



Life Sciences

Accounting and Financial Reporting Update —
Interpretive Guidance on Branded Prescription Drug Fee

March 2018

Branded Prescription Drug Fee

Background

The 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](#)¹ 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.

¹ T.D. 9684, *Branded Prescription Drug Fee*.

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.

Appendix A — Glossary 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*

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

AICPA *Technical Questions and Answers*, Q&A paragraph 2260.03, "Other Assets; Legal Expenses Incurred to Defend Patent Infringement Suit"

FASB Accounting Standards Updates (ASUs)

ASU 2018-03, *Technical Corrections and Improvements to Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*

ASU 2018-02, *Income Statement — Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects From Accumulated Other Comprehensive Income*

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

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

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 2017-09, *Compensation — Stock Compensation (Topic 718): Scope of Modification Accounting*

ASU 2017-07, *Compensation — Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ASU 2015-02, *Consolidation (Topic 810): Amendments to the Consolidation Analysis*

ASU 2015-01, *Income Statement — Extraordinary and Unusual Items (Subtopic 225-20): Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items*

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

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

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

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

ASU 2009-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements* — a consensus of the FASB Emerging Issues Task Force

FASB Accounting Standards Codification (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 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 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 915, *Development Stage Entities*

ASC 958, *Not-for-Profit Entities*

ASC 985, *Software*

Proposed FASB Accounting Standards Updates (Proposed ASUs)

Proposed ASU 2018-200, *Leases (Topic 842): Targeted Improvements*

Proposed ASU 2017-310, *Technical Corrections and Improvements to Recently Issued Standards: I. Accounting Standards Update No. 2016-01, Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities and II. Accounting Standards Update No. 2016-02, Leases (Topic 842)*

FASB Proposed Accounting Standards Update 2017-280, *Consolidation (Topic 812): Reorganization*

FASB Proposed Accounting Standards Update 2017-240, *Consolidation (Topic 810): Targeted Improvements to Related Party Guidance for Variable Interest Entities*

Proposed ASU 2017-220, *Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*

Proposed ASU 2017-210, *Inventory (Topic 330): Disclosure Framework — Changes to the Disclosure Requirements for Inventory*

Proposed ASU 2017-200, *Debt (Topic 470): Simplifying the Classification of Debt in a Classified Balance Sheet (Current Versus Noncurrent)*

Proposed ASU 2016-270, *Income Taxes (Topic 740) Disclosure Framework: Changes to the Disclosure Requirements for Income Taxes*

Proposed ASU 2015-340, *Government Assistance (Topic 832): Disclosures by Business Entities About Government Assistance*

Proposed ASU 2015-310, *Notes to Financial Statements (Topic 235): Assessing Whether Disclosures Are Material*

Other FASB Proposal

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

FASB Statements (Pre-Codification Literature)

Statement No. 167, *Amendments to FASB Interpretation No. 46(R)*

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

Statement No. 141(R), *Business Combinations*

FASB Interpretations (Pre-Codification Literature)

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

FASB Interpretation No. 46 (revised December 2003), *Consolidation of Variable Interest Entities*

FASB Concepts Statements

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

No. 6, *Elements of Financial Statements*

EITF Issues (Pre-Codification Literature)

Issue 09-4, "Seller Accounting for Contingent Consideration"

Issue 08-1, "Revenue Arrangements With Multiple Deliverables"

Issue 04-5, "Determining Whether a General Partner, or the General Partners as a Group, Controls a Limited Partnership or Similar Entity When the Limited Partners Have Certain Rights"

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

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

Issue 00-21, "Revenue Arrangements With Multiple Deliverables"

PCAOB Auditing Standard

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 C&DI Topic

Non-GAAP Financial Measures

SEC 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*

SEC Regulation G

"Conditions for Use of Non-GAAP Financial Measures"

SEC Regulation S-K

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

Item 103, "Business; Legal Proceedings."

SEC Regulation S-X

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"

SEC Staff Accounting Bulletins (SABs)

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 13.A.4, "Revenue Recognition; Selected Revenue Recognition Issues; Fixed or Determinable Sales Price"

SAB Topic 13.B, "Revenue Recognition; Disclosures"

SAB 116, "Staff Accounting Bulletin No. 116"

SAB 118, codified as SEC Staff Accounting Bulletin Topic 5.EE, "Miscellaneous Accounting; Income Tax Accounting Implications of the Tax Cuts and Jobs Act"

Internal Revenue Code (IRC)

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

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

IRC Section 199, "Income Attributable to Domestic Production Activities"

IRC Section 383, "Special Limitations on Certain Excess Credits, Etc."

IRC Section 787, "Termination of Private Foundation Status"

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

IRC Section 4191, "Medical Devices"

International Standards

IFRS 16, *Leases*

IFRS 15, *Revenue From Contracts With Customers*

IFRS 11, *Joint Arrangements*

IFRS 3, *Business Combinations*

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

Appendix B — Abbreviations

Abbreviation	Description	Abbreviation	Description
AFS	available for sale	E&P	earnings and profits
AICPA	American Institute of Certified Public Accountants	EPS	earnings per share
AMT	alternative minimum tax	EU	European Union
AOCI	accumulated other comprehensive income	FAQ	frequently asked question
API	active pharmaceutical ingredient	FASB	Financial Accounting Standards Board
APIC	additional paid-in capital	FDA	Food and Drug Administration
ASC	FASB Accounting Standards Codification	FDII	foreign derived intangible income
ASU	FASB Accounting Standards Update	FIFO	first in, first out
BCF	beneficial conversion feature	FIN	FASB Interpretation Number (superseded)
BEAT	base erosion anti-abuse tax	FOB	free on board
BEMTA	base erosion minimum tax amount	GAAP	generally accepted accounting principles
BPD	branded prescription drug	GILTI	global intangible low-taxed income
BOLI	bank-owned life insurance	GPO	group purchasing organization
CAM	critical audit matter	IAS	International Accounting Standard
C&DI	SEC Compliance and Disclosure Interpretation	IASB	International Accounting Standards Board
CECL	current expected credit loss	IFRS	International Financial Reporting Standard
CFC	controlled foreign corporation	IIR	investigator-initiated research
CODM	chief operating decision maker	IP	intellectual property
COLI	corporate-owned life insurance	IPO	initial public offering
CRO	contract research organization	IPR&D	in-process research and development
CTA	cumulative translation adjustment	IRC	Internal Revenue Code
DCPs	disclosure controls and procedures	IRS	Internal Revenue Service
DTA	deferred tax asset	IT	information technology
DTL	deferred tax liability	LIFO	last in, first out
EBITDA	earnings before interest, taxes, depreciation, and amortization	LLC	limited liability company
EITF	FASB Emerging Issues Task Force		

Abbreviation	Description
LP	limited partnership
M&A	merger and acquisition
MD&A	Management's Discussion and Analysis
MDET	medical device excise tax
MSL	medical science liaison
NFP	not-for-profit entity
NOL	net operating loss
OCI	other comprehensive income
OEM	original equipment manufacturer
OECD	Organisation for Economic Co-operation and Development
PBE	public business entity
PCAOB	Public Company Accounting Oversight Board
PCC	Private Company Council
PCD asset	purchased financial asset with credit deterioration
PRV	priority review voucher

Abbreviation	Description
PTRS	probability of technical and regulatory success
Q&A	question and answer
R&D	research and development
R&E	research and experimentation
REMS	risk evaluation and mitigation strategy
ROU	right-of-use
SAB	SEC Staff Accounting Bulletin
SEC	Securities and Exchange Commission
SFC	specified foreign corporation
SIFMA	Securities Industry and Financial Markets Association
T.D.	Treasury Decision
TRG	transition resource group
UTB	unrecognized tax benefit
VIE	variable interest entity
WAC	wholesaler acquisition cost

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