

## **Life Sciences**

Accounting and Financial Reporting Update —  
Interpretive Guidance on Other Accounting and  
Financial Reporting Topics

March 2019

# Contacts

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



**Jeff Ellis**  
U.S. Audit Leader — Life  
Sciences and Health Care  
Life Sciences Industry  
Professional Practice Director  
Deloitte & Touche LLP  
+1 412 338 7204  
[jeellis@deloitte.com](mailto:jeellis@deloitte.com)



**Dennis Howell**  
Senior Consultation Partner,  
Accounting and Reporting  
Services  
Life Sciences Deputy  
Industry Professional  
Practice Director  
Deloitte & Touche LLP  
+1 203 761 3478  
[dhowell@deloitte.com](mailto:dhowell@deloitte.com)

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# Preface

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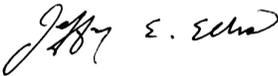
To our clients, colleagues, and other friends:

The life sciences industry represents 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 related to research and development (R&D) costs, acquisitions and divestitures, consolidation, contingencies, revenue recognition, income taxes, financial instruments, and financial statement presentation and disclosure. The full life sciences accounting and financial reporting update, our 10th edition, addresses these and other topics affecting the industry in 2019. It includes updated interpretive guidance as well as new sections that discuss initial public offerings (IPOs), accounting considerations for health technology companies, and the latest developments in standard setting. In addition, it discusses the outlook for the life sciences industry in 2019.

[Appendix A](#) lists the titles of standards and other literature we cited, and [Appendix B](#) defines the abbreviations we used.

Sincerely,



Jeff Ellis  
U.S. Audit Leader — Life Sciences and Health Care  
Life Sciences Industry Professional  
Practice Director  
Deloitte & Touche LLP



Dennis Howell  
Senior Consultation Partner, Accounting  
and Reporting Services  
Life Sciences Deputy Industry Professional  
Practice Director  
Deloitte & Touche LLP

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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 November 14, 2018, meeting, the Board affirmed its decision on the effective date and scope of the final ASU. As stated in the FASB's [tentative Board decisions](#), the final ASU would be effective for fiscal years ending after December 15, 2020, for PBEs and fiscal years ending after December 15, 2021, for non-PBEs (i.e., private companies). Early adoption would be permitted. Further, the final ASU "should be applied on a modified prospective basis in the first set of financial statements following the effective date to agreements that are either (1) existing at the effective date or (2) entered into after the effective date. Retrospective application also is permitted." The Board also "decided that the scope of the amendments would apply to grants of assets, tax assistance, low-interest-rate loans, loan guarantees, and forgiveness of liabilities." In addition, the Board "affirmed its decision that the disclosure requirements for [PBEs] and private companies would be the same."

Further, the Board "directed the staff to draft a final [ASU] and perform additional outreach with stakeholders for the staff to bring to another meeting to address the feedback, any sweep issues, and the costs and benefits of the amendments." The Board will continue its redeliberations at a future meeting.



#### **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.<sup>1</sup> 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](#).



### 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 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."

<sup>1</sup> The proposed Concepts Statement was [finalized](#) in August 2018.

- “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.<sup>2</sup> 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.

### 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

<sup>2</sup> AICPA Issues Paper, *Identification and Discussion of Certain Financial Accounting and Reporting Issues Concerning LIFO Inventories*.

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 Reporting 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<sup>3</sup> would need to be available at least 60 days before the spin-off, while carve-out financial statements prepared for compliance with SEC Regulation S-X, Rule 3-05,<sup>4</sup> would need to be available within 75 days post-closing.

Accordingly, assessing the potential audience 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.

<sup>3</sup> A Form 10 is the spin-off equivalent of a Form S-1 filed by new registrants in connection with an IPO.

<sup>4</sup> 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.

## **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 in the operations or human resources departments. In addition, management may need to engage external specialists (e.g., accounting advisory, tax, legal, 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.

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, they 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 publication and Deloitte's *A Roadmap to Reporting 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 profits and sales of opioid-based products have 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) the surcharge imposed on opioid manufacturers, distributors, and importers under the state of New York's Opioid Stewardship Act.

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

<sup>5</sup> TD 9684, *Branded Prescription Drug Fee*.

### 13.6.3 New York State Opioid Stewardship Act

In April 2018, the Opioid Stewardship Act was enacted in the state of New York, with an effective date of July 1, 2018. The Act establishes a program in which manufacturers, distributors, and importers of certain opioid controlled substances licensed by the New York State Department of Health (the “licensees”) are collectively required to contribute \$100 million annually to a fund to aid in the fight against the opioid epidemic. The Act provides that licensees are to report transaction information for opioids sold or distributed in the state of New York (subject to an exemption list published by the state). The state will then determine each licensee’s market share percentage of total opioids sold and distributed in the state to calculate the licensee’s share of the \$100 million. Determinations are based on the initial transaction in the distribution chain when opioids are first sold or distributed in the state. The market share calculation to be performed is based on morphine milligram equivalents. The payment for 2017 applicable sales transactions was due on January 1, 2019.

However, on December 19, 2018, in an adjudication of civil claims brought by a trade association of pharmaceutical distributors, a trade association of pharmaceutical manufacturers, and a pharmaceutical manufacturer to challenge the constitutionality of the Act, the U.S. District Court for the Southern District of New York ruled in favor of the plaintiffs and enjoined enforcement of the Act. In light of the court’s ruling, companies that otherwise would be subject to the requirements of the Act are encouraged to consult with their legal and accounting advisers to determine how the ruling applies to their particular facts and circumstances.

## 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).<sup>6</sup> 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.”

<sup>6</sup> An entity that is neither an SEC filer nor a conduit bond obligor for debt securities that are traded in a public market would use the date on which the financial statements are available to be issued (in a manner consistent with the going-concern standard’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 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.

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.<sup>7</sup>

<sup>7</sup> See [footnote 4](#).

### 13.7.4 Disclosure Content

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

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

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.

## 13.8 Health Tech

The health tech marketplace is a high-growth environment in which participants (i.e., life sciences companies, health care providers, and health plans) 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 artificial intelligence, and Web-based simulation for R&D.

Tech companies 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 publication is likely to be applicable to companies in the health tech sector. 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 software with respect to capitalization of costs and recognition of revenue that have historically been the focus of more traditional software companies could be of importance to companies operating in this space. Accordingly, the table below references recent standard-setting activity as well as interpretive guidance for certain software issues that companies in the health tech sector may find helpful. Some of the guidance was 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 to apply the new revenue standard to various industries. See the AICPA's [Web site](#) for status updates and further information about the software entities task force.

Topic	Title	Publication
Stand-alone selling price	"Estimating the Stand-Alone Selling Price — Use of the Residual Approach"	AICPA Revenue Recognition Task Force Working Draft: <i>Software Revenue Recognition Implementation Issue #14-6</i> (finalized in <a href="#">Sections 9.4.01 through 9.4.20</a> of the AICPA Revenue Guide)
	"Challenges Associated With Applying the New Revenue Standard: Establishing the Stand-Alone Selling Price as a Range"	Deloitte's December 14, 2018, <a href="#">Technology Alert</a>
	"Stand-Alone Selling Price of Postcontract Support Based on a Stated Renewal Percentage"	<a href="#">Q&amp;A 7-1</a> of Deloitte's <a href="#">A Roadmap to Applying the New Revenue Recognition Standard</a> (the "Revenue Roadmap")
	"Different Stand-Alone Selling Price for the Same Good or Service in a Single Contract"	<a href="#">Q&amp;A 7-2</a> of Deloitte's Revenue Roadmap
	"Different Selling Price for the Same Product to Different Customers"	<a href="#">Q&amp;A 7-3</a> of Deloitte's Revenue Roadmap
Cloud computing arrangements	"Determining Whether Software Intellectual Property Is Distinct in Cloud Computing Arrangements"	AICPA Revenue Recognition Task Force Working Draft: <i>Software Revenue Recognition Implementation Issue #14-1</i> (finalized in <a href="#">Sections 9.2.10 through 9.2.15</a> of the AICPA Revenue Guide)
	"FASB Amends Guidance on Cloud Computing Arrangements"	Deloitte's September 11, 2018, <a href="#">Heads Up</a>
Price concessions	"Defining and Identifying Potential Price Concessions"	AICPA Revenue Recognition Task Force Working Draft: <i>Software Revenue Recognition Implementation Issue #14-4(a)</i> (finalized in <a href="#">Sections 9.3.01 through 9.3.14</a> of the AICPA Revenue Guide)
Termination rights	"Challenges Associated with Applying the New Revenue Standard: Termination Rights"	Deloitte's July 24, 2018, <a href="#">Technology Alert</a>
Refund liabilities	"Classification and Presentation of Refund Liabilities"	<a href="#">Q&amp;A 13-1A</a> of Deloitte's Revenue Roadmap

## 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.”

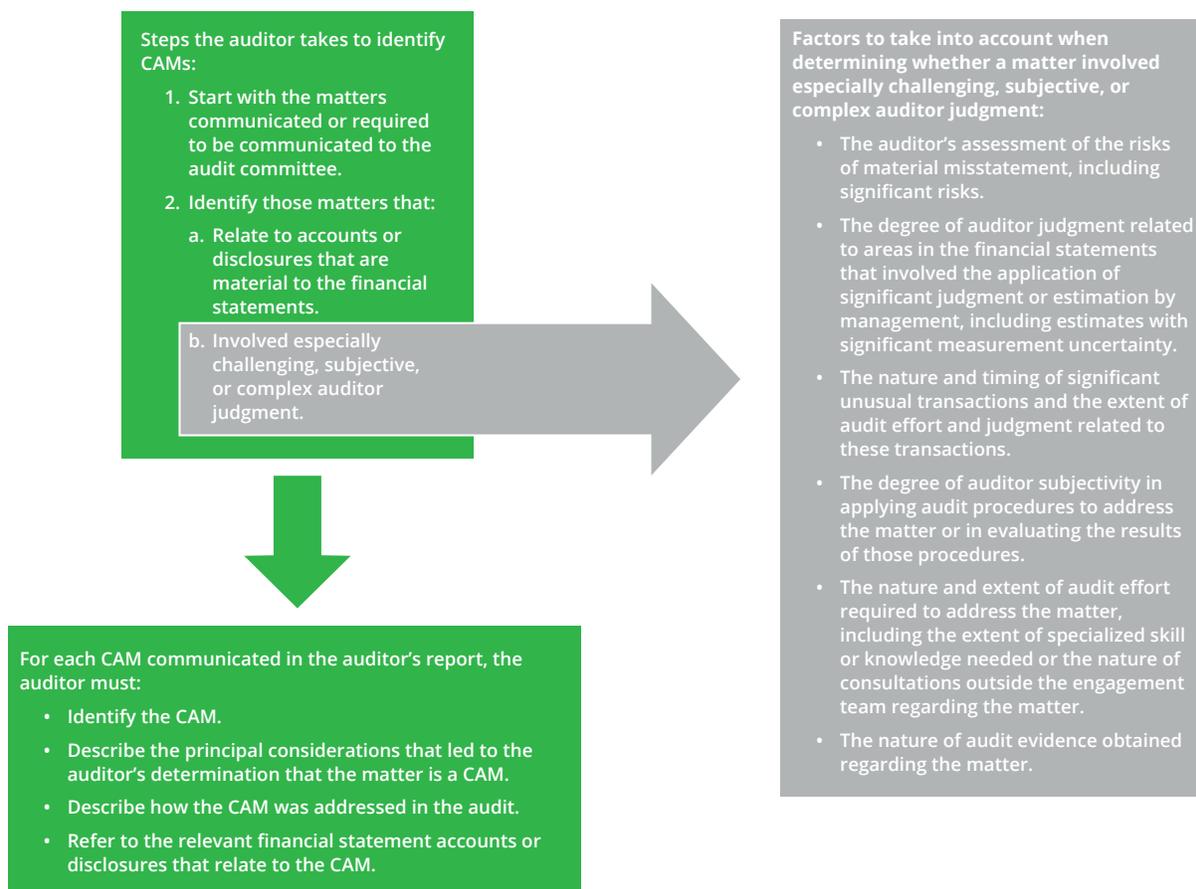
The standard includes a nonexclusive list of factors for the auditor to take into account, alone or in combination, in determining whether a matter involved especially challenging, subjective, or complex auditor judgment.

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 being phased in 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 at any point after SEC approval.

Communication of CAMs is not required for audits of emerging growth companies as defined in Section 3(a)(80) of the Securities Exchange Act of 1934. 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

Although the standard will be implemented in accordance with phased-in effective dates, management and audit committees will most likely want to start to consider the implications of the new requirements. 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 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?

For more information about the PCAOB changes to the auditor's report, see the following publications:

- Deloitte's June 20, 2017, [Heads Up](#).
- The CAQ's July 2018 [publication](#).<sup>8</sup>
- The CAQ's December 2018 [publication](#).<sup>9</sup>

<sup>8</sup> *Critical Audit Matters: Key Concepts and FAQs for Audit Committees, Investors, and Other Users of Financial Statements.*

<sup>9</sup> *Critical Audit Matters: Lessons Learned, Questions to Consider, and an Illustrative Example.*

# Appendix A — Titles of Standards and Other Literature

The standards and other literature below were cited or linked to in this publication.

## **AICPA Literature**

### **Accounting and Valuation Guide**

*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 Paper**

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

### **Other**

AICPA Technical Practice Aid, 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 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 325, *Investments — Other*

ASC 326, *Financial Instruments — Credit Losses*

ASC 330, *Inventory*

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 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 715, *Compensation — Retirement Benefits*

ASC 718, *Compensation — Stock Compensation*

ASC 720, *Other Expenses*

ASC 730, *Research and Development*

ASC 740, *Income Taxes*

ASC 805, *Business Combinations*

ASC 808, *Collaborative Arrangements*

ASC 810, *Consolidation*

ASC 815, *Derivatives and Hedging*

ASC 820, *Fair Value Measurement*

ASC 825, *Financial Instruments*

ASC 830, *Foreign Currency Matters*

ASC 840, *Leases*

ASC 842, *Leases*

ASC 845, *Nonmonetary Transactions*

ASC 850, *Related Party Disclosures*

ASC 855, *Subsequent Events*

ASC 915, *Development Stage Entities*

ASC 958, *Not-for-Profit Entities*

ASC 985, *Software*

## **ASUs**

2010-20, *Receivables (Topic 310): Disclosures About the Credit Quality of Financing Receivables and the Allowance for Credit Losses*

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

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

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

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

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*

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*

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

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

2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*

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

2016-02, *Leases (Topic 842)*

2016-04, *Liabilities — Extinguishment of Liabilities (Subtopic 405-20): Recognition of Breakage for Certain Prepaid Store-Valued Products* — a consensus of the FASB Emerging Issues Task Force

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

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

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

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*

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

- 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*
- 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments — a consensus of the FASB Emerging Issues Task Force*
- 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory*
- 2016-17, *Consolidation (Topic 810): Interests Held Through Related Parties That Are Under Common Control*
- 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash — a consensus of the FASB Emerging Issues Task Force*
- 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue From Contracts With Customers*
- 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*
- 2017-04, *Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*
- 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*
- 2017-07, *Compensation — Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost*
- 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*
- 2017-12, *Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities*
- 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)*
- 2017-14, *Income Statement — Reporting Comprehensive Income (Topic 220), Revenue Recognition (Topic 605), and Revenue From Contracts With Customers (Topic 606) (SEC Update)*
- 2018-01, *Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842*
- 2018-02, *Income Statement — Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects From Accumulated Other Comprehensive Income*
- 2018-03, *Technical Corrections and Improvements to Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*
- 2018-07, *Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*
- 2018-08, *Not-For-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*
- 2018-10, *Codification Improvements to Topic 842, Leases*
- 2018-11, *Leases (Topic 842): Targeted Improvements*
- 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement*

2018-14, *Compensation — Retirement Benefits — Defined Benefit Plans — General (Subtopic 715-20): Disclosure Framework — Changes to the Disclosure Requirements for Defined Benefit Plans*

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

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

## 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 1, The Objective of General Purpose Financial Reporting, and Chapter 3, Qualitative Characteristics of Useful Financial Information*

## 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. 2016-270, *Income Taxes (Topic 740) Disclosure Framework — Changes to the Disclosure Requirements for Income Taxes*

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. 2018-300, *Codification Improvements — Financial Instruments*

No. 2019-100, *Targeted Transition Relief for Topic 326, Financial Instruments — Credit Losses*

## Other FASB Proposal

Proposed Concepts Statement 2014-200, *Conceptual Framework for Financial Reporting: Chapter 8: Notes to Financial Statements*

## International Standards

IFRS 3, *Business Combinations*

IFRS 11, *Joint Arrangements*

IFRS 15, *Revenue From Contracts With Customers*

IFRS 16, *Leases*

IAS 10, *Events After the Reporting Period*

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

## **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 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"

Section 965, "Treatment of Deferred Foreign Income Upon Transition to Participation Exemption System of Taxation"

Section 4191, "Medical Devices"

## **PCAOB Literature**

Release No. 2017-001, *The Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion and Related Amendments to PCAOB Standards*

## **SEC Literature**

### **FRM**

Topic 1, "Registrant's Financial Information"

Topic 2, "Other Financial Statements Required"

Topic 3, "Pro Forma Financial Information"

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*

### **Regulation S-K**

Item 103, "Business; Legal Proceedings"

## **Regulation S-X**

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

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 3-14, “Special Instructions for Real Estate Operations to Be Acquired”

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”

Article 11, “Pro Forma Financial Information”

Rule 11-01 “Presentation Requirements”

## **SAB Topics**

SAB Topic 1.M, “Financial Statements; Materiality”

SAB Topic 5.Y, “Miscellaneous Accounting; Accounting and Disclosures Relating to Loss Contingencies”

SAB Topic 11.A, “Miscellaneous Disclosure; Operating-Differential Subsidiaries”

SAB Topic 13, “Revenue Recognition”

SAB Topic 14.B, “Share-Based Payment; Transition From Nonpublic to Public Entity Status”

SAB Topic 14.D.1, “Certain Assumptions Used in Valuation Methods; Expected Volatility”

SAB Topic 14.D.2, “Certain Assumptions Used in Valuation Methods; Expected Term”

SAB 116, “Staff Accounting Bulletin No. 116”

## **Superseded Literature**

### **EITF Issues**

Issue 00-21, “Revenue Arrangements With Multiple Deliverables”

Issue 01-8, “Determining Whether an Arrangement Contains a Lease”

Issue 01-9, “Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor’s Products)”

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. 48, *Accounting for Uncertainty in Income Taxes* — an interpretation of FASB Statement No. 109

## **FASB Statements**

No. 5, *Accounting for Contingencies*

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

No. 141(R), *Business Combinations*

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

## Appendix B — Abbreviations

Abbreviation	Description
<b>ABO</b>	accumulated benefit obligation
<b>AFS</b>	available for sale
<b>AICPA</b>	American Institute of Certified Public Accountants
<b>AMT</b>	alternative minimum tax
<b>AOCI</b>	accumulated other comprehensive income
<b>API</b>	active pharmaceutical ingredient
<b>APIC</b>	additional paid-in capital
<b>ASC</b>	FASB Accounting Standards Codification
<b>ASR</b>	accelerated share repurchase
<b>ASU</b>	FASB Accounting Standards Update
<b>BCF</b>	beneficial conversion feature
<b>BEAT</b>	base erosion anti-abuse tax
<b>BEMTA</b>	base erosion minimum tax amount
<b>BOLI</b>	bank-owned life insurance
<b>BPD</b>	branded prescription drug
<b>CAM</b>	critical audit matter
<b>CAQ</b>	Center for Audit Quality
<b>CDO</b>	chief digital officer
<b>CECL</b>	current expected credit loss
<b>CFC</b>	controlled foreign corporation
<b>CMO</b>	contract manufacturing organization
<b>CODM</b>	chief operating decision maker
<b>COLI</b>	corporate-owned life insurance
<b>CRO</b>	contract research organization
<b>CTA</b>	cumulative translation adjustment

Abbreviation	Description
<b>DTA</b>	deferred tax asset
<b>DTL</b>	deferred tax liability
<b>E&amp;P</b>	earnings and profits
<b>EBITDA</b>	earnings before interest, taxes, depreciation, and amortization
<b>EDGAR</b>	SEC electronic data gathering, analysis, and retrieval system
<b>EGC</b>	emerging growth company
<b>EITF</b>	Emerging Issues Task Force
<b>ESPP</b>	employee stock purchase plan
<b>EU</b>	European Union
<b>FAQ</b>	frequently asked question
<b>FASB</b>	Financial Accounting Standards Board
<b>FAST Act</b>	Fixing America's Surface Transportation Act
<b>FDA</b>	Food and Drug Administration
<b>FDII</b>	foreign derived intangible income
<b>FIFO</b>	first in, first out
<b>FOB</b>	free on board
<b>FRM</b>	SEC Division of Corporation Finance Financial Reporting Manual
<b>GAAP</b>	generally accepted accounting principles
<b>GILTI</b>	global intangible low-taxed income
<b>GPO</b>	group purchasing organization
<b>IAS</b>	International Accounting Standard
<b>IASB</b>	International Accounting Standards Board

Abbreviation	Description
<b>IFRS</b>	International Financial Reporting Standard
<b>IIR</b>	investigator-initiated research
<b>IP</b>	intellectual property
<b>IPO</b>	initial public offering
<b>IPR&amp;D</b>	in-process research and development
<b>IRC</b>	Internal Revenue Code
<b>IRS</b>	Internal Revenue Service
<b>ISO</b>	incentive stock option
<b>IT</b>	information technology
<b>JOBS Act</b>	Jumpstart Our Business Startups Act
<b>LIFO</b>	last in, first out
<b>LLC</b>	limited liability company
<b>LP</b>	limited partnership
<b>M&amp;A</b>	merger and acquisition
<b>MD&amp;A</b>	Management's Discussion & Analysis
<b>MDET</b>	medical device excise tax
<b>MSL</b>	medical science liaison
<b>NFP</b>	not-for-profit entity
<b>NOL</b>	net operating loss
<b>NQSO</b>	non-qualified stock option
<b>NSO</b>	nonstatutory option
<b>OCI</b>	other comprehensive income
<b>OECD</b>	Organisation for Economic Co-operation and Development
<b>OEM</b>	original equipment manufacturer
<b>PBE</b>	public business entity
<b>PBO</b>	projected benefit obligation

Abbreviation	Description
<b>PCAOB</b>	Public Company Accounting Oversight Board
<b>PCC</b>	Private Company Council
<b>PCD asset</b>	purchased financial asset with credit deterioration
<b>PP&amp;E</b>	property, plant, and equipment
<b>PRV</b>	priority review voucher
<b>PTRS</b>	probability of technical and regulatory success
<b>Q&amp;A</b>	question and answer
<b>R&amp;D</b>	research and development
<b>R&amp;E</b>	research and experimentation
<b>REMS</b>	risk evaluation and mitigation strategy
<b>ROI</b>	return on investment
<b>ROU</b>	right of use
<b>SAB</b>	Staff Accounting Bulletin
<b>SAC</b>	subjective acceleration clause
<b>SEC</b>	Securities and Exchange Commission
<b>SFC</b>	specified foreign corporation
<b>SIFMA</b>	Securities Industry and Financial Markets Association
<b>S&amp;P 500</b>	Standard & Poor's 500 Index
<b>TD</b>	Treasury Decision
<b>TPA</b>	AICPA Technical Practice Aid
<b>TRG</b>	transition resource group
<b>UTB</b>	unrecognized tax benefit
<b>VIE</b>	variable interest entity
<b>VWAP</b>	volume-weighted average daily market price