td>Tax Cuts and Jobs Act of 2017</td>
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