



Sustainability Accounting Standards

PROPOSED CHANGES TO PROVISIONAL STANDARDS

EXPOSURE DRAFTS

REDLINE OF STANDARDS FOR PUBLIC COMMENT

HEALTH CARE SECTOR

Biotechnology & Pharmaceuticals
Medical Equipment & Supplies
Health Care Delivery
Health Care Distributors
Managed Care
Drug Retailers

Prepared by the
Sustainability Accounting Standards Board®

HEALTH CARE SECTOR

Table of Contents

BIOTECHNOLOGY & PHARMACEUTICALS 1

MEDICAL EQUIPMENT & SUPPLIES 40

HEALTH CARE DELIVERY 66

HEALTH CARE DISTRIBUTORS 105

MANAGED CARE 126

DRUG RETAILERS 154



HEALTH CARE SECTOR

BIOTECHNOLOGY & PHARMACEUTICALS*

Sustainability Accounting Standard

PROPOSED CHANGES TO PROVISIONAL STANDARDS

EXPOSURE DRAFT

REDLINE OF STANDARD FOR PUBLIC COMMENT

Prepared by the
Sustainability Accounting Standards Board®

October 2017

* Sustainable Industry Classification System™ (SICS™) #HC0101

BIOTECHNOLOGY & PHARMACEUTICALS

Sustainability Accounting Standard

About the SASB

The Sustainability Accounting Standards Board (SASB) was founded in 2011 as an independent standard-setting organization. The SASB issues and maintains sustainability accounting standards for 79 industries, focusing on the subset of industry-specific sustainability factors that are reasonably likely to have material financial impacts on companies within that industry. Companies can use the standards to disclose material information to investors in SEC filings, including Forms 10-K, 20-F, and 8-K, as well as S-1 and S-3, in a cost-effective and decision-useful manner. The standards are designed to help companies better comply with existing disclosure obligations, working within the framework of existing U.S. securities laws.

The SASB Standards Board is responsible for developing and issuing the standards, maintaining technical agendas, proposing updates to the standards, and executing the standard-setting process. The SASB staff is responsible for performing research and engaging in consultation on the standards, supporting the work of the Standards Board.

The SASB Foundation, an independent 501(c)3 non-profit, is responsible for the funding and oversight of the SASB, including safeguarding the SASB's independence and integrity through due process oversight and inquiry resolution. The SASB Foundation Board of Directors appoints members of the SASB.

About this Standard

This Standard is an exposure draft presented for public review and comment. **This version is not intended for implementation.**

The public comment period lasts for 90 days, beginning on October 2, 2017, and ending on December 31, 2017. The Standard is subject to change thereafter. SASB Standards are scheduled to be ratified by the SASB in early 2018.

For instructions on providing comments to SASB, please click [here](https://www.sasb.org/public-comment) (<https://www.sasb.org/public-comment>).

SUSTAINABILITY ACCOUNTING STANDARDS BOARD

1045 Sansome Street, Suite 450
San Francisco, CA 94111

www.sasb.org

The information, text, and graphics in this publication (the "Content") is owned by the Sustainability Accounting Standards Board. All rights reserved. You may use the Content only for non-commercial and scholarly use, provided that you keep intact all copyright and other proprietary notices related to the Content, and that you make no modifications to the Content. The Content may not be otherwise disseminated, distributed, republished, reproduced, or modified without the prior written permission of the Sustainability Accounting Standards Board. To request permission, please contact us at info@sasb.org.

Purpose & Structure

This document contains the SASB Sustainability Accounting Standard (SASB Standard) for the Biotechnology & Pharmaceuticals industry.

SASB Sustainability Accounting Standards comprise **(1) disclosure guidance and (2) accounting standards or metrics** for use by U.S. and foreign public companies in their disclosures to investors, such as in annual reports and filings with the U.S. Securities and Exchange Commission (SEC), including Forms 10-K, 20-F, 40-F, 10-Q, 8-K and S-1 and S-3. The Standards facilitate the meaningful disclosure of sustainability information that is useful to investors in making decisions on investments and corporate suffrage.¹ The Standards reflect the fact that certain sustainability information is important for assessing the future financial performance of an issuer, particularly over the long term.

SASB Standards identify sustainability topics that are reasonably likely to constitute material information for a company within a particular industry. Company management is responsible for determining whether those identified topics reflect information that is material to investors and should be disclosed in filings, based on that company's specific circumstances. For further details regarding the use of the SASB Standards, in particular guidance on determinations of materiality, please see SASB's Implementation Guide.²

SASB Standards provide companies with sustainability metrics designed to communicate performance on industry-level sustainability topics in a concise, comparable format using existing reporting mechanisms. Companies can use the Standards to help ensure that disclosure is reliable, decision-useful for investors, and cost-effective for issuers.

SASB Standards are intended to constitute "suitable criteria" for purposes of an attestation engagement as defined by Paragraph .A42 of AT-C section 105³ and referenced in AT-C section 395.⁴ "Suitable criteria" have the following attributes:

- *Relevance*—Criteria are relevant to the subject matter.
- *Objectivity*—Criteria are free from bias.
- *Measurability*—Criteria permit reasonably consistent measurements, qualitative or quantitative, of subject matter.
- *Completeness*—Criteria are complete when subject matter prepared in accordance with them does not omit relevant factors that could reasonably be expected to affect decisions of the intended users made on the basis of that subject matter.

Industry Description

The Biotechnology & Pharmaceuticals industry develops, manufactures, and markets a range of medications and health care products. The industry is driven by research and development, a high risk of product failure during clinical trials, and the need to obtain regulatory approval. Concern over pricing practices, pressure from generic competition,

¹ The AICPA defines sustainability information in its Guide, [Attestation Engagements on Sustainability Information \(Including Greenhouse Gas Emissions Information\)](#) (Issued July 2017), as follows: "information about sustainability matters (such as economic, environmental, social and governance performance)." It further explains that "sustainability metrics and sustainability indicators are components of sustainability information. Sustainability information may be nonquantitative (narrative), historical, or forward-looking."

² <https://library.sasb.org/implementation-guide>

³ <https://www.aicpa.org/Research/Standards/AuditAttest/DownloadableDocuments/AT-C-00105.pdf>

⁴ <http://pcaobus.org/Standards/Attestation/Pages/AT701.aspx>

and consolidation within the sector have created downward pricing pressures. Demand for the industry's products is largely driving by population demographics, rates of insurance coverage, disease profiles, and economic conditions.

Users of the SASB Standards

The SASB Standards are intended for use by public companies and by investors to inform investment decisions. The standards facilitate disclosure of financially material sustainability-related information in a concise, comparable, cost-effective, decision-useful format.

The SASB Standards are designed for integration into existing reporting mechanisms, such as SEC filings. This keeps the administrative and cost burden to a minimum. SEC filings include Form 10-K for U.S. companies, Form 20-F for foreign issuers, Form 40-F for Canadian issuers, quarterly reports on Form 10-Q, current reports on Form 8-K, and registration statements on Forms S-1 and S-3. The SASB Standards are also recognized by the European Commission as a suitable framework for companies to provide information to investors pursuant to EU Directive 2014/95/EU. See "Guidelines on non-financial reporting (methodology for reporting non-financial information)." ⁵ Thus, SASB standards are a cost-effective way to satisfy both U.S. and European reporting requirements.

SASB evaluates the materiality of sustainability-related topics by using the high threshold of financial materiality that is established under the U.S. securities laws.⁶ Although designed to meet the rigorous disclosure requirements of the U.S. capital markets (thereby producing a high-quality set of evidence-based standards focused on material investor-focused topics), the standards represent a best practice that can be used by companies of all types (public and private) to describe their material sustainability-related risks and opportunities.

Guidance for Disclosure of Sustainability Topics in SEC Filings

1. Industry-Level Sustainability Topics

For the Biotechnology & Pharmaceuticals industry, the SASB has identified the following sustainability disclosure topics:

⁵ https://ec.europa.eu/info/publications/170626-non-financial-reporting-guidelines_en

⁶ https://library.sasb.org/materiality_bulletin/

- Access to Medicines
- Drug Safety ~~and Side Effects~~
- Safety of Clinical Trial Participants
- Affordability and Fair Pricing
- Ethical Marketing
- Employee Recruitment, Development, and Retention
- Employee Health and Safety
- Counterfeit Drugs
- Energy, Water, and Waste Efficiency
- Corruption and Bribery
- Manufacturing and Supply Chain Quality Management

2. Determination of Materiality

In the U.S., sustainability disclosures are governed by the same laws and regulations that generally govern disclosures by securities issuers. According to the U.S. Supreme Court, a fact is material if, in the event such fact is omitted from a particular disclosure, there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of the information made available.⁷

Through a rigorous process of research, review of evidence, and public input, the SASB has identified sustainability topics that are reasonably likely to have a material effect on the financial condition or operating performance of companies within each Sustainable Industry Classification System™ (SICS™) industry.⁸ **However, the issuer must determine what information is (or is reasonably likely to be) material to the reasonable investor.** For further information regarding a process that corporations can use to assess the financial materiality of the sustainability-related topics in SASB standards, please see SASB’s Implementation Guide.⁹

3. SEC Requirements Relating to Disclosure of Material Sustainability Information

If a public company determines that certain sustainability information is reasonably likely to be material, it must then determine whether disclosure of some or all of the information under applicable SASB Standards is required under the U.S. federal securities laws. Several provisions of those laws are relevant to sustainability disclosures.

Regulation S-K sets forth certain disclosure requirements associated with Form 10-K and other SEC filings. Item 303 of Regulation S-K requires companies to, among other things, describe in the Management’s Discussion and Analysis of Financial Condition and Results of Operations (MD&A) section of Form 10-K “any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed.”¹⁰

⁷ *TSC Industries v. Northway, Inc.*, 426 U.S. 438 (1976).

⁸ https://library.sasb.org/materiality_bulletin/

⁹ <https://library.sasb.org/implementation-guide>

¹⁰ C.F.R. 229.303(Item 303)(a)(3)(ii).

Furthermore, the instructions to Item 303 state that the MD&A “shall focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition.”¹¹

The SEC has provided guidance for companies to use in determining whether a trend or uncertainty should be disclosed. The two-part assessment prescribed by the SEC can be applied to the topics included within this Standard:

- First, a company is not required to make disclosure about a known trend or uncertainty if its management determines that such trend or uncertainty is not reasonably likely to occur.
- Second, if a company’s management cannot make a reasonable determination of the likelihood of an event or uncertainty, then disclosure is required “unless management determines that a material effect on the registrant’s financial condition or results of operation is not reasonably likely to occur.”

Companies should also consider the applicability of other Regulation S-K requirements. Specifically, Item 101 (“Description of Business”) requires a company to provide a description of its business and its subsidiaries. Item 103 (“Legal Proceedings”) requires a company to describe briefly any material pending or contemplated legal proceedings; instructions to Item 103 provide specific disclosure requirements for administrative or judicial proceedings arising from laws and regulations that target discharge of materials into the environment, or that are primarily for the purpose of protecting the environment. Item 503(c) (“Risk Factors”) requires a company to provide discussion of the most significant factors that make an investment in the registrant speculative or risky, clearly stating the risk and specifying how it affects the company.

Finally, as a general matter, Securities Act Rule 408 and Exchange Act Rule 12b-20 require a registrant to disclose, in addition to the information expressly required by law or regulation, “such further material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they are made, not misleading.”

4. Where Disclosures Should Be Made in SEC Filings

In using the definition of materiality established under the U.S. federal securities laws, the SASB has identified and developed industry-specific sustainability topics and metrics that are reasonably likely to have a material effect on the financial condition or operating performance of companies within a particular industry. As a general matter, the SASB believes that investors are best served when disclosure of such information is made in SEC filings. An issuer might, for example, make the disclosure in a sub-section of MD&A with a caption, “**Sustainability-Related Information**,” with a section that includes the material topics, performance metrics, and management’s view with respect to corporate positioning. See SASB’s “Mock 10-Ks” for examples of preparing an MD&A using the SASB Standards.¹² Issuers are not precluded from using the Standards elsewhere, such as in stand-alone communications to investors or in sustainability reports (sometimes referred to as corporate social responsibility reports or environmental, social, and governance reports), company websites, or elsewhere. Corporate communication on material topics, including

¹¹ SEC [Release Nos. 33-8056; 34-45321; FR-61] Commission Statement about Management’s Discussion and Analysis of Financial Condition and Results of Operations: “We also want to remind registrants that disclosure must be both useful and understandable. That is, management should provide the most relevant information and provide it using language and formats that investors can be expected to understand. Registrants should be aware also that investors will often find information relating to a particular matter more meaningful if it is disclosed in a single location, rather than presented in a fragmented manner throughout the filing.”

¹² <http://using.sasb.org/mock-10-k-library/>

sustainability-related material topics, should be consistent across communication channels. As discussed above, SEC regulations may compel inclusion of material sustainability information in an SEC filing where it is deemed financially material.

The SASB recognizes that sustainability topics are relatively new areas of investor interest, and it may be difficult to determine whether particular sustainability information is material in certain situations. Accordingly, issuers might also consider using the SASB Standards in filings using Form 8-K, Item 8.01 (“Other Events”). This provision states that “The registrant may, at its option, disclose under this Item 8.01 any events, with respect to which information is not otherwise called for by this form, that the registrant deems of importance to security holders.” Making a disclosure under Item 8.01 would not require the issuer to make a decision regarding materiality, and might also provide the company with more time to make the disclosure than is permitted under filing rules applicable to Form 10-K, thereby facilitating the completeness and accuracy of the disclosed information.

When using the Standards, issuers should cite or refer to the relevant SASB Standard.

More detailed guidance on preparing disclosures of material information related to sustainability topics and making topic-level materiality determinations can be found in the **SASB Conceptual Framework**, available for download via <http://www.sasb.org/approach/conceptual-framework/>, and the **SASB Implementation Guide for Companies**, available for download via <https://library.sasb.org/implementation-guide/>.

Guidance on Accounting for Sustainability Topics

The SASB has identified accounting metrics for each sustainability topic included in this Standard. The SASB recommends that companies within this industry consider using these sustainability accounting metrics when preparing disclosures on the sustainability topics identified herein.

When disclosing information related to a sustainability topic identified by this Standard, companies should consider including a narrative description of any material factors necessary to ensure completeness, accuracy, and comparability of the data reported, as appropriate. Such a description might in certain circumstances include a discussion of the following:¹³

- The registrant’s **governance** around the risks and opportunities related to the topic, including board oversight of and management’s role in assessing and managing such risks and opportunities.
- The registrant’s **strategic approach** regarding actual and potential impacts of topic-related risks and opportunities on the organization’s **businesses, strategy, and financial planning**, over the **short, medium, and long term**.
- The registrant’s process to **identify, assess, and manage** topic-related risks, and how these risks are integrated into the registrant’s overall risk management process.
- The registrant’s **use of metrics or targets** to assess and manage topic-related risks and opportunities.

¹³ These areas for possible additional narrative description are generally aligned with the [Recommendations of the Task Force on Climate-related Financial Disclosures](#), which contains a more extensive discussion of such disclosure matters.

- Data for the registrant’s **last three completed fiscal years** (when available).

The SASB recommends that registrants use SASB Standards specific to their primary industry as identified in SICSTM. If a registrant generates significant revenue from multiple industries, the SASB recommends that it also consider sustainability topics that the SASB has identified for those industries, and disclose the associated SASB accounting metrics.

Further, the SASB recommends that companies design, implement, and maintain adequate systems of internal control over sustainability performance information to provide reasonable confidence regarding the achievement of related reporting objectives, such as those relating to the reliability of disclosed information.¹⁴

The SASB takes no position as to whether third-party attestation is necessary to enhance the credibility of the disclosed sustainability information, but as a matter of good governance, the SASB suggests that such assurance be considered.¹⁵

Scope of Disclosure

Unless otherwise specified, the SASB recommends:

- That a registrant disclose information on sustainability topics and metrics for itself and for entities that are consolidated for financial reporting purposes, as defined by accounting principles generally accepted in the United States (“US GAAP”), for consistency with other accompanying information within SEC filings;¹⁶
- That for consolidated entities, disclosures be made, and accounting metrics calculated, for the whole entity, regardless of the size of the minority interest; and
- That information from unconsolidated entities not be included in the computation of SASB accounting metrics. However, the registrant should disclose information about unconsolidated entities to the extent that the registrant considers the information necessary for investors to understand the effect of sustainability topics on the company’s financial condition or operating performance. (Typically, this disclosure would be limited to risks and opportunities associated with these entities.)

Reporting Format

Use of Financial Data

In instances where accounting metrics, activity metrics, and technical protocols in this Standard incorporate financial data (e.g., revenues, cost of sales, expenses recorded and disclosed for fines, etc.), such financial data shall be prepared in accordance with US GAAP, and be consistent with the corresponding financial data reported in the

¹⁴ In this regard, companies are referred to the report of a group of experts in this area. Robert H. Herz, Brad J. Monterio, Jeffrey C. Thomson, Leveraging the COSO Internal Control – Integrated Framework to Improve confidence in Sustainability Performance Data (August 2017).

¹⁵ The AICPA’s Guide (see supra note 1) provides guidance to assist accounting practitioners in performing attestation engagements on sustainability information.

¹⁶ See US GAAP consolidation rules (Section 810).

registrant’s SEC filings. Should accounting metrics, activity metrics, and technical protocols in this Standard incorporate disclosure of financial data that is not prepared in accordance with US GAAP, the registrant shall disclose such information in accordance with SEC Regulation G.¹⁷

Activity Metrics and Normalization

The SASB recognizes that normalizing accounting metrics is important for the analysis of SASB disclosures.

The SASB recommends that a registrant disclose any basic business data that may assist in the accurate evaluation and comparability of disclosure, to the extent that they are not already disclosed in Form 10-K (e.g., revenue, EBITDA, etc.).

Such data—termed “activity metrics”—may include high-level business data, including total number of employees, quantity of products produced or services provided, number of facilities, or number of customers. It may also include industry-specific data such as plant capacity utilization (e.g., for specialty chemical companies), number of transactions (e.g., for Internet media and services companies), hospital bed days (e.g., for health care delivery companies), or proven and probable reserves (e.g., for oil and gas exploration and production companies).

Activity metrics disclosed should:

- Convey contextual information that would not otherwise be apparent from SASB accounting metrics.
- Be deemed generally useful for investors relying on SASB accounting metrics to perform their own calculations and create their own ratios.
- Be explained and consistently disclosed from period to period to the extent that they continue to be relevant. However, a decision to make a voluntary disclosure in one period does not obligate a continuation of that disclosure if it is no longer relevant, or if a better metric becomes available.¹⁸

Where relevant, the SASB recommends specific activity metrics that—at a minimum—should accompany SASB accounting metric disclosures.

Table 1. Activity Metrics

<u>ACTIVITY METRIC</u>	<u>CATEGORY</u>	<u>UNIT OF MEASURE</u>	<u>CODE</u>
<u>Number of patients treated</u>	<u>Quantitative</u>	<u>Number</u>	<u>TA01-06-01</u>
<u>Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3)</u>	<u>Quantitative</u>	<u>Number</u>	<u>TA01-06-02</u>

¹⁷ <https://www.sec.gov/rules/final/33-8176.htm>

¹⁸ Improving Business Reporting: Insights into Enhancing Voluntary Disclosures, FASB Business Reporting Research Project, January 29, 2001.

Units of Measure

Unless specified, disclosures should be reported in International System of Units (SI units).

Uncertainty

The SASB recognizes that there may be inherent uncertainty when measuring or disclosing certain sustainability data and information. This uncertainty may be related to variables such as the reliance on data from third-party reporting systems and technologies, or the unpredictable nature of climate events. Where uncertainty around a particular disclosure exists, the SASB recommends that the registrant should consider discussing its nature and likelihood.¹⁹

Estimates

The SASB recognizes that scientifically-based estimates, such as the reliance on certain conversion factors or the exclusion of *de minimis* values, may occur for certain quantitative disclosures. Where appropriate, the SASB does not discourage the use of estimates or ranges. When using an estimate for a particular disclosure, the SASB expects that the registrant discuss its nature and substantiate its basis.

Timing

Unless otherwise specified, disclosure shall be for the registrant's fiscal year.

Limitations

There is no guarantee that SASB Standards address all sustainability impacts or opportunities associated with a sector, industry, or company; therefore, a company must determine for itself the topics that warrant discussion in its SEC filings.

Use of the SASB Standards is voluntary. The Standards are not intended to replace any legal or regulatory requirements that may be applicable to a company's operations. When such laws or regulations address legal or regulatory topics, disclosure under SASB Standards is not meant to supersede those requirements.

Use of the SASB Standards is not required or endorsed by the SEC or various entities governing financial reporting, including the Financial Accounting Standards Board, the Government Accounting Standards Board, or the International Accounting Standards Board.

Forward-Looking Statements

Disclosures on sustainability topics can, in some circumstances, involve discussion of future trends and uncertainties related to the registrant's operations and financial condition, including those influenced by external variables (e.g., environmental, social, regulatory, and political). Companies making these disclosures in SEC filings should familiarize themselves with the safe harbor provisions of Section 27A of the Securities Act, and Section 21E of the Exchange Act, which preclude civil liability for material misstatements or omissions in such statements if the registrant takes certain

¹⁹ The AICPA's Guide (see *supra* note 1) provides guidance related to measurement uncertainty.

steps. These include, among other things, identifying the disclosure as “forward-looking,” and accompanying such disclosure with “meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statements.”

Notes on the Sustainability Accounting Standards

The following sections contain the disclosure guidance associated with each accounting metric, including guidance on definitions, scope, accounting, compilation, and presentation.

The term “shall” is used throughout this document to indicate those elements that reflect requirements of the Standard. The terms “should” and “may” are used to indicate guidance, which, although not required, provides a recommended means of disclosure.

Table 2. Sustainability Disclosure Topics & Accounting Metrics

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
Access to Medicines	Description of initiatives to promote access to health care products in priority countries as defined by the Access to Medicine Index.	Discussion and Analysis	n/a	HC0101-01
	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP).	Discussion and Analysis	n/a	HC0101-02
Drug Safety and Side Effects	List of products listed in the FDA's MedWatch Safety Alerts for Human Medical Products (Drugs and Therapeutic Biological Products) database, including those products with Potential Signals of Serious Risks or that have New Safety Information identified by the FDA Adverse Event Reporting System (FAERS).	Discussion and Analysis	n/a	HC0101-03
	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System.	Quantitative	Number	HC0101-04
	List of products recalled.	Discussion and Analysis	n/a	HC0101-05
	Description of product stewardship initiatives to promote take-back and redistribution or safe permanent disposal of unused product at the end of its lifecycle. Where applicable: (1) amount of direct funding for such initiatives and (2) amount of product (by weight) accepted for take-back, reuse, or disposal.	Discussion and Analysis	n/a	HC0101-06
Safety of Clinical Trial Participants	Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials, including those conducted with third-party clinical research organizations (CROs). Description of processes for obtaining informed consent, of incentives offered to participants, and of any clinical trials terminated due to failure to follow good clinical practice standards.	Discussion and Analysis	n/a	HC0101-07
	Number of FDA Clinical Investigator Inspections of investigators used for clinical trials during the past year that resulted in: (1) Voluntary Action Indicated (VAI) and (2) Official Action Indicated (OAI).	Quantitative	Number	HC0101-08

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
	Description Total amount of losses as a result of legal and regulatory fines and settlements proceedings associated with clinical trials in World Bank Low-income and Lowermiddle-income Countries (LICs and LMICs) and UN HDI Medium-High-Development-Countries (MHDCs) that are not captured by the World Bank's LIC or LMIC rankings. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events. developing countries. ²⁰	Quantitative	U.S. Dollars (\$)	HC0101-09- TA01-02-01
Affordability and Fair Pricing	Number of settlements of Abbreviated New Drug Application (ANDA) litigation that involved payments and/or provisions to delay bringing an authorized generic product to market for a defined time period.	Quantitative	Number	HC0101-10
	Ratio of weighted average rate of net price increases (for all products) to the annual increase in the U.S. Consumer Price Index Percent change in a) average list price and b) average net price across U.S. product portfolio compared to previous year.	Quantitative	Percentage (%), U.S. Dollars (\$)	HC0101-11- TA01-03-01
	Percent change in a) list price and b) net price of product with largest increase compared to previous year.	Quantitative	Percentage (%), U.S. Dollars (\$)	TA01-03-02
Ethical Marketing	Description Total amount of losses as a result of legal and regulatory fines and settlements proceedings associated with false marketing claims, including Federal Food, Drug, and Cosmetic Act violations for off-label marketing prosecuted under the False Claims Act. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events. ²¹	Quantitative	U.S. Dollars (\$)	HC0101-12- TA01-04-01
	Description of code of ethics governing promotion of off-label use of products, including mechanisms to ensure compliance.	Discussion and Analysis	n/a	HC0101-13
Employee Recruitment, Development, and Retention	Description of talent recruitment and retention efforts for scientists and other research and development (R&D) personnel, such as mentorship and career development programs, leadership training, or unique incentive structures.	Discussion and Analysis	n/a	HC0101-14
	Training and development expenditures per full time employee by: (1) expenditures for industry or professional qualification and advanced industry education; (2) all other.	Quantitative	U.S. Dollars (\$)	HC0101-15

²⁰ Note to **TA01-02-01**— The registrant shall briefly describe the nature, context, and any corrective actions taken as a result of the losses.

²¹ Note to **TA01-04-01**— The registrant shall briefly describe the nature, context, and any corrective actions taken as a result of the losses.

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
	Employee turnover by voluntary and involuntary for: Executives/Senior Managers, Mid-level Managers, Professionals, All others (EEO-1 categories: technicians, sales, admin support, service workers).	Quantitative	Rate	HC0101-16
Employee Health and Safety	Total Injury Rate – (Number of recordable injuries and illnesses / Hours Worked)*200,000.	Quantitative	Rate	HC0101-17
	Days Away, Restricted, or Transferred (DART) rate – (Number of recordable injuries and illnesses resulting in days away from work, restricted work activity, or job transfers / Hours Worked)*200,000.	Quantitative	Rate	HC0101-18
	Laboratory-acquired infection (LAI) rate – LAIs per 1000 employees in human and animal diagnostic laboratories	Quantitative	Rate	HC0101-19
Counterfeit Drugs	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting.	Discussion and Analysis	n/a	HC0101-20
	Description of process for alerting end customers and business partners of potential or known risks associated with counterfeit products.	Discussion and Analysis	n/a	HC0101-21
	Number (and description) of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products.	Quantitative	Number	HC0101-22
Energy, Water, and Waste Efficiency	Total annual energy consumed (gigajoules) and percentage renewable (e.g., wind, biomass, solar).	Quantitative	Gigajoules, Percentage (%)	HC0101-23
	Total water withdrawals and percentage in water-stressed regions – High or Extremely High Baseline Water Stress as defined by the WRI Water Risk Atlas; percentage of process water recycled.	Quantitative	Cubic meters (m ³), Percentage (%)	HC0101-24
	Overall Process Mass Intensity (PMI) and PMI broken down for water and organic solvents, where PMI = quantity of raw materials input (kg) / quantity of active pharmaceutical product (API) output (kg).	Quantitative	Rate, Kilograms (kg)	HC0101-25
	Amount of waste (metric tons); percentage that is recycled, incinerated (including for energy recovery), and landfilled.	Quantitative	Metric Tons (t), Percentage (%)	HC0101-26
Corruption and Bribery	<u>Total amount of losses as a result of legal proceedings associated with corruption and bribery.</u> ²²	<u>Quantitative</u>	<u>U.S. Dollars (\$)</u>	<u>HC0101-27, TA01-05-01</u>

²² Note to **TA01-05-01**— The registrant shall briefly describe the nature, context, and any corrective actions taken as a result of the losses

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
	Description of code of ethics governing interactions with health care professionals, including mechanisms to ensure employee compliance.	Discussion and Analysis	n/a	HC0101-28
Manufacturing and Supply Chain Quality Management	Description of FDA enforcement actions taken in response to violations of current good manufacturing practices (cGMP), including: product deemed adulterated, form 483s, suggested recall (Class I, II, III), Warning Letters, Border Alerts, license suspension or revocation, product seizure, Consent Decrees, criminal prosecution. Description of corrective actions implemented in response to actions.	Discussion and Analysis	n/a	HC0101-29
	Percentage of facilities and Tier I suppliers participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients (e.g., APIs, chemical, raw material, excipients, etc.).	Quantitative	Percentage (%)	HC0101-30

Access to Medicines

Description

Biotechnology and pharmaceuticals companies play an important role in providing access to the industry's products around the world. Firms can develop pricing frameworks that account for differing levels of economic development and health care needs across various countries. Further, the industry can target priority diseases in developing countries. A strategic approach to access to medicines can yield opportunities for growth, innovation, and unique partnerships, which can enhance shareholder value.

Accounting Metrics

HC0101-01. Description of initiatives to promote access to health care products in priority countries as defined by the Access to Medicine Index .

- .01 Disclosure applies to initiatives the registrant, launched, funded, supported, or otherwise participated in during the fiscal year that related to improving access to health care in priority countries. A product shall be discussed if it was authorized for sale and available during the fiscal year. Initiatives shall be discussed if implementation was ongoing during the fiscal year. Initiatives that began or concluded during the fiscal year may be discussed; the registrant, however, should indicate this condition.
- .02 The following issues as they relate to access to health care initiatives may be relevant for the registrant to discuss: research and development, pricing, public policy and market influence efforts, manufacturing and distribution, patents and licensing, product donations, and philanthropic activities.
- .03 The Access to Medicine Foundation considers the priority issues and diseases in priority countries to be those with the highest Disability Adjusted Life Years (DALY) based on WHO data. These include communicable, non-communicable, neglected tropical diseases, neonatal infections, and maternal health conditions. A full list is on page 17 of the [Access to Medicine Index Methodology 2012](#).
- .04 Initiatives discussed should focus on the aforementioned diseases and conditions. The registrant may discuss additional or alternative diseases and conditions but should provide evidence that they are considered a priority in the priority countries discussed.
- .05 Priority countries comprise those that meet the following definition: (1) Low-income and Lowermiddle- income Countries (LICs and LMICs) based on World Bank classifications (updated in July 2011) or (2) UN HDI Medium-High Development Countries (MHDCs) (updated in 2011) that are not automatically captured by the World Bank LIC or LMIC rankings. The full list of countries included is on [Page 14 of Access to Medicine Index Page 14 of Methodology 2012](#).

Note to HC0101-01

- .06 Priority diseases include: the top 10 communicable diseases based on Disability Adjusted Life Years (DALY) from the WHO Global Burden of Disease; the top 10 non-communicable diseases based on DALYs from the WHO Global Burden of Disease; 14 of the WHO Neglected Tropical Diseases. A full list is in on page 17 of the [Access to Medicine Index Methodology 2012](#).

HC0101-02. List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP).

- .07 Using the WHO List of Prequalified Medicinal Products (publicly accessible [here](#)), the registrant shall conduct a search within the “Applicant” field for the registrant and count all products listed by International Nonproprietary Name (INN).
- .08 Multiple listings of the same active pharmaceutical product (API) in different strengths (e.g., 30 mg and 20 mg) shall be counted once. Multiple listings of the same API in different formulations (e.g., tablet and capsule) shall be counted once. Listings of single APIs (e.g., Lamivudine) and combinations of the same API with one or more additional APIs (e.g., Lamivudine + Stavudine) shall be counted separately but following guidance for multiple strengths and formulations. Products listed under the status “Suspended” shall not be counted.
- .09 An itemized list should be provided of products by International Nonproprietary Name (INN), including brand name(s) in parentheses where applicable. The registrant may also choose to disclose the number of its products targeting each WHO-defined therapeutic area: Diarrhoea, HIV/AIDS, Influenza, Malaria, Reproductive Health, and Tuberculosis.
- .10 Disclosure applies to products manufactured and/or marketed by the registrant during the fiscal year. A product should be discussed if it was authorized for sale and available during the fiscal year. Initiatives should be discussed if implementation was ongoing during the fiscal year.

Drug Safety ~~and Side Effects~~

Description

Information on product safety ~~and side effects~~ can surface after controlled clinical trials and approval. Subsequently, companies are exposed to the financial implications of recalls and other adverse events. Biotechnology and pharmaceuticals firms that limit safety issues will be better positioned to protect shareholder value. In addition, concern over the abuse or resale of certain medications has led to mandated take-back programs. Firms that are able to successfully engage in these programs will likely limit future liabilities.

Accounting Metrics

HC0101-03 . List of products listed in the FDA’s MedWatch Safety Alerts for Human Medical Products (Drugs and Therapeutic Biological Products) database, including those products with Potential Signals of Serious Risks or that have New Safety Information identified by the FDA Adverse Event Reporting System (FAERS).

- .11 The registrant should access the publicly available list of Safety Alerts for Human Medical Products issued as part of the FDA’s MedWatch Safety Information and Adverse Event Reporting Program by navigating to the “Safety Alerts for Human Medical Products” subsection of the “Safety Information” section of the “MedWatch: The FDA Safety Information and Adverse Event Reporting Program” page, [here](#).
- .12 The safety alerts are organized into four categories: (1) Drugs and Therapeutic Biological Products, (2) Medical Devices, (3) Special Nutritional and Cosmetic Products, and (4) Products with Undeclared Drug Ingredients.
- .13 The registrant should review the Product Names on the Drugs and Therapeutic Biological Products and disclose all listings associated with the registrant. This includes trade names for which the registrant has patents or active ingredients or classes of product that it manufactures and markets.
- .14 Additionally, the registrant should access the publicly available list of products for which the FDA staff in the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) have identified potential safety issues. The registrant should access the quarterly reports via www.fda.gov by navigating to the “Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS) (formerly AERS)” page under the FDA Adverse Event Reporting System (FAERS) page, [here](#).

Note to HC0101-03

- .16 MedWatch is the Food and Drug Administration’s mechanism for consumers and health professionals to report serious adverse event, product quality problem, product use error, therapeutic inequivalence/failure, or suspected counterfeit medical products associated with FDA-regulated drug, biologic, medical device, dietary supplement, or cosmetic products.
- .17 The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA’s post-marketing safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS

database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation (ICH E2B). Adverse events and medication errors are coded to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology.

Additional References

[Instructions](#) for Completing Form FDA 3500A

[MedWatch Online Voluntary Reporting Form](#) (3500)

Products are listed by “active ingredient and trade name (if applicable)” or by “product class.”

The registrant shall disclose all listings associated with the registrant. This includes trade names for which the registrant has patents and active ingredients or classes of product that it manufactures and markets.

If the registrant manufactures a product with an active ingredient or a product in a product class listed in the database but has evidence that the listing does not apply to its specific products, it shall provide such evidence.

HC0101-04. Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System.

- .18 Registrants should access the ASCII or SGML data files that are publicly available through “The FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files” system by navigating to the “The FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files” page under the “FDA Adverse Event Reporting System (FAERS)” page, [here](#).
- .19 Data files are summarized and reported quarterly; the registrant should download and access files covering its entire fiscal year. Files can be viewed by creating a relational database using applications such as ORACLE®, Microsoft Office Access, MySQL® and IBM DB2 or SAS® analytic tools.
- .20 The registrant should open the quarterly files “DEMOyyQq.TXT,” which contains patient demographic and administrative information for each event report, including the manufacturer of the drug or biologic product associated with the event.
- .21 The registrant should query the database column “MFR_SNDR,” which contains the verbatim name of the manufacturer that submitted each report. Because the database is a verbatim record of submittals, the registrant must ensure that its query accounts for any and all variations and abbreviations of its name.
- .22 Furthermore, it must account for the fact that the database does not allow for special characters or symbols such as ampersand (“&”) and replaces them with a period (“.”).
- .23 The registrant should record all Individual Safety Report (ISR) numbers for entries associated with it; the ISR number uniquely identifies an AERS report and is the primary link field between data files.
- .24 Finally, the registrant should open the quarterly Outcome files “OUTCyyQq.TXT” and query all ISR numbers associated with it that have an outcome code of “DE” for death/fatality.

- .25 Using the “The FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files” system, the registrant shall disclose the absolute number of fatalities associated with all drugs and biologic products it manufactures. The registrant shall disclose all fatalities that occurred during the fiscal year for which it is disclosing, even if the adverse event began in a prior period.

HC0101-05. List of products recalled

- .26 A recall is an action taken by a registrant to remove a product from the market. Recalls may be conducted voluntarily by a registrant, or they may be mandatory and initiated by FDA request or by FDA order under statutory authority. Registrants shall disclose each type of recall.
- .27 Registrants should review the weekly Enforcement Reports published by the FDA, which are publicly available on the “Recalls, Market Withdrawals, & Safety Alerts” subsection of the FDA’s “Safety” webpage. The registrant may access the list of recalls via www.fda.gov, by navigating to the “Enforcement Reports” subsection of the “Recalls, Market Withdrawals, & Safety Alerts” section of the FDA’s “Safety” page, [here](#). These reports contain all recalls by Product Type, Product Description, Code Info, Classification, Reason for Recall, and Recalling Firm. The registrant shall identify all products manufactured by it or its subsidiaries for which it is listed as the Recalling Firm in the “Biologics” and “Drugs” product types.
- .28 The registrant shall also disclose recalls in foreign markets that have been initiated voluntarily, at the request of a foreign national regulatory authority, or by order of a foreign national regulatory authority under statutory authority. The registrant shall also disclose recalls initiated voluntarily that have not been reported to the FDA (or national regulatory authority) and/or are not listed in an FDA Enforcement Report.
- .29 For FDA-initiated recalls, the registrant may choose to disclose the FDA classification of each recall: Class I, Class II, or Class III.
- .30 For each recalled product, the registrant may choose to disclose revenues from the twelve months prior to the date of recall. This twelve-month period may extend beyond the fiscal year for which the registrant is disclosing; the figure is intended to indicate annual revenues associated with the product so that the financial impact of the recall can be gauged.
- .31 If a recall relates to only a subset of a product (e.g., specific lots or a particular style) then the registrant should indicate the scope of the recall; and, if the registrant is disclosing revenue associated with the recall, it should be limited to the portion of the product affected by the recall.
- .32 The registrant should list recalls associated with all drugs and biologic products manufactured by the registrant and its subsidiaries.

Note to HC0101-05

Definitions:

Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

HC0101-06. Description of product stewardship initiatives to promote take-back and redistribution or safe permanent disposal of unused product at the end of its lifecycle. Where applicable: (1) amount of direct funding for such initiatives, and (2) amount of product (by weight) accepted for take-back, reuse, or disposal.

- .33 The registrant shall discuss systemic efforts related to end-of-life management of its products, including those intended to preventing black-market sales, abuse, and release into the environment.
- .34 Unused product includes that which is expired, unwanted, waste, or excess. Product take-back includes reclaiming unused products from end-consumers or medical facilities for redistribution or disposal. Biopharmaceutical reuse programs would include redistribution initiatives aimed at providing medication to underserved populations, subject to state or local laws. Safe permanent disposal of biopharmaceutical products often involves high-temperature incineration and must be conducted in accordance with federal or state laws governing management of unused pharmaceuticals, such as the Controlled Substance Act, the Resource Conservation and Recovery Act (RCRA), the Centers for Medicare & Medicaid Services (CMS), and the Health Insurance Portability and Accountability Act (HIPAA).
- .35 Direct funding of initiatives includes programs or initiatives that are financially supported and administered by the registrant as well as initiatives funded by the registrant that are administered by third parties for the express purpose of product take-back. The registrant should disclose expenditures in dollars for the fiscal year.
- .36 The registrant shall disclose the amount of product (in metric tons) that is accepted through the initiatives. For initiatives that are co-funded by the registrant, it shall prorate the amount of product accepted for take-back by its percentage contribution to the funding of the initiative.

Safety of Clinical Trial Participants

Description

Clinical trials are an essential component of the approval process for biotechnology [and pharmaceutical](#) products. The safety of clinical trial participants reflects a company's ability to successfully bring a product to market. Oversight of these trials is of increasing importance as the number of clinical trials conducted by third party contract research organizations in emerging countries continues to rise. Biotechnology [and pharmaceuticals](#) companies that effectively manage clinical trials may be positioned to enhance shareholder value through the revenue associated with new products.

Accounting Metrics

HC0101-07. Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials, including those conducted with third-party clinical research organizations (CROs). Description of processes for obtaining informed consent, of incentives offered to participants, and of any clinical trials terminated due to failure to follow good clinical practice standards.

- .37 Registrant shall describe its oversight of CROs' quality and safety systems, such as the type of procedures followed (e.g., if it is proprietary to the registrant, developed by the CRO, and/or it follows established third-party guidelines), use and frequency of audits or inspections, and enforcement mechanisms.
- .38 As outlined by the U.S. Department of Health and Human Services, informed consent requires more than legally effective acceptance of participation in a clinical trial – it also involves, on the part of the registrant, [\(1\)](#) disclosing to potential research subjects information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research.
- .39 A Clinical Research Organization or Contract Research Organization (CRO) is a scientific organization (commercial, academic or other) to which the registrant has transferred some of its tasks and obligations as a sponsor.
- .40 Registrant shall disclose the management process for CROs, broken down by the following world regions: North America, Central and Latin America, Asia (including the Middle East), and Africa.
- .41 The registrant should describe the nature and terms of monetary incentives that it uses or that are used by CROs with which it contracts. Reimbursements for meal, travel, or lodging should not be discussed.
- .42 Additionally, the registrant shall list all trials, conducted by the registrant (including those outsourced to third parties such as CROs), that were terminated for failure to follow good clinical practice standards.
- .43 Good Clinical Practice ([GCP](#)) are defined and regulated by the U.S. Food and Drug Administration and through International CGP guidance that has been adopted by the FDA.
- .44 The registrant shall list all clinical trials terminated – whether the decision was made by investigator(s) or the study sponsor, and whether it was made with or without the input of a Data Monitoring Committee (DMC).

- .45 Disclosure should not include clinical trials terminated for reasons other than those related to GCP, such as reallocation of funding, loss of personnel, failure to meet study benchmarks, lack of participants, etc.
- .46 **Scope:** The registrant should discuss its management process with respect to all CROs it has worked with during the past fiscal year or with which it has worked with in the past and plans to work with in the future.

HC0101-08. Number of FDA Clinical Investigator Inspections of investigators used for clinical trials during the past year that resulted in: (1) Voluntary Action Indicated and (2) Official Action Indicated.

- .47 Registrant should access the publicly available Clinical Investigator Inspection Search via the “Drug Approvals and Databases” page on the FDA’s “Drugs” site. The current link is [here](#).
- .48 Registrants should search the database for inspections of investigators that they have used for clinical trials during the fiscal year. The FDA’s Clinical Investigator Inspection List (CLIL) is organized by individual investigators
- .49 (i.e., individual persons at research locations); however, a search can be conducted by “location” for the name – or variations of the name – of the registrant’s facilities or Clinical Research Organizations (CROs) it uses.
- .50 The registrant shall disclose inspections of investigators that conducted clinical trials for the registrant or on behalf of the registrant (such as at a CRO).
- .51 The registrant shall disclose the number of inspections that resulted in a classification of Voluntary Action Indicated (VAI) or Official Action Indicated (OAI), as listed in the “Classification” column.
- .52 **Scope:** The registrant shall disclose VAIs and OAIs issued to investigators who participated in the registrant’s or its subsidiaries’ clinical trials during the past year. This includes investigators working on behalf of the registrants or its subsidiaries at a CRO.

~~HC0101-09~~ **TA01-02-01. Total amount of losses as a result of legal and regulatory fines and settlements/proceedings associated with clinical trials in developing countries.**

- .53 The registrant shall disclose the total amount of losses in U.S. Dollars it incurred as a result of legal proceedings associated with clinical trials in developing countries.
- .54 The legal proceedings shall include any adjudicative proceeding, whether before a court, a regulator, an arbitrator, or otherwise, in which the registrant was involved.
- .55 The losses shall include all fines, settlements, and other monetary liabilities as a result of civil actions (e.g., civil judgments or settlements), regulatory proceedings (e.g., penalties, disgorgement, or restitution), and criminal actions (e.g., criminal judgment, penalties, or restitution) brought by any entity (governmental, business, or individual).
- .56 The losses shall exclude legal fees incurred by the registrant.
- .57 The scope of the disclosure shall include, but is not limited to, legal proceedings associated with clinical trials in countries that meet the criteria established by the [Access to Medicine Index Methodology](#) ~~World Bank~~, including:

- Low-income as defined by the World Bank income classifications
- Lower-middle-income as defined by the World Bank income classifications
- Least Developed Country as defined by the UN Committee for Development Policy and Lower middle-income Countries (LICs and LMICs) and UN HDI
- Low or Medium-High Human Development Countries (MHDCs) that are not captured by the UN Human Development Index World Bank's LIC or LMIC rankings. Dollar
- All countries that receive a score of less than 0.6 on the UN Inequality-Adjusted Human Development Index amount of fines and settlements and a description of corrective actions implemented in response to events. The registrant shall briefly describe the nature and context of fines and Disclosure shall include civil actions (e.g., civil judgment, settlements associated with clinical trials in the specified countries, including civil actions (e.g., civil judgment, settlements, or regulatory penalties) and criminal actions (e.g., criminal judgment, penalties, or restitutions) taken by any entity (government, businesses, or individuals).

Note to TA01-02-01

~~53.58~~ The registrant shall disclose briefly describe the amount of any fine or order issued after trial, settlement associated with each incident, not including, guilty plea, deferred prosecution agreement, non-prosecution agreement) and context of all losses as a result of legal fees/proceedings.

~~54.59~~ The registrant shall describe any corrective actions it has implemented as a result of each incident. The registrant shall describe any corrective actions it has implemented as a result of the legal proceedings. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology

~~55~~ The scope of countries comprises those that meet the following definition: (1) Low income and Lower middle-income Countries (LIC and LMICs) based on World Bank classifications, updated in July 2011, or (2) UN HDI-Medium-High-Development Countries (MHDCs) (updated in 2011) that are not automatically captured by the World Bank LIC or LMIC rankings. A current, full list of countries within the scope of disclosure is on page 14 of

Additional References

Definitions

~~—Objectionable conditions were found but the problems do not justify further regulatory action. Any corrective action is left to the investigator to take voluntarily.~~

~~—Official Action Indicated. Objectionable conditions were found and regulatory and/or administrative sanctions by FDA are indicated.~~

Affordability and Fair Pricing

Description

~~Legislative Stakeholder~~ emphasis in the U.S. and abroad on health care cost containment and increased access will continue to place downward pricing pressures on ~~biotechnology products~~ the Biotechnology & Pharmaceuticals industry. As a result, companies that have relied on raising drug prices, contractual advantages, and reverse payments to protect profits may be challenged to enhance value as efforts to reduce costs gain traction. Firms that are able to avoid stakeholder scrutiny on pricing practices and ensure access and fair pricing may limit the negative impact of cost containment, ~~while recognizing the potential revenue opportunities associated with expanded access~~.

Accounting Metrics

HC0101-10. Number of settlements of Abbreviated New Drug Application (ANDA) litigation that involved payments and/or provisions to delay bringing an authorized generic product to market for a defined time period.

~~56.60~~ The registrant shall disclose all instances in which it entered into settlement relating to a challenge of one of its patents under the Paragraph IV-certified Abbreviated New Drug Application (ANDA) process established under the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act") and in which that settlement involved compensation for the generic challenger and/or an agreement on behalf of the generic challenger to delay entry to the market of a generic bioequivalent.

~~57.61~~ Payments include direct monetary settlement paid to a generic manufacturer as well as forms of implicit compensation, such as reduced royalty payment for delayed market entry or agreement by the registrant not to introduce its own authorized generic (AG) during the 180-day "first filer" period.

~~58.62~~ The registrant should indicate if it entered multiple settlements for the same product.

~~TA01-03-01. HC0101-11. Ratio of weighted Percent change in a) average rate of netlist price increases (for all products) to the annual increase in the U.S. Consumer Price Index. The and b) average net price increases should be weighted based on sales volume of across U.S. product portfolio compared to previous year.~~

~~59.63~~ The registrant shall disclose the average list price increase across all of the registrant's pharmaceutical products sold in the U.S. during the fiscal year, where:

- ~~• The registrant should use the annual (December to December) average list price increase of the Consumer Price Index shall be calculated as percent change versus the prior year for All Urban Consumer (CPI-U) each product weighted by list price across the registrant's U.S. portfolio of pharmaceutical products.~~
- ~~• The list price shall represent the average wholesale acquisition cost (WAC) and shall represent the average WAC for the year in which it is being calculated.~~

~~64~~ The registrant shall disclose the average net price increase across all the registrant's pharmaceutical products sold in the U.S. during the fiscal year. Current Consumer Price Index data from the U.S. Department, where:

- The annual average net price increase shall be calculated as percent change versus the prior year and for each product weighted by list price across the registrant's U.S. portfolio of ~~labor can be accessed~~ pharmaceutical products.
- The net price shall represent the average wholesale acquisition cost (WAC) minus rebates, discounts, and returns and shall represent the average WAC minus rebates, discounts, and returns for the year in which it is being calculated.

Additional References

~~Pharmaceutical Agreement filings with the FTC under The Medicare Prescription Drug, Improvement, and Modernization Act of 2003:~~

TA01-03-02. Percent change in a) list price and b) net price of product with largest increase compared to previous year

.65 The registrant shall disclose the percent change in list price and the name of the product with the largest increase in list price compared to previous year, where

- The change in net price increase shall be calculated as the percent change in price between the current and prior year for an individual product.
- List price should represent the average wholesale acquisition cost (WAC) for the specific product and shall represent the average WAC for the year in which it is being calculated.

.66 The registrant shall disclose the percent change in net price and the name of the product with the largest increase in net price compared to previous year, where:

- The change in net price increase should be calculated as percent change in price between the current and prior year for an individual product.
- The net price shall represent: the average wholesale acquisition cost (WAC) minus rebates, discounts, and returns for the specific product and shall represent the average WAC minus rebates, discounts, and returns for the year in which it is being calculated.

Ethical Marketing

Description

Biotechnology and pharmaceuticals companies face challenges associated with the marketing of specific products. Consumer-directed advertisements for prescription drugs in the U.S. provide opportunities for increasing market share. However, challenges also arise from the potential for marketing off-label uses. Corporate disclosure of legal and regulatory fines and the codes of ethics that govern interactions with health professionals will allow shareholders to monitor performance in this area.

Accounting Metrics

~~TA01-04-01. HC0101-12 . Description Total amount of losses as a result of legal and regulatory fines and settlements proceedings associated with false marketing claims, including Federal Food, Drug,~~

~~.67 The registrant shall disclose the total amount of losses in U.S. dollars it incurred as a result of legal proceedings associated with false marketing claims.~~

~~.68 The legal proceedings shall include any adjudicative proceeding, whether before a court, a regulator, an arbitrator, or otherwise, in which the registrant was involved.~~

~~.69 The losses shall include all fines, settlements, and other monetary liabilities as a result of civil actions (e.g., civil judgments or settlements), regulatory proceedings (e.g., penalties, disgorgement, or restitution), and criminal actions (e.g., criminal judgment, penalties, or restitution) brought by any entity (governmental, business, or individual).~~

~~.70 The losses shall exclude legal fees incurred by the registrant.~~

~~.71 The scope of disclosure shall include legal proceedings associated with enforcement of Biotechnology & Pharmaceuticals industry regulations promulgated by U.S. and Cosmetic Act violations for off label marketing prosecuted under the False Claims Act. Dollar amount of fines foreign regulatory authorities. Such regulatory authorities may include, but are not limited to:~~

- ~~• The Department of Justice~~
- ~~• The Food and settlements and a description of corrective actions implemented in response to events-Drug Administration~~

Note to **TA01-04-01**

~~.72 The registrant shall briefly describe the nature (e.g., judgment or order issued after trial, settlement, guilty plea, deferred prosecution agreement, non-prosecution agreement) and context of fines and settlements related to promotion of all losses as a result of legal proceedings. off label use of its products, including civil actions (e.g., civil judgment, settlements or regulatory penalties) and criminal actions (e.g., criminal judgment, penalties or restitutions) taken by any entity (government, businesses, or individuals).~~

~~60~~ This includes whistleblower cases related to off-label marketing of the registrant's products in violation of the Federal Food, Drug, and Cosmetic Act prosecuted under the False Claims Act.

~~61~~ The registrant shall disclose the amount of any fine or settlement associated with each incident, not including legal fees.

~~62.73~~ The registrant shall describe any corrective actions it has implemented as a result of each incident. ~~This~~These may include, but ~~is~~are not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

~~63.74~~ If relevant, the registrant should discuss other implications associated with the fine or settlement, such as exclusion from government reimbursement programs, entry into Corporate Integrity Agreements (CIAs) with governmental agencies and amendments to existing CIAs.

HC0101-13. Description of code of ethics governing promotion of off-label use of products, including mechanisms to ensure compliance.

~~64.75~~ The registrant shall describe the aspects of its code of ethics that relate to ethical marketing and off-label promotion, including describing how it defines and/or what it considers "off-label promotion."

~~65.76~~ A corporate policy, code of conduct, guideline, or contractual term that is similar in intent to a code of ethics shall be treated as equivalent for the purposes of this metric.

~~66.77~~ The registrant shall describe the mechanisms it has in place to ensure compliance with its code, which may include training, internal audits, regulatory review committees, or disciplinary actions for violations.

Additional References

Definitions

~~Promotion—any proactive activities (written, oral, or otherwise) that directly or indirectly market, sell, or support product sales and use, or that contribute to the sales growth of the registrant's products.~~

~~—when a drug is used in a way that is different from that described in the FDA-approved drug label, it's said to be an "off-label" use. This can mean that the drug is: used for a different disease or medical condition, given in a different way (such as by a different route), or given in a different dose than in the approved label.~~

Employee Recruitment, Development, and Retention

Description

Biotechnology and pharmaceuticals companies face intense competition for employees. The industry relies on highly skilled employees to develop new products, conduct clinical trials, manage government regulations, and commercialize new products. Firms that are able to attract and retain employees in light of a limited talent pool may be better positioned to protect and enhance shareholder value.

Accounting Metrics

HC0101-14. Description of talent recruitment and retention efforts for scientists and other research and development (R&D) personnel, such as mentorship and career development programs, leadership training, or unique incentive structures.

~~67.78~~ The registrant shall describe its strategy to attract and retain talent, including specific efforts related to mentorship programs, career development programs, and leadership training, as well as any incentive structures employed by the registrant that may be unique (such as team-based incentives). It may be relevant to describe the following elements of programs: overview, implementation, participation, effectiveness (with any quantitative metrics).

~~68.79~~ Discussion shall focus on scientists and other personnel that are directly involved in research and development of activities for new biopharmaceutical products.

HC0101-15. Training and development expenditures per full-time employee by: (1) expenditures for industry or professional qualification and advanced industry education; (2) all other.

~~69.80~~ The registrant shall calculate (1) qualification and education expenditures per employee as: total dollar amount for the fiscal year spent on industry and professional qualification (such as credentialing programs and board certification) plus total dollar amount for the fiscal year spent on advanced industry education (such as degree and certificate programs directly related to job function) divided by full time employees (monthly average for fiscal year).

~~70.81~~ The registrant shall calculate (2) all other training expenditures per employee as the absolute value of: total dollar amount spend on all employee job-related training less dollar amount spent on industry and professional qualification and advanced industry education (calculated above) divided by full time employees (monthly average for fiscal year).

HC0101-16. Employee turnover by voluntary and involuntary for: Executives/Senior Managers, Mid-level Managers, Professionals, All others (EEO-1 categories technicians, sales, admin support, service workers)-).

~~71.82~~ The registrant shall classify all employees according to the [U.S. Equal Employment Opportunity Commission EEO-1 Job Classification Guide](#) and record the number of employees employed at any time during the fiscal year in each classification.

~~72.83~~ For each classification, the registrant shall calculate monthly voluntary turnover as = total number of employee- initiated voluntary separations (such as resignation, retirement, etc.) for each month divided by the average number of employees for the month (the sum of the employees on the registrant's payroll at each pay period / number of pay periods). The registrant shall disclose its annual voluntary turnover rate which is calculated by adding the 12 monthly turnover figures together and multiplying by 100 to arrive at a percentage.

~~73.84~~ For each classification the registrant shall calculate monthly involuntary turnover as = total number of registrant-initiated separation (such as dismissal, downsizing, redundancy, expiry of contract, etc.) for each month divided by the average number of employees for the month (the sum of the employees on the registrant's payroll at each pay period / number of pay periods). The registrant shall disclose its annual involuntary turnover rate, which is calculated by adding the 12 monthly turnover figures together and multiplying them by 100 to arrive at a percentage.

Additional References

~~Society of Human Resources Management, Executive Brief: Tracking Trends in Employee Turnover~~

Employee Health and Safety

Description

~~The biotechnology~~ [The Biotechnology & Pharmaceuticals](#) industry is subject to federal, state, and local regulations regarding workplace safety. Companies must ensure compliance and in many cases exceed current regulations to protect the health and safety of employees who are exposed to hazardous materials, chemicals, viruses, and other essential inputs. A failure to manage these risks may result in negative material impacts through litigation, fines, and penalties.

Accounting Metrics

HC0101-17. Total Injury Rate – (Number of recordable injuries and illnesses / Hours Worked)*200,000 .

~~.74.85~~ If a registrant's workforce is entirely U.S.-based, it shall disclose its total injury rate as calculated and reported in the Occupational Safety and Health Administration's (OSHA) Form 300.

~~.75.86~~ If a registrant's workforce includes non-U.S.-based employees, it shall calculate its total injury rate according to the [U.S. Bureau of Labor Statistics guidance](#) and/or using the [U.S. Bureau of Labor Statistics calculator](#).

HC0101-18. Days Away, Restricted, or Transferred (DART) rate – (Number of recordable injuries and illnesses resulting in days away from work, restricted work activity, or job transfers ~~+~~/Hours Worked)*200,000.

~~.76.87~~ If a registrant's workforce is entirely U.S.-based, it shall disclose its DART rate as calculated and reported in the Occupational Safety and Health Administration's (OSHA) Form 300.

~~.77.88~~ If a registrant's workforce includes non-U.S.-based employees, it shall calculate its DART rate according to the [U.S. Bureau of Labor Statistics guidance and/or using the U.S. Bureau of Labor Statistics calculator](#).

HC0101-19. Laboratory-acquired infection (LAI) rate – LAIs per 1000 employees in human and animal diagnostic laboratories.

~~.78.89~~ Laboratory-acquired infections include all infections acquired through laboratory or laboratory-related activities, regardless whether they are symptomatic or asymptomatic in nature.

~~.79.90~~ The registrant shall disclose the number of laboratory-acquired infections per 1000 employees, even if these incidents are included in data for HC0101-17 and/or HC0101-18.

Counterfeit Drugs

Description

The World Health Organization estimates that ~~the global market for~~ counterfeit drugs ~~has reached \$431 billion, representing~~ represent one percent of the U.S.'s supply, and 10–15 percent of the world's pharmaceuticals market. This issue presents a significant health and safety risk to consumers with an estimated 100,000 annual deaths attributed to substandard or counterfeit drugs worldwide. Biotechnology and pharmaceuticals companies may subsequently face material risks associated with the potential loss of public confidence and reduced revenue.

Accounting Metrics

HC0101-20. Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting.

~~80.91~~ Traceability refers to the ability to track identifying information (e.g., chemical composition, supplier, production date, production location, processing history, etc.) of a product throughout various stages of manufacturing and distribution (such as raw material source, manufacturing, distribution, and retail). For the ~~biotechnology pharmaceutical~~ Biotechnology & Pharmaceuticals industry, relevant stages include manufacturing, logistics transportation, drug wholesale and distribution, and pharmacy retail.

~~81.92~~ The registrant shall discuss the type and sophistication of technology it uses to maintain traceability and serialization of its products. This may range from the use of a barcode to the use of radio frequency identification (RFID) tagging.

Additional References

[Prescription Drug Marketing Act pedigree requirements](#)

HC0101-21. Description of process for alerting end customers and business partners of potential or known risks associated with counterfeit products.

~~82.93~~ Business partners include suppliers, wholesalers, retailers, hospitals, etc.

~~83.94~~ In addition to providing an overview of its procedures, the registrant shall describe how it communicates potential or known risks associated with the counterfeit products (e.g., through maintenance of a list of products with a higher risk of being counterfeited), recommended actions for the respective parties to minimize risks of counterfeiting, and mechanisms for product recall.

HC0101-22. Number (and description) of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products.

~~84.95~~ The registrant shall disclose the number of instances in which it took action to alert and/or aid regulatory authorities or law enforcement agencies with respect to counterfeiting. This may include having provided information or evidence that led to raids or arrests of counterfeiters or the seizure of counterfeit products, or instances where it the filed criminal charges against counterfeiters. If the registrant collaborated with other

entities, such as manufacturers, wholesalers, or pharmacies, it may disclose these instances but should indicate which other entities were involved.

~~85.96~~ The registrant shall also provide a description of actions taken, including – where relevant – the parties involved, role of the registrant, type and value of products in question, and outcome of the action.

~~86.97~~ Relevant authorities and agencies include the U.S. FDA, the British Medicines and Healthcare products Regulatory Authority (MHRA), the Australian Therapeutic Goods Administration (TGA), or equivalent agencies.

Energy, Water, and Waste Efficiency

Description

The manufacturing of biotechnology and pharmaceutical products requires the use of energy, water, and material inputs, in addition to the creation of waste. As concerns over climate change and dwindling natural resources continue to impact pricing, ~~biotechnology~~ biotechnology and pharmaceuticals companies will be exposed to fluctuations in costs of these key inputs. Firms that are able to improve manufacturing efficiencies and limit dependence on finite resources ~~are likely to~~ may enhance shareholder value.

Accounting Metrics

HC0101-23. Total annual energy consumed (gigajoules) and percentage renewable (e.g., wind, biomass, solar).

~~-87.98~~ The registrant shall convert the amount of electricity it consumed from kilowatt hours (kWh) to gigajoules (GJ).

~~-88.99~~ The registrant shall disclose fossil fuel consumption in terms of its energy content, using higher heating values (HHV), also known as gross calorific values (GCV), and which are directly measured or taken from the Intergovernmental Panel on Climate Change (IPCC), the U.S. Department of Energy (DOE), or the U.S. Energy Information Administration (EIA).

~~-89.100~~ The registrant shall disclose renewable energy consumption as a percentage of its overall energy consumption, in terms of its energy content. For biofuels, the registrant shall use HHVs from the sources mentioned above. For solar or wind energy consumption, the registrant shall convert from electricity production (kWh) to gigajoules (GJ).

~~-90.101~~ The registrant shall disclose renewable energy data for renewable energy it directly produces, or which it purchases through renewable energy certificates (RECs) that are certified (i.e., through Green-e), or renewable power purchase agreements (PPAs). It shall not disclose the renewable portion of the energy drawn from electricity grids.

HC0101-24. Total water withdrawals and percentage in water-stressed regions – High or Extremely High Baseline Water Stress as defined by the WRI Water Risk Atlas; percentage of process water recycled.

~~-91.102~~ Water withdrawal is the total amount of water removed from freshwater sources for use in operations. This figure should not include water use in manufacturing that is recycled. Water withdrawals shall be disclosed in terms of cubic meters (m³).

~~-92.103~~ Using the World Resources Institute's (WRI) Water Risk Atlas tool, Aqueduct (publicly available online [here](#)), the registrant shall analyze all of its manufacturing facilities for water risks and identify facilities that are in a location with High (40–80%) or Extremely High (>80%) Baseline Water Stress.

~~-93.104~~ The registrant shall separately disclose the percentage of total water withdrawals by volume (m³) that was recycled during the fiscal year. This figure shall include the amount recycled in closed loop and open loop systems. Water recycled for purposes other than manufacturing processes (e.g., grey water reuse) shall not be included in this figure.

Additional References

~~Corporate Water Disclosure Guidelines: Toward a Common Approach to Reporting Water Issues, CEO Water Mandate, August 2012.~~

HC0101-25. Overall Process Mass Intensity (PMI) and PMI broken down for water and organic solvents, where PMI = quantity of raw materials input (kg) / quantity of active pharmaceutical product (API) output (kg).

~~.94.105~~ PMI is as defined by the American Chemical Society (ACS) Green Chemistry Institute Pharmaceutical Roundtable. "Process" is defined as all steps of a synthetic path from commonly available materials to the final bulk active pharmaceutical ingredient (API). "Raw material input" is defined as all materials, including water, that are used directly in the process of synthesizing, isolating, and purifying the API salt. "Quantity of API output" is defined as the final salt form of the active ingredient that was produced in the synthesis, dried to the expected specification.

~~.95.106~~ The registrant should disclose total PMI for all raw material inputs, as well as separate PMI figures for water inputs and organic solvent inputs.

Additional References

~~Using the Right Green Yardstick: Why Process Mass Intensity Is Used in the Pharmaceutical Industry To Drive More Sustainable Processes, Concepcion Jimenez-Gonzalez, Celia S. Ponder, Quirinus B. Broxterman, and Julie B. Manley-Organic Process Research & Development 2011 15 (4), 912-917~~

HC0101-26. Amount of waste (metric tons); percentage that is recycled, incinerated (including for energy recovery), and landfilled.

~~.96.107~~ The registrant shall calculate and disclose the total amount of waste that is recycled (or reused), incinerated, and landfilled. The registrant should specify other methods for disposition of waste (e.g., composting or permanent long-term storage).

~~.97.108~~ Waste includes hazardous and non-hazardous wastes. Hazardous waste includes EPA-listed wastes, characteristic wastes, universal wastes, and mixed wastes. The U.S. EPA provides a [hazardous waste identification process](#).

~~.98.109~~ Waste shall be limited to that which is produced during the manufacturing process.

~~.99.110~~ Non-hazardous waste includes both municipal and solid waste.

Additional References:

~~40 CFR—Title 40—Protection of the Environment, Parts 239—282~~

Corruption and Bribery

Description

Biotechnology and pharmaceuticals firms are subject to various state, federal, and international laws pertaining to health care fraud and abuse. Anti-kickback laws and the U.S. Foreign Corrupt Practices Act generally prohibit companies from making payments for the purpose of obtaining or retaining business. The ability of companies to ensure compliance both in the U.S. and abroad ~~is likely to~~may have material implications.

Accounting Metrics

~~HC0101-27. Description of legal and regulatory fines and settlements associated with bribery, corruption, or other unethical business practices, including violations of the Foreign Corrupt Practices Act and those associated with providing kickbacks to physicians. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events.~~

~~TA01-05-01. Total amount of losses as a result of legal proceedings associated with corruption and bribery.~~

~~.111~~ The registrant shall ~~briefly describe~~disclose ~~the nature and context~~total amount of fines and settlements (e.g., non-prosecution agreement)~~losses~~ in U.S. dollars it incurred as a result of legal proceedings associated with bribery, corruption, ~~or other unethical business practices (e.g., indirect enticements such as kick backs). These~~ and bribery.

~~.112~~ The legal proceedings shall include any adjudicative proceeding, whether before a court, a regulator, an arbitrator, or otherwise, in which the registrant was involved.

~~.100, .113~~ The losses shall include all fines, settlements, and other monetary liabilities as a result of civil actions (e.g., civil judgment, judgments or settlements, or), regulatory proceedings (e.g., penalties), disgorgement, or restitution), and criminal actions (e.g., criminal judgment, penalties, or restitutions) takenrestitution) brought by any entity (~~government, businesses~~governmental, business, or individuals~~individual~~).

~~.114~~ DisclosureThe losses shall exclude legal fees incurred by the registrant.

~~.115~~ The scope of disclosure shall include ~~violations of the Foreign Corrupt Practices Act related to its anti-bribery or accounting provisions~~legal proceedings associated with enforcement of Biotechnology & Pharmaceuticals industry regulations promulgated by U.S. and enforced by the foreign regulatory authorities. Such regulatory authorities may include, but are not limited to:

- The Department of Justice~~or the Securities and Exchange Commission.~~

Note to TA01-05-01

~~.101, .116~~ The registrant shall ~~disclose~~briefly describe the amount of any fine~~ature~~ (e.g., judgment or order issued after trial, settlement ~~associated with each incident, not including, guilty plea, deferred prosecution agreement, non-prosecution agreement~~) and context (e.g., kickbacks, corruption, etc.) of all losses as a result of legal ~~fees~~proceedings.

~~.117 The registrant shall describe any corrective actions it has implemented as a result of each incident. The registrant shall describe any corrective actions it has implemented as a result of each incident. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology. These may include, but are not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.~~

HC0101-28. Description of code of ethics governing interactions with health care professionals including mechanisms to ensure employee compliance.

~~-102.118~~ The registrant shall describe aspects of any code of ethics that relate to the registrant's interactions with health care professions. Relevant aspects to discuss include the content (topics such as food and entertainment, training and education, and participation in committees that set formularies) and scope (type and percentage of staff to which it relates).

~~-103.119~~ "Health Care Professionals" includes individuals or entities which are involved in the provision of health care services and/or items to patients, such as physicians, dentists, pharmacists, and nurses. Additionally, the term includes those who purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe the registrant's products, but do not necessarily provide health care services directly, such as purchasing agents, practice managers, and group purchasing organizations (GPOs).

~~-104.120~~ A corporate policy, code of conduct, guidelines, or contractual term that is similar in intent to a code of ethics shall be treated as equivalent for the purposes of this metric.

~~-105.121~~ The registrant shall discuss mechanisms to ensure compliance with its code, such as training (including the degree and frequency) and enforcement (for example, inspections or review committees).

~~-106.122~~ If the registrant has adopted a second- or third-party code of ethics such as PhRMA's [Code on Interactions with Healthcare Professionals](#), it may reference this code without describing the content.

Manufacturing and Supply Chain Quality Management

Description

Manufacturing and supply chain quality is essential to protecting consumer health and corporate value. Biotechnology and pharmaceuticals firms that fail to manage quality in these areas are susceptible to significant fines, lost revenue associated with manufacturing stoppages, and the potential loss of independence. Disclosure of Federal Drug Administration enforcement actions and supply chain audit programs provide shareholders with an understanding of how companies in this industry are managing the associated risks.

Accounting Metrics

HC0101-29. Description of FDA enforcement actions taken in response to violations of current good manufacturing practices (cGMP), including: product deemed adulterated, form 483s, suggested recall (Class I, II, III), Warning Letters, Border Alerts, license suspension or revocation, product seizure, Consent Decrees, criminal prosecution. Description of corrective actions implemented in response to actions.

~~107.123~~ The registrant shall briefly describe the type (e.g., form 483, recall, Consent Decree, etc.), nature, and context of any FDA enforcement action taken during the fiscal year in response to current good manufacturing practice violations at its facilities.

~~108.124~~ The registrant shall describe any corrective actions it has implemented as a result of each incident. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

~~109.125~~ Scope: Facilities discussed shall be those recognized by the registrant as physical assets under Property, Plant, and Equipment (Topic 360).

HC0101-30. Percentage of facilities and Tier I suppliers participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients (e.g., APIs, chemical, raw material, excipients, etc.).

~~110.126~~ The registrant shall disclose the percentage of its facilities that participate in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients.

~~111.127~~ The registrant shall disclose the percentage of its Tier I suppliers' facilities (limited to facilities with which the registrant conducts business) that participate in the Rx-360 (or equivalent) audit program.

- Tier I suppliers are those that transact directly with the registrant.
- The registrant may limit its disclosure to those suppliers that in aggregate account for greater than or equal to 90% of its supplier spending (in dollars).

~~112.128~~ An equivalent third-party audit program is one conducted by an external auditing agency and that contains the same integrity of supply chain and integrity of ingredient requirements as the Rx-360 program.

~~113.129~~ Facilities discussed shall be those recognized by the registrant as physical assets under Property, Plant, and Equipment (Topic 360)



HEALTH CARE SECTOR

MEDICAL EQUIPMENT & SUPPLIES*

Sustainability Accounting Standard

PROPOSED CHANGES TO PROVISIONAL STANDARDS

EXPOSURE DRAFT

REDLINE OF STANDARD FOR PUBLIC COMMENT

Prepared by the
Sustainability Accounting Standards Board®

October 2017

* Sustainable Industry Classification System™ (SICS™) #HC0201

MEDICAL EQUIPMENT & SUPPLIES

Sustainability Accounting Standard

About the SASB

The Sustainability Accounting Standards Board (SASB) was founded in 2011 as an independent standard-setting organization. The SASB issues and maintains sustainability accounting standards for 79 industries, focusing on the subset of industry-specific sustainability factors that are reasonably likely to have material financial impacts on companies within that industry. Companies can use the standards to disclose material information to investors in SEC filings, including Forms 10-K, 20-F, and 8-K, as well as S-1 and S-3, in a cost-effective and decision-useful manner. The standards are designed to help companies better comply with existing disclosure obligations, working within the framework of existing U.S. securities laws.

The SASB Standards Board is responsible for developing and issuing the standards, maintaining technical agendas, proposing updates to the standards, and executing the standard-setting process. The SASB staff is responsible for performing research and engaging in consultation on the standards, supporting the work of the Standards Board.

The SASB Foundation, an independent 501(c)3 non-profit, is responsible for the funding and oversight of the SASB, including safeguarding the SASB's independence and integrity through due process oversight and inquiry resolution. The SASB Foundation Board of Directors appoints members of the SASB.

About this Standard

This Standard is an exposure draft presented for public review and comment. **This version is not intended for implementation.**

The public comment period lasts for 90 days, beginning on October 2, 2017, and ending on December 31, 2017. The Standard is subject to change thereafter. SASB Standards are scheduled to be ratified by the SASB in early 2018.

For instructions on providing comments to SASB, please click [here](https://www.sasb.org/public-comment) (https://www.sasb.org/public-comment).

SUSTAINABILITY ACCOUNTING STANDARDS BOARD

1045 Sansome Street, Suite 450
San Francisco, CA 94111

www.sasb.org

The information, text, and graphics in this publication (the "Content") is owned by the Sustainability Accounting Standards Board. All rights reserved. You may use the Content only for non-commercial and scholarly use, provided that you keep intact all copyright and other proprietary notices related to the Content, and that you make no modifications to the Content. The Content may not be otherwise disseminated, distributed, republished, reproduced, or modified without the prior written permission of the Sustainability Accounting Standards Board. To request permission, please contact us at info@sasb.org.

Purpose & Structure

This document contains the SASB Sustainability Accounting Standard (SASB Standard) for the Medical Equipment & Supplies industry.

SASB Sustainability Accounting Standards comprise **(1) disclosure guidance and (2) accounting standards or metrics** for use by U.S. and foreign public companies in their disclosures to investors, such as in annual reports and filings with the U.S. Securities and Exchange Commission (SEC), including Forms 10-K, 20-F, 40-F, 10-Q, 8-K and S-1 and S-3. The Standards facilitate the meaningful disclosure of sustainability information that is useful to investors in making decisions on investments and corporate suffrage.¹ The Standards reflect the fact that certain sustainability information is important for assessing the future financial performance of an issuer, particularly over the long term.

SASB Standards identify sustainability topics that are reasonably likely to constitute material information for a company within a particular industry. Company management is responsible for determining whether those identified topics reflect information that is material to investors and should be disclosed in filings, based on that company's specific circumstances. For further details regarding the use of the SASB Standards, in particular guidance on determinations of materiality, please see SASB's Implementation Guide.²

SASB Standards provide companies with sustainability metrics designed to communicate performance on industry-level sustainability topics in a concise, comparable format using existing reporting mechanisms. Companies can use the Standards to help ensure that disclosure is reliable, decision-useful for investors, and cost-effective for issuers.

SASB Standards are intended to constitute "suitable criteria" for purposes of an attestation engagement as defined by Paragraph .A42 of AT-C section 105³ and referenced in AT-C section 395.⁴ "Suitable criteria" have the following attributes:

- *Relevance*—Criteria are relevant to the subject matter.
- *Objectivity*—Criteria are free from bias.
- *Measurability*—Criteria permit reasonably consistent measurements, qualitative or quantitative, of subject matter.
- *Completeness*—Criteria are complete when subject matter prepared in accordance with them does not omit relevant factors that could reasonably be expected to affect decisions of the intended users made on the basis of that subject matter.

Industry Description

The Medical Equipment & Supplies industry researches, develops, and produces medical, surgical, dental, ophthalmic, and veterinary instruments and devices. Products are used in settings, including hospitals, clinics, and laboratories, and

¹ The AICPA defines sustainability information in its Guide, [Attestation Engagements on Sustainability Information \(Including Greenhouse Gas Emissions Information\)](#) (Issued July 2017), as follows: "information about sustainability matters (such as economic, environmental, social and governance performance)." It further explains that "sustainability metrics and sustainability indicators are components of sustainability information. Sustainability information may be nonquantitative (narrative), historical, or forward-looking."

² <https://library.sasb.org/implementation-guide>

³ <https://www.aicpa.org/Research/Standards/AuditAttest/DownloadableDocuments/AT-C-00105.pdf>

⁴ <http://pcaobus.org/Standards/Attestation/Pages/AT701.aspx>

range from disposable items to highly specialized equipment. The Medical Equipment & Supplies industry is driven by demand for health care services and rates of insurance coverage. The increased prevalence of diseases associated with unhealthy lifestyles and an aging population will likely contribute to growth in this industry. Emerging markets and the expansion of health insurance in the U.S. will contribute to further growth. However, the extension of government insurance programs, provider and payer consolidation, and regulatory emphasis on reduced costs will create downward pricing pressure.

Users of the SASB Standards

The SASB Standards are intended for use by public companies and by investors to inform investment decisions. The standards facilitate disclosure of financially material sustainability-related information in a concise, comparable, cost-effective, decision-useful format.

The SASB Standards are designed for integration into existing reporting mechanisms, such as SEC filings. This keeps the administrative and cost burden to a minimum. SEC filings include Form 10-K for U.S. companies, Form 20-F for foreign issuers, Form 40-F for Canadian issuers, quarterly reports on Form 10-Q, current reports on Form 8-K, and registration statements on Forms S-1 and S-3. The SASB Standards are also recognized by the European Commission as a suitable framework for companies to provide information to investors pursuant to EU Directive 2014/95/EU. See “Guidelines on non-financial reporting (methodology for reporting non-financial information).”⁵ Thus, SASB standards are a cost-effective way to satisfy both U.S. and European reporting requirements.

SASB evaluates the materiality of sustainability-related topics by using the high threshold of financial materiality that is established under the U.S. securities laws.⁶ Although designed to meet the rigorous disclosure requirements of the U.S. capital markets (thereby producing a high-quality set of evidence-based standards focused on material investor-focused topics), the standards represent a best practice that can be used by companies of all types (public and private) to describe their material sustainability-related risks and opportunities.

Guidance for Disclosure of Sustainability Topics in SEC Filings

1. Industry-Level Sustainability Topics

For the Medical Equipment & Supplies industry, the SASB has identified the following sustainability disclosure topics:

- Product Safety
- Ethical Marketing
- Affordability and Fair Pricing
- Product Design and Lifecycle Management
- Corruption and Bribery
- Manufacturing and Supply Chain Quality Management

2. Determination of Materiality

⁵ https://ec.europa.eu/info/publications/170626-non-financial-reporting-guidelines_en

⁶ https://library.sasb.org/materiality_bulletin/

In the U.S., sustainability disclosures are governed by the same laws and regulations that generally govern disclosures by securities issuers. According to the U.S. Supreme Court, a fact is material if, in the event such fact is omitted from a particular disclosure, there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of the information made available.⁷

Through a rigorous process of research, review of evidence, and public input, the SASB has identified sustainability topics that are reasonably likely to have a material effect on the financial condition or operating performance of companies within each Sustainable Industry Classification System™ (SICS™) industry.⁸ **However, the issuer must determine what information is (or is reasonably likely to be) material to the reasonable investor.** For further information regarding a process that corporations can use to assess the financial materiality of the sustainability-related topics in SASB standards, please see SASB's Implementation Guide.⁹

3. SEC Requirements Relating to Disclosure of Material Sustainability Information

If a public company determines that certain sustainability information is reasonably likely to be material, it must then determine whether disclosure of some or all of the information under applicable SASB Standards is required under the U.S. federal securities laws. Several provisions of those laws are relevant to sustainability disclosures.

Regulation S-K sets forth certain disclosure requirements associated with Form 10-K and other SEC filings. Item 303 of Regulation S-K requires companies to, among other things, describe in the Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) section of Form 10-K "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed."¹⁰

Furthermore, the instructions to Item 303 state that the MD&A "shall focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition."¹¹

The SEC has provided guidance for companies to use in determining whether a trend or uncertainty should be disclosed. The two-part assessment prescribed by the SEC can be applied to the topics included within this Standard:

- First, a company is not required to make disclosure about a known trend or uncertainty if its management determines that such trend or uncertainty is not reasonably likely to occur.

⁷ *TSC Industries v. Northway, Inc.*, 426 U.S. 438 (1976).

⁸ https://library.sasb.org/materiality_bulletin/

⁹ <https://library.sasb.org/implementation-guide>

¹⁰ C.F.R. 229.303(Item 303)(a)(3)(ii).

¹¹ SEC [Release Nos. 33-8056; 34-45321; FR-61] Commission Statement about Management's Discussion and Analysis of Financial Condition and Results of Operations: "We also want to remind registrants that disclosure must be both useful and understandable. That is, management should provide the most relevant information and provide it using language and formats that investors can be expected to understand. Registrants should be aware also that investors will often find information relating to a particular matter more meaningful if it is disclosed in a single location, rather than presented in a fragmented manner throughout the filing."

- Second, if a company's management cannot make a reasonable determination of the likelihood of an event or uncertainty, then disclosure is required "unless management determines that a material effect on the registrant's financial condition or results of operation is not reasonably likely to occur."

Companies should also consider the applicability of other Regulation S-K requirements. Specifically, Item 101 ("Description of Business") requires a company to provide a description of its business and its subsidiaries. Item 103 ("Legal Proceedings") requires a company to describe briefly any material pending or contemplated legal proceedings; instructions to Item 103 provide specific disclosure requirements for administrative or judicial proceedings arising from laws and regulations that target discharge of materials into the environment, or that are primarily for the purpose of protecting the environment. Item 503(c) ("Risk Factors") requires a company to provide discussion of the most significant factors that make an investment in the registrant speculative or risky, clearly stating the risk and specifying how it affects the company.

Finally, as a general matter, Securities Act Rule 408 and Exchange Act Rule 12b-20 require a registrant to disclose, in addition to the information expressly required by law or regulation, "such further material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they are made, not misleading."

4. Where Disclosures Should Be Made in SEC Filings

In using the definition of materiality established under the U.S. federal securities laws, the SASB has identified and developed industry-specific sustainability topics and metrics that are reasonably likely to have a material effect on the financial condition or operating performance of companies within a particular industry. As a general matter, the SASB believes that investors are best served when disclosure of such information is made in SEC filings. An issuer might, for example, make the disclosure in a sub-section of MD&A with a caption, "**Sustainability-Related Information**," with a section that includes the material topics, performance metrics, and management's view with respect to corporate positioning. See SASB's "Mock 10-Ks" for examples of preparing an MD&A using the SASB Standards.¹² Issuers are not precluded from using the Standards elsewhere, such as in stand-alone communications to investors or in sustainability reports (sometimes referred to as corporate social responsibility reports or environmental, social, and governance reports), company websites, or elsewhere. Corporate communication on material topics, including sustainability-related material topics, should be consistent across communication channels. As discussed above, SEC regulations may compel inclusion of material sustainability information in an SEC filing where it is deemed financially material.

The SASB recognizes that sustainability topics are relatively new areas of investor interest, and it may be difficult to determine whether particular sustainability information is material in certain situations. Accordingly, issuers might also consider using the SASB Standards in filings using Form 8-K, Item 8.01 ("Other Events"). This provision states that "The registrant may, at its option, disclose under this Item 8.01 any events, with respect to which information is not otherwise called for by this form, that the registrant deems of importance to security holders." Making a disclosure under Item 8.01 would not require the issuer to make a decision regarding materiality, and might also provide the company with more time to make the disclosure than is permitted under filing rules applicable to Form 10-K, thereby facilitating the completeness and accuracy of the disclosed information.

¹² <http://using.sasb.org/mock-10-k-library/>

When using the Standards, issuers should cite or refer to the relevant SASB Standard.

More detailed guidance on preparing disclosures of material information related to sustainability topics and making topic-level materiality determinations can be found in the **SASB Conceptual Framework**, available for download via <http://www.sasb.org/approach/conceptual-framework/>, and the **SASB Implementation Guide for Companies**, available for download via <https://library.sasb.org/implementation-guide/>.

Guidance on Accounting for Sustainability Topics

The SASB has identified accounting metrics for each sustainability topic included in this Standard. The SASB recommends that companies within this industry consider using these sustainability accounting metrics when preparing disclosures on the sustainability topics identified herein.

When disclosing information related to a sustainability topic identified by this Standard, companies should consider including a narrative description of any material factors necessary to ensure completeness, accuracy, and comparability of the data reported, as appropriate. Such a description might in certain circumstances include a discussion of the following:¹³

- The registrant's **governance** around the risks and opportunities related to the topic, including board oversight of and management's role in assessing and managing such risks and opportunities.
- The registrant's **strategic approach** regarding actual and potential impacts of topic-related risks and opportunities on the organization's **businesses, strategy, and financial planning**, over the **short, medium, and long term**.
- The registrant's process to **identify, assess, and manage** topic-related risks, and how these risks are integrated into the registrant's overall risk management process.
- The registrant's **use of metrics or targets** to assess and manage topic-related risks and opportunities.
- Data for the registrant's **last three completed fiscal years** (when available).

The SASB recommends that registrants use SASB Standards specific to their primary industry as identified in SICSTM. If a registrant generates significant revenue from multiple industries, the SASB recommends that it also consider sustainability topics that the SASB has identified for those industries, and disclose the associated SASB accounting metrics.

Further, the SASB recommends that companies design, implement, and maintain adequate systems of internal control over sustainability performance information to provide reasonable confidence regarding the achievement of related reporting objectives, such as those relating to the reliability of disclosed information.¹⁴

¹³ These areas for possible additional narrative description are generally aligned with the [Recommendations of the Task Force on Climate-related Financial Disclosures](#), which contains a more extensive discussion of such disclosure matters.

¹⁴ In this regard, companies are referred to the report of a group of experts in this area. Robert H. Herz, Brad J. Monterio, Jeffrey C. Thomson, Leveraging the COSO Internal Control – Integrated Framework to Improve confidence in Sustainability Performance Data (August 2017).

The SASB takes no position as to whether third-party attestation is necessary to enhance the credibility of the disclosed sustainability information, but as a matter of good governance, the SASB suggests that such assurance be considered.¹⁵

Scope of Disclosure

Unless otherwise specified, the SASB recommends:

- That a registrant disclose information on sustainability topics and metrics for itself and for entities that are consolidated for financial reporting purposes, as defined by accounting principles generally accepted in the United States (“US GAAP”), for consistency with other accompanying information within SEC filings;¹⁶
- That for consolidated entities, disclosures be made, and accounting metrics calculated, for the whole entity, regardless of the size of the minority interest; and
- That information from unconsolidated entities not be included in the computation of SASB accounting metrics. However, the registrant should disclose information about unconsolidated entities to the extent that the registrant considers the information necessary for investors to understand the effect of sustainability topics on the company’s financial condition or operating performance. (Typically, this disclosure would be limited to risks and opportunities associated with these entities.)

Reporting Format

Use of Financial Data

In instances where accounting metrics, activity metrics, and technical protocols in this Standard incorporate financial data (e.g., revenues, cost of sales, expenses recorded and disclosed for fines, etc.), such financial data shall be prepared in accordance with US GAAP, and be consistent with the corresponding financial data reported in the registrant’s SEC filings. Should accounting metrics, activity metrics, and technical protocols in this Standard incorporate disclosure of financial data that is not prepared in accordance with US GAAP, the registrant shall disclose such information in accordance with SEC Regulation G.¹⁷

Activity Metrics and Normalization

The SASB recognizes that normalizing accounting metrics is important for the analysis of SASB disclosures.

The SASB recommends that a registrant disclose any basic business data that may assist in the accurate evaluation and comparability of disclosure, to the extent that they are not already disclosed in Form 10-K (e.g., revenue, EBITDA, etc.).

¹⁵ The AICPA’s Guide (see supra note 1) provides guidance to assist accounting practitioners in performing attestation engagements on sustainability information.

¹⁶ See US GAAP consolidation rules (Section 810).

¹⁷ <https://www.sec.gov/rules/final/33-8176.htm>

Such data—termed “activity metrics”—may include high-level business data, including total number of employees, quantity of products produced or services provided, number of facilities, or number of customers. It may also include industry-specific data such as plant capacity utilization (e.g., for specialty chemical companies), number of transactions (e.g., for Internet media and services companies), hospital bed days (e.g., for health care delivery companies), or proven and probable reserves (e.g., for oil and gas exploration and production companies).

Activity metrics disclosed should:

- Convey contextual information that would not otherwise be apparent from SASB accounting metrics.
- Be deemed generally useful for investors relying on SASB accounting metrics to perform their own calculations and create their own ratios.
- Be explained and consistently disclosed from period to period to the extent that they continue to be relevant. However, a decision to make a voluntary disclosure in one period does not obligate a continuation of that disclosure if it is no longer relevant, or if a better metric becomes available.¹⁸

Where relevant, the SASB recommends specific activity metrics that—at a minimum—should accompany SASB accounting metric disclosures.

Table 1. Activity Metrics

<u>ACTIVITY METRIC</u>	<u>CATEGORY</u>	<u>UNIT OF MEASURE</u>	<u>CODE</u>
<u>Number of units sold by product category</u>	<u>Quantitative</u>	<u>Number</u>	<u>TA01-10-01</u>

Units of Measure

Unless specified, disclosures should be reported in International System of Units (SI units).

Uncertainty

The SASB recognizes that there may be inherent uncertainty when measuring or disclosing certain sustainability data and information. This uncertainty may be related to variables such as the reliance on data from third-party reporting systems and technologies, or the unpredictable nature of climate events. Where uncertainty around a particular disclosure exists, the SASB recommends that the registrant should consider discussing its nature and likelihood.¹⁹

Estimates

The SASB recognizes that scientifically-based estimates, such as the reliance on certain conversion factors or the exclusion of *de minimis* values, may occur for certain quantitative disclosures. Where appropriate, the SASB does not

¹⁸ Improving Business Reporting: Insights into Enhancing Voluntary Disclosures, FASB Business Reporting Research Project, January 29, 2001.

¹⁹ The AICPA’s Guide (see *supra* note 1) provides guidance related to measurement uncertainty.

discourage the use of estimates or ranges. When using an estimate for a particular disclosure, the SASB expects that the registrant discuss its nature and substantiate its basis.

Timing

Unless otherwise specified, disclosure shall be for the registrant's fiscal year.

Limitations

There is no guarantee that SASB Standards address all sustainability impacts or opportunities associated with a sector, industry, or company; therefore, a company must determine for itself the topics that warrant discussion in its SEC filings.

Use of the SASB Standards is voluntary. The Standards are not intended to replace any legal or regulatory requirements that may be applicable to a company's operations. When such laws or regulations address legal or regulatory topics, disclosure under SASB Standards is not meant to supersede those requirements.

Use of the SASB Standards is not required or endorsed by the SEC or various entities governing financial reporting, including the Financial Accounting Standards Board, the Government Accounting Standards Board, or the International Accounting Standards Board.

Forward-Looking Statements

Disclosures on sustainability topics can, in some circumstances, involve discussion of future trends and uncertainties related to the registrant's operations and financial condition, including those influenced by external variables (e.g., environmental, social, regulatory, and political). Companies making these disclosures in SEC filings should familiarize themselves with the safe harbor provisions of Section 27A of the Securities Act, and Section 21E of the Exchange Act, which preclude civil liability for material misstatements or omissions in such statements if the registrant takes certain steps. These include, among other things, identifying the disclosure as "forward-looking," and accompanying such disclosure with "meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statements."

Notes on the Sustainability Accounting Standards

The following sections contain the disclosure guidance associated with each accounting metric, including guidance on definitions, scope, accounting, compilation, and presentation.

The term "shall" is used throughout this document to indicate those elements that reflect requirements of the Standard. The terms "should" and "may" are used to indicate guidance, which, although not required, provides a recommended means of disclosure.

Table 2. Sustainability Disclosure Topics & Accounting Metrics

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
Product Safety	List of products recalled.	Discussion and Analysis	n/a	HC0201-01
	List of products listed in the FDA's MedWatch Safety Alerts for Human Medical Products (Medical Devices) database.	Discussion and Analysis	n/a	HC0201-02
	Number of fatalities related to products as reported in the FDA Adverse Event Reporting System.	Quantitative	Number	HC0201-03
Ethical Marketing	Description of legal and regulatory fines and settlements associated with false marketing claims, including Federal Food, Drug, and Cosmetic Act violations for off-label marketing prosecuted under the False Claims Act. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events. Total amount of losses as a result of legal proceedings associated with false marketing claims. ²⁰	Discussion and analysis Quantitative	n/a U.S. Dollar (\$)	HC0201-04 TA01-07-01
	Description of code of ethics governing promotion of off-label use of products, including mechanisms to ensure compliance.	Discussion and analysis	n/a	HC0201-05
Affordability and Fair Pricing	Ratio of weighted average rate of net price increases (for all products) to the annual increase in the U.S. Consumer Price Index.	Quantitative	Ratio	HC0201-06
	Description of how price information (such as average and median) for each product is disclosed to customers or their agents (e.g., group purchasing organizations or consultants).	Discussion and Analysis	n/a	HC0201-07
Energy, Water, and Waste Efficiency	Total annual energy consumed (gigajoules) and percentage renewable (e.g., wind, biomass, solar).	Quantitative	Gigajoules (GJ), Percentage (%)	HC0201-08, TA01-08-01
	Total water withdrawals and percentage from water-stressed regions — High or Extremely High Baseline Water Stress as defined by the WRI Water Risk Atlas; percentage of process water recycled.	Quantitative	Cubic meters (m³), Percentage (%)	HC0201-09, TA01-08-02
	Amount of waste (metric tons); percentage that is recycled, incinerated, and landfilled.	Quantitative	Metric Tons (t), Percentage (%)	HC0201-10, TA01-08-03
Product Design and Lifecycle Management	Description of environmental and human health considerations made at product lifecycle stages such as design, procurement, manufacturing, distribution, use, and end-of-life and the type and percentage of products to which efforts apply.	Discussion and Analysis	n/a	HC0201-11

²⁰ Note to **TA01-07-01**— The registrant shall briefly describe the nature, context, and any corrective actions taken as a result of the losses

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
	Description of Extended Producer Responsibility (EPR) initiatives to promote manufacturer take-back, reuse, or proper safe disposal at the end of the lifecycle. Amount (by weight) of products accepted for take-back and reused, recycled, or donated, broken down by: (1) devices and equipment and (2) supplies.	Discussion and Analysis	n/a	HC0201-12
Corruption and Bribery	Description of legal and regulatory fines and settlements associated with bribery, corruption, or unethical business practices, including violations of the Foreign Corrupt Practices Act and those associated with providing kickbacks to physicians. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events. Total amount of losses as a result of legal proceedings associated with bribery and corruption. ²¹	Discussion and analysis- Quantitative	n/a U.S. Dollars (\$)	TA01-09-01
	Description of code of ethics governing interactions with health care professionals including mechanisms to ensure employee compliance.	Discussion and Analysis	n/a	HC0201-14
Manufacturing and Supply Chain Quality Management	Number and type of FDA enforcement actions taken in response to violations of current good manufacturing practices (cGMP) including: product deemed adulterated, form 483s, suggested recall (Class I, II, III), Warning Letters, Border Alerts, license suspension or revocation, product seizure, Consent Decrees, criminal prosecution.	Quantitative	Number	HC0201-15
	Percentage of facilities and Tier I suppliers participating in third-party audit programs for integrity of supply chain and products (e.g., materials, devices, packaging, etc.).	Quantitative	Percentage (%)	HC0201-16
	Description of efforts to maintain traceability within the distribution chain, particularly with respect to wholesalers, re-packagers, and/or contract distributors.	Discussion and Analysis	n/a	HC0201-17
	Discussion of any existing or projected risks or constraints with obtaining raw materials (or components) within the supply chain, including those related to restricted/limited availability, political situations, local labor conditions, natural disasters, climate change, or regulations.	Discussion and Analysis	n/a	HC0201-18

²¹ Note to **TA01-09-01**— The registrant shall briefly describe the nature, context, and any corrective actions taken as a result of the losses

Product Safety

Description

Information on product safety and side effects can surface after controlled clinical trials and approval. Subsequently, companies are exposed to the financial implications of recalls and other adverse events. Equipment failures, manufacturing defects, design flaws, or inadequate disclosure of product-related risks can lead to significant product liability claims. Firms that limit the incidence of these claims may be better positioned to protect shareholder value.

Accounting Metrics

HC0201-01. List of products recalled.

- .01 A recall is an action taken by a registrant to remove a product from the market. Recalls may be conducted voluntarily by a registrant, or they may be mandatory and initiated by FDA request or by FDA order under statutory authority. Registrants shall disclose each type of recall.
- .02 Registrants should review the weekly Enforcement Reports published by the FDA, which are publicly available on the “Recalls, Market Withdrawals, & Safety Alerts” subsection of the FDA’s “Safety” webpage. The registrant may access the list of recalls via www.fda.gov, by navigating to the “Enforcement Reports” subsection of the “Recalls, Market Withdrawals, & Safety Alerts” section of the FDA’s “Safety” page, [here](#). These reports contain all recalls by Product Type, Product Description, Code Info, Classification, Reason for Recall, and Recalling Firm. The registrant shall identify all products that it or its subsidiaries for which it is listed as the Recalling Firm in the “Devices” product type.
- .03 The registrant shall also disclose recalls in foreign markets that have been initiated voluntarily, at the request of a foreign national regulatory authority, or by order of a foreign national regulatory authority under statutory authority. The registrant shall also disclose recalls initiated voluntarily that have not been reported to the FDA (or national regulatory authority) and/or are not listed in an FDA Enforcement Report.
- .04 For FDA-initiated recalls, the registrant may choose to disclose the FDA classification of each recall: Class I, Class II, or Class III.
- .05 For each recalled product the registrant may choose to disclose revenues from the twelve months prior to the date of recall. This twelve-month period may extend beyond the fiscal year for which the registrant is disclosing; the figure is intended to indicate annual revenues associated with the product such that the financial impact of the recall can be gauged
- .06 If a recall relates to only a subset of a product (e.g., specific lots or a particular style), then the registrant should indicate the scope of the recall; and, if the registrant is disclosing revenue associated with the recall, it should be limited to the portion of the product affected by the recall.
- .07 The registrant should list recalls associated with all medical devices manufactured by the registrant and its subsidiaries.

Additional References

Definitions:

Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences. ~~Additional references: Chapter 7 Recall Procedures (FDA Regulatory Procedures—July 2012)~~

HC0201-02. List of products listed in the FDA’s MedWatch Safety Alerts for Human Medical Products (Medical Devices) database-

- .08 The registrant should access the publicly available list of Safety Alerts for Human Medical Products issued as part of the FDA’s MedWatch Safety Information and Adverse Event Reporting Program by navigating to the “Safety Alerts for Human Medical Products” subsection of the “Safety Information” section of the “MedWatch: The FDA Safety Information and Adverse Event Reporting Program” page, [here](#).
- .09 The safety alerts are organized into four categories: (1) Drugs and Therapeutic Biological Products, (2) Medical Devices, (3) Special Nutritional and Cosmetic Products, and (4) Products With Undeclared Drug Ingredients.
- .10 The registrant should review the Medical Devices and disclose all listings associated with the company or its subsidiaries. This includes trade names for which the registrant has patents and products that it manufactures and markets.

HC0201-03. Number of fatalities related to products as reported in the FDA Adverse Event Reporting System-

- .11 Registrants should access the ASCII or SGML data files that are publicly available through “The FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files” system by navigating to the “The FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files” page under the “FDA Adverse Event Reporting System (FAERS)” page, [here](#).
- .12 Data files are summarized and reported quarterly; the registrant should download and access files covering its entire fiscal year. Files can be viewed by creating a relational database using applications such as ORACLE®, Microsoft Office Access, MySQL®, and IBM DB2 or SAS® analytic tools.
- .13 The registrant should open the quarterly files “DEMOyyQq.TXT,” which contains patient demographic and administrative information for each event report, including the manufacturer of the medical device associated with the event.
- .14 The registrant should query the database column “MFR_SNDR,” which contains the verbatim name of the manufacturer that submitted each report. Because the database is a verbatim record of submittals, the registrant must ensure that its query accounts for any and all variations and abbreviations of its name.

.15 Furthermore, it must account for the fact that the database does not allow for special characters or symbols such as ampersand (“&”) and replaces them with a period (“.”).

Additional References

Definitions:

The [FDA Adverse Event Reporting System \(FAERS\)](#) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA’s post-marketing safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation (ICH E2B). Adverse events and medication errors are coded to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology.

Ethical Marketing

Description

Medical equipment and supplies companies face challenges associated with marketing of specific products. Consumer-directed advertisements for medical devices in the U.S. and outreach to physicians provide opportunities for increasing market share. However, challenges arise from the potential for marketing off-label uses. ~~In 2011, the federal government collected \$1.45 billion in fines from pharmaceutical and medical equipment and supplies companies to settle charges, the majority of which focused on, and the government has issued numerous fines in recent years related to~~ the promotion of off-label use. Corporate disclosure of legal and regulatory fines and the codes of ethics that govern interactions with health professionals will allow shareholders to monitor performance in this area.

Accounting Metrics

~~**HC0201-04. Description of legal and regulatory fines and settlements associated with false marketing claims, including Federal Food, Drug, and Cosmetic Act violations for off-label marketing prosecuted under the False Claims Act. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events.**~~

~~.18 The registrant shall briefly describe the nature and context of fines and settlements related to promotion of off-label use of its products, including civil actions (e.g., civil judgment, settlements or regulatory penalties) and criminal actions (e.g., criminal judgment, penalties or restitutions) taken by any entity (government, businesses, or individuals).~~

~~.19 Promotion shall mean any proactive activities (written, oral, or otherwise) that directly or indirectly market, sell or support product sales and use, or that contribute to the sales growth of the registrant's products. This includes whistleblower cases specifically related to off-label marketing of the registrant's products in violation of the Federal Food, Drug, and Cosmetic Act and prosecuted under the False Claims Act.~~

~~**TA01-07-01. Total amount of losses as a result of legal proceedings associated with false marketing claims.**~~

~~.16 The registrant shall disclose the total amount of any fine or settlement losses in U.S. dollars it incurred as a result of legal proceedings associated with each incident, not including false marketing claims.~~

~~.17 The legal proceedings shall include any adjudicative proceeding, whether before a court, a regulator, an arbitrator, or otherwise, in which the registrant was involved.~~

~~.18 The losses shall include all fines, settlements, and other monetary liabilities as a result of civil actions (e.g., civil judgments or settlements), regulatory proceedings (e.g., penalties, disgorgement, or restitution), and criminal actions (e.g., criminal judgment, penalties, or restitution) brought by any entity (governmental, business, or individual).~~

~~.17.19 The losses shall exclude legal fees incurred by the registrant.~~

~~.20 The registrant shall describe any corrective actions it has implemented as a result of each incident. This may include, but is not limited to, the following: The scope of disclosure shall include legal proceedings associated with enforcement of Medical~~

Equipment & Supplies industry regulations promulgated by U.S. and foreign regulatory authorities. Such regulatory authorities may include, but are not limited to:

- The Department of Justice
- The Food and Drug Administration

Note to **TA01-07-01**

~~18.21~~ The registrant shall briefly describe the nature (e.g., judgment or order issued after trial, settlement, guilty plea, deferred prosecution agreement, non-prosecution agreement) and context of all losses as a result of legal proceedings.

~~19.22~~ The registrant shall describe any corrective actions it has implemented as a result of each incident. These may include, but are not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

~~23~~ If relevant, the registrant should discuss other implications associated with the fine or settlement, such as exclusion from government reimbursement programs, entry into Corporate Integrity Agreements (CIAs) with governmental agencies and amendments to existing CIAs

~~Additional references:~~

~~Description of Corporate Integrity Agreements via the Office of Inspector General.~~

HC0201-05. Description of code of ethics governing promotion of off-label use of products, including mechanisms to ensure compliance.

~~20.24~~ The registrant shall describe the aspects of its code of ethics that relate to ethical marketing and off-label promotion, including describing how it defines and/or what it considers “off-label promotion.”

~~21.25~~ A corporate policy, code of conduct, guideline, or contractual term that is similar in intent to a code of ethics shall be treated as equivalent for the purposes of this metric.

~~22.26~~ The registrant shall describe the mechanisms it has in place to ensure compliance with its code, which may include training, internal audits, regulatory review committees, or disciplinary actions for violations.

~~23~~ **NOTES**

HC0201-05

Definitions:

Promotion—any proactive activities (written, oral, or otherwise) that directly or indirectly market, sell, or support product sales and use or that contribute to the sales growth of the registrant’s products.

Affordability and Fair Pricing

Description

Legislative emphasis in the U.S. and abroad on health care cost containment and increased access will continue to place downward pricing pressures on the ~~medical equipment and supplies~~ Medical Equipment & Supplies industry. This pressure will be further articulated by continued consolidation among health care providers and the ~~increasing~~ role of government-sponsored insurance programs. As a result, companies that have relied on contractual advantages to protect profits may be challenged to enhance value as the government seeks to reduce its Medicare and Medicaid spending. Firms that are able to ensure access and fair pricing are likely to limit the negative impact of cost containment while recognizing the potential revenue opportunities associated with expanded access.

Accounting Metrics

HC0201-06. Ratio of weighted average rate of net price increases (for all products) to the annual increase in the U.S. Consumer Price Index.

~~24.27~~ The average net price increases should be weighted based on sales volume of all of the registrant's products sold in the U.S. during the fiscal year.

~~25.28~~ The registrant should use the annual (December to December increase) of the Consumer Price Index for All Urban Consumer (CPI-U) for the fiscal year. Current Consumer Price Index data from the U.S. Department of Labor can be accessed [here](#).

HC0201-07. Description of how price information (such as average and median) for each product is disclosed to customers or their agents (e.g., ~~group purchasing organizations or consultants~~).

~~26.29~~ The registrant shall describe the nature, scope, and implementation of policies and initiatives related to providing price information to customers, specifically indicating if aspects of the price such as the range, median, or typical price are provided to customers.

~~27.30~~ Customers shall include those purchasing directly from the registrant or thorough intermediaries, such as group purchasing organizations (GPOs) or consultants negotiating on behalf of the customer.

~~28.31~~ The registrant shall describe the frequency with which it uses confidentiality clauses in purchasing agreements with health care providers that restrict them from sharing with third parties the price they paid for the registrant's products.

~~29.32~~ The registrant may explain the factors that affect price, such as product volume, geographic market of customer, or type of facility customer is operating (e.g., teaching or non-teaching), or other characteristics.

Energy, Water, and Waste Efficiency

The manufacturing of medical equipment and supplies requires the use of energy, water, and material inputs in addition to the creation of waste. As concern over climate change and dwindling natural resources continues to impact pricing, medical equipment and supplies companies will be exposed to fluctuations in costs for these key inputs. Firms that are able to improve manufacturing efficiencies and limit dependence on resources are likely to enhance shareholder value.

~~HC0201-08. Total annual energy consumed (gigajoules) and percentage renewable (e.g., wind, biomass, solar).~~

- ~~.20 The registrant shall convert the amount of electricity it purchased from kilowatt hours (kWh) to gigajoules (GJ).~~
- ~~.21 The registrant shall disclose fossil fuel consumption in terms of its energy content, using higher heating values (HHV), also known as gross calorific values (GCV), and which are directly measured or taken from the Intergovernmental Panel on Climate Change (IPCC), the U.S. Department of Energy (DOE), or the U.S. Energy Information Administration (EIA).~~
- ~~.22 The registrant shall disclose renewable energy consumption as a percentage of its overall energy consumption, in terms of its energy content. For biofuels the registrant shall use HHVs from the sources mentioned above. For solar or wind energy consumption, the registrant shall convert from electricity production (kWh) to gigajoules (GJ).~~
- ~~.23 The registrant shall disclose renewable energy data for renewable energy it directly produces, or which it purchases through renewable energy certificates (RECs) that are certified (i.e., through Green-e), or renewable power purchase agreements (PPAs). It shall not disclose the renewable portion of the energy that is drawn from electricity grids.~~

~~HC0201-09. Total water withdrawals and percentage from water-stressed regions— High or Extremely High Baseline Water Stress as defined by the WRI Water Risk Atlas; percentage of process water recycled~~

~~:~~

- ~~.24 Process water withdrawal is the total amount of water removed from freshwater sources for use in manufacturing operations. This figure should not include water use in manufacturing that is recycled. Water withdrawals shall be disclosed in terms of cubic meters (m³).~~
- ~~.25 Using the World Resources Institute (WRI)'s Water Risk Atlas tool, "Aqueduct," (publicly available online [here](#)), the registrant shall analyze all of its manufacturing facilities for water risks and identify facilities that are in a location with High (40–80%) or Extremely High (>80%) Baseline Water Stress.~~
- ~~.26 The registrant shall separately disclose the percentage of total water withdrawals by volume (m³) that was recycled during fiscal year. This figure shall include the amount recycled in closed-loop and open-loop systems. Water recycled for purposes other than manufacturing processes (e.g., grey water reuse) shall not be included in this figure.~~

~~HC0201-10. Amount of waste (metric tons); percentage that is recycled, incinerated (including for energy recovery), and landfilled.~~

- ~~.27 The registrant shall calculate and disclose the total amount of waste that is recycled (or reused),~~

incinerated, and landfilled. The registrant should specify other methods for disposition of waste (e.g., composting or permanent long term storage).

~~.28 Waste includes hazardous and non-hazardous wastes. Hazardous waste includes EPA listed wastes, characteristic wastes, universal wastes, and mixed wastes. The U.S. EPA provides a hazardous waste [identification process](#).~~

~~.29 Waste shall be limited to that which is produced during the manufacturing process.~~

~~.30 Non-hazardous waste includes municipal and solid waste.~~

Product Design and Lifecycle Management

Description

Medical equipment and supplies companies face increasing challenges associated with the human and environmental impact of the industry's products. Companies will likely face consumer and regulatory pressure to limit the use of toxic and/or scarce material inputs, while also addressing issues such as the energy efficiency and end-of-life disposal of specific products. Firms that are able to limit these externalities may be better positioned to meet consumer demand and reduce future liabilities.

Accounting Metrics

HC0201-11. Description of environmental and human health considerations made at product lifecycle stages such as design, procurement, manufacturing, distribution, use, and end-of-life, and the type and percentage of products to which efforts apply.

~~30.33~~ The registrant shall describe its strategic approach to addressing specific environmental and human health impacts of its products, such as those related to toxicity of materials, material efficiency (e.g., the use of recycled or bio-based materials), product packaging (e.g., dematerialization, design for consolidated shipping), energy efficiency of products during use, or the disposal of the products (e.g., design and labeling for reuse or recycling).

~~31.34~~ The registrant shall only discuss design considerations which it can determine will deliver a specific, demonstrable reduced environmental impact. Furthermore, it shall provide an indication of how central the environmental benefit imparted its effort is to functionality of products (i.e., a primary benefit may be elimination of Bisphenol-A from a device, whereas an ancillary benefit may be reducing the weight of a product for more energy-efficient shipping). It shall make its determination in good faith and following guidance from applicable laws and statutes, such as the US Federal Trade Commission's "Green Guides" (16 C.F.R. Part 260: Guides For the Use of Environmental Marketing Claims). This includes clarity as to whether the benefit relates to the product, package, or service and avoiding general statement of environmental benefit (such as "eco-friendly").

~~32.35~~ The registrant shall specify during which lifecycle stage(s) it takes into account the environmental impacts associated with its products.

~~33.36~~ Environmental considerations shall be taken to mean those related to human health (e.g., exposure to toxic materials) as well as impacts such as waste generation, energy consumption, water use, and/or environmental health.

~~34.37~~ The registrant shall reference the mechanism through which it implements efforts, including but not limited to the use of design protocols, procurement policies, restricted substances lists (RSLs), certifications (e.g., Energy Star), product take-back programs, and packaging take-back.

~~35.38~~ For efforts related to the end of life of product management, the registrant shall discuss only design-related considerations (e.g., design for disassembly, design for recycling, etc.). Efforts such as take-back programs should be addressed in HC0201-12.

~~36.39~~ The registrant shall disclose the percentage of products, by revenue, for which it has integrated the aforementioned environmental considerations into the design.

HC0201-12. Description of extended producer responsibility (EPR) efforts for take-back, reuse, or proper safe disposal of products at the end of their lifecycle. Amount (by weight) of products accepted for take-back and reused, recycled, or donated, broken down by: (1) devices and equipment and (2) supplies.

~~37.40~~ The registrant shall describe programs and initiatives it implements, funds, or in which it participates related to product take-back for end-of-life management of its products.

~~38.41~~ The registrant shall disclose the amount, in tons, of its products that it recovered and which was reused (refurbished), recycled, or donated.

- This figure shall be broken down into: (1) devices and equipment and (2) supplies, where devices and equipment includes high-value machines (e.g., imaging machines, ventilators, dialysis equipment, monitors) and advanced devices (e.g., implants, prostheses); as well as where supplies includes simple supplies (e.g., sutures, gauze, disinfectant) and low-cost equipment (e.g., scalpels, gloves, thermometers).
- This figure shall not include products that were accepted for take-back but that were ultimately discarded as waste. The registrant may, however, indicate, if it reclaimed any products for which proper safe disposal is necessary (e.g., mercury-containing), and/or which the registrant is unable to recycle or reuse.

Corruption and Bribery

Description

Medical equipment and supplies companies are subject to various state, federal, and international laws pertaining to health care fraud and abuse. Anti-kickback laws and the U.S. Foreign Corrupt Practices Act generally prohibit companies from making payments for the purpose of obtaining or retaining business. The ability of companies to ensure compliance, both in the U.S. and abroad, ~~is likely to may~~ have material implications.

Accounting Metrics

~~HC0201-13. Description of legal and regulatory fines and settlements associated with bribery, corruption, or unethical business practices, including violations of the Foreign Corrupt Practices Act and those associated with providing kickbacks to physicians. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events.~~

TA01-09-01. Total amount of losses as a result of legal proceedings associated with bribery and corruption.

~~.42~~ The registrant shall ~~briefly describe the nature and context of fines and settlements (e.g., non-prosecution agreement)~~ disclose the total amount of losses in U.S. dollars it incurred as a result of legal proceedings associated with bribery, and corruption, regulations or other unethical business practices (e.g., indirect enticements such as kickbacks). These ~~applicable laws or regulations.~~

~~.43~~ The legal proceedings shall include any adjudicative proceeding, whether before a court, a regulator, an arbitrator, or otherwise, in which the registrant was involved.

~~.39.44~~ The losses shall include all fines, settlements, and other monetary liabilities as a result of civil actions (e.g., civil judgment, judgments or settlements or), regulatory proceedings (e.g., penalties, disgorgement, or restitution), and criminal actions (e.g., criminal judgment, penalties, or restitutions) taken, restitution) brought by any entity (government, businesses governmental, business, or individuals individual).

~~.45~~ Disclosure ~~The losses shall exclude legal fees incurred by the registrant.~~

~~.46~~ The scope of disclosure shall include violations of the Foreign Corrupt Practices Act related to its anti-bribery or accounting provisions legal proceedings associated with enforcement of Medical Equipment & Supplies industry regulations promulgated by U.S. and enforced by the foreign regulatory authorities. Such regulatory authorities may include, but are not limited to:

- ~~The Department of Justice or Securities and Exchange Commission.~~

Note to **TA01-09-01**

~~.40.47~~ The registrant shall ~~disclose~~ briefly describe the amount of any fine nature (e.g., judgment or order issued after trial, settlement associated with each incident, not including, guilty plea, deferred prosecution agreement, non-prosecution agreement) and context (e.g., anti-kickback, etc.) of all losses as a result of legal fees proceedings.

~~.41- The registrant shall describe any corrective actions it has implemented as a result of each incident. These may include, but are not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.~~

HC0201-14. Description of code of ethics governing interactions with health care professionals, including mechanisms to ensure employee compliance.

~~.42.48~~ The registrant shall describe aspects of any code of ethics that relate to the registrant's interactions with health care professionals. Relevant aspects to discuss include the content (topics such as food and entertainment, training and education, and participation in committees that set formularies) and scope (type and percentage of staff to which it relates).

~~.43.49~~ "Health Care Professionals" includes individuals or entities which are involved in the provision of health care services and/or items to patients, such as physicians, dentists, pharmacists, and nurses. Additionally, the term includes those which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe the registrant's products, but do not necessarily provide health care services directly, such as purchasing agents, practice managers, and group purchasing organizations ("GPOs").

~~.44.50~~ A corporate policy, code of conduct, guidelines, or contractual term that is similar in intent to a code of ethics shall be treated as equivalent for the purposes of this metric.

~~.45.51~~ The registrant shall discuss mechanisms to ensure compliance with its code, such as education and training (including the degree and frequency) and enforcement (such as inspection, compliance or review committees, and implementing corrective actions when the code is violated).

~~.46.52~~ If the registrant has adopted a second- or third-party code of ethics, such as AdvaMed's [Code of Ethics on Interactions with Healthcare Professionals](#), it may reference this code without describing the content.

~~.47~~ — NOTES

HC0201-14

~~Companies are strongly encouraged to follow the seven elements of an effective compliance program, appropriately tailored for each company, namely: (1) implementing written policies and procedures; (2) designating a compliance officer and compliance committee; (3) conducting effective training and education; (4) developing effective lines of communication (including an anonymous reporting function); (5) conducting internal monitoring and auditing; (6) enforcing standards through well-publicized disciplinary guidelines; and (7) responding promptly to detected problems and undertaking corrective action.~~

Manufacturing and Supply Chain Quality Management

Description

Manufacturing and supply chain quality is essential to protecting consumer health and corporate value. Medical equipment and supplies firms that fail to manage quality in these areas are susceptible to significant fines, lost revenue associated with manufacturing stoppages, and the potential loss of independence. Disclosure of Federal Drug Administration enforcement actions and supply chain audit programs provide shareholders with an understanding of how companies in this industry are managing the associated risks.

Accounting Metrics

HC0201-15. Number and type of FDA enforcement actions taken in response to violations of current good manufacturing practices (cGMP) including: products deemed adulterated, form 483s, suggested recall (Class I, II, III), Warning Letters, Border Alerts, license suspension or revocation, product seizure, Consent Decrees, criminal prosecution.

~~48.53~~ The registrant shall briefly describe the type (e.g., form 483, recall, Consent Decree, etc.), nature, and context of any FDA enforcement action taken during the fiscal year in response to current good manufacturing practice violations at its facilities.

~~49.54~~ The registrant shall describe any corrective actions it has implemented as a result of each incident. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

~~50.55~~ Scope: Facilities discussed shall be those recognized by the registrant as physical assets under Property, Plant, and Equipment (Topic 360).

HC0201-16. Percentage of facilities and Tier I suppliers participating in third-party audit programs for manufacturing and product quality (e.g., materials, devices, packaging, etc.).

~~51.56~~ The registrant shall disclose the percentage of its facilities that participate in third-party audit programs intended to maintain the quality of manufacturing, management, and/or products (including materials and components).

~~52.57~~ The registrant shall disclose the percentage of its Tier I suppliers' facilities that participate in third-party audit program, such as to ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes.

- Tier I suppliers are those that transact directly with the registrant.
- The registrant may limit its disclosure to those suppliers that in aggregate account for greater than or equal to 90% of its supplier spending (in dollars).

~~53.58~~ A third-party audit program is one conducted by an external auditing agency to a recognized, independent standard.

~~-54.59~~ Scope: Facilities discussed shall be those recognized by the registrant as physical assets under Property, Plant, and Equipment (Topic 360).

HC0201-17- Description of efforts to maintain traceability within the distribution chain, particularly with respect to wholesalers, re-packagers, and/or contract distributors.

~~-55.60~~ Traceability refers to the ability to track identifying information (e.g., material composition, supplier, production date, production location, processing history, etc.) of a product throughout various stages of manufacturing and distribution (such as raw material source, manufacturing, distribution, and retail). For the Medical Equipment & Supplies industry, relevant stages include manufacturing, logistics transportation, product wholesale and distribution, and point of delivery at the health care provider.

~~-56.61~~ The registrant shall discuss the type and sophistication of programs and technology it uses to maintain traceability, such as chain of custody audits and/or serialization of its products. Serialization technology may range from the use of a barcode to the use of radio frequency identification (RFID) tagging.

HC0201-18. Discussion of actual or potential constraints in sourcing raw materials (or components), including those related to restricted/limited availability, political situations, local labor conditions, natural disasters, climate change, or regulations.

~~-57.62~~ The registrant shall discuss existing constraints or risks of future constraints that directly affect its access to raw materials or components or that indirectly affect it through impacts on its suppliers.

~~-58.63~~ Actual constraints include those that affected the registrant during the fiscal year, are currently affecting the registrant, or have a very high likelihood of affecting the registrant in the near term (e.g., those for which the registrant currently has inventoried material but has already enacted a contingency plan).

~~-59.64~~ Potential constraints include, but are not limited to, physical limits to natural resources globally, constraints due to regulatory efforts ~~such as the Dodd-Frank Section 1502 requirements related to conflict minerals~~, supply chain disruptions due to increased frequency and severity of natural disasters and other effects of climate change, and labor risks particular to geographic areas in which the registrant conducts business.



HEALTH CARE SECTOR

HEALTH CARE DELIVERY*

Sustainability Accounting Standard

PROPOSED CHANGES TO PROVISIONAL STANDARDS

EXPOSURE DRAFT

REDLINE OF STANDARD FOR PUBLIC COMMENT

Prepared by the
Sustainability Accounting Standards Board®

October 2017

* Sustainable Industry Classification System™ (SICS™) #HC0301

HEALTH CARE DELIVERY

Sustainability Accounting Standard

About the SASB

The Sustainability Accounting Standards Board (SASB) was founded in 2011 as an independent standard-setting organization. The SASB issues and maintains sustainability accounting standards for 79 industries, focusing on the subset of industry-specific sustainability factors that are reasonably likely to have material financial impacts on companies within that industry. Companies can use the standards to disclose material information to investors in SEC filings, including Forms 10-K, 20-F, and 8-K, as well as S-1 and S-3, in a cost-effective and decision-useful manner. The standards are designed to help companies better comply with existing disclosure obligations, working within the framework of existing U.S. securities laws.

The SASB Standards Board is responsible for developing and issuing the standards, maintaining technical agendas, proposing updates to the standards, and executing the standard-setting process. The SASB staff is responsible for performing research and engaging in consultation on the standards, supporting the work of the Standards Board.

The SASB Foundation, an independent 501(c)3 non-profit, is responsible for the funding and oversight of the SASB, including safeguarding the SASB's independence and integrity through due process oversight and inquiry resolution. The SASB Foundation Board of Directors appoints members of the SASB.

About this Standard

This Standard is an exposure draft presented for public review and comment. **This version is not intended for implementation.**

The public comment period lasts for 90 days, beginning on October 2, 2017, and ending on December 31, 2017. The Standard is subject to change thereafter. SASB Standards are scheduled to be ratified by the SASB in early 2018.

For instructions on providing comments to SASB, please click [here](https://www.sasb.org/public-comment) (https://www.sasb.org/public-comment).

SUSTAINABILITY ACCOUNTING STANDARDS BOARD

1045 Sansome Street, Suite 450
San Francisco, CA 94111

www.sasb.org

The information, text, and graphics in this publication (the "Content") is owned by the Sustainability Accounting Standards Board. All rights reserved. You may use the Content only for non-commercial and scholarly use, provided that you keep intact all copyright and other proprietary notices related to the Content, and that you make no modifications to the Content. The Content may not be otherwise disseminated, distributed, republished, reproduced, or modified without the prior written permission of the Sustainability Accounting Standards Board. To request permission, please contact us at info@sasb.org.

Purpose & Structure

This document contains the SASB Sustainability Accounting Standard (SASB Standard) for the Health Care Delivery industry.

SASB Sustainability Accounting Standards comprise **(1) disclosure guidance and (2) accounting standards or metrics** for use by U.S. and foreign public companies in their disclosures to investors, such as in annual reports and filings with the U.S. Securities and Exchange Commission (SEC), including Forms 10-K, 20-F, 40-F, 10-Q, 8-K and S-1 and S-3. The Standards facilitate the meaningful disclosure of sustainability information that is useful to investors in making decisions on investments and corporate suffrage.¹ The Standards reflect the fact that certain sustainability information is important for assessing the future financial performance of an issuer, particularly over the long term.

SASB Standards identify sustainability topics that are reasonably likely to constitute material information for a company within a particular industry. Company management is responsible for determining whether those identified topics reflect information that is material to investors and should be disclosed in filings, based on that company's specific circumstances. For further details regarding the use of the SASB Standards, in particular guidance on determinations of materiality, please see SASB's Implementation Guide.²

SASB Standards provide companies with sustainability metrics designed to communicate performance on industry-level sustainability topics in a concise, comparable format using existing reporting mechanisms. Companies can use the Standards to help ensure that disclosure is reliable, decision-useful for investors, and cost-effective for issuers.

SASB Standards are intended to constitute "suitable criteria" for purposes of an attestation engagement as defined by Paragraph .A42 of AT-C section 105³ and referenced in AT-C section 395.⁴ "Suitable criteria" have the following attributes:

- *Relevance*—Criteria are relevant to the subject matter.
- *Objectivity*—Criteria are free from bias.
- *Measurability*—Criteria permit reasonably consistent measurements, qualitative or quantitative, of subject matter.
- *Completeness*—Criteria are complete when subject matter prepared in accordance with them does not omit relevant factors that could reasonably be expected to affect decisions of the intended users made on the basis of that subject matter.

¹ The AICPA defines sustainability information in its Guide, [Attestation Engagements on Sustainability Information \(Including Greenhouse Gas Emissions Information\)](#) (Issued July 2017), as follows: "information about sustainability matters (such as economic, environmental, social and governance performance)." It further explains that "sustainability metrics and sustainability indicators are components of sustainability information. Sustainability information may be nonquantitative (narrative), historical, or forward-looking."

² <https://library.sasb.org/implementation-guide>

³ <https://www.aicpa.org/Research/Standards/AuditAttest/DownloadableDocuments/AT-C-00105.pdf>

⁴ <http://pcaobus.org/Standards/Attestation/Pages/AT701.aspx>

Industry Description

The Health Care Delivery industry owns and manages hospitals, clinics, and other health care-related facilities. Companies provide a range of services, including inpatient and outpatient care, surgery, mental health, rehabilitation, and clinical laboratory services. Demand for health care delivery services is driven largely by rates of insurance coverage, demographics, illness, and injury rates. The Affordable Care Act increased the number of individuals with insurance, however the future of this legislation remains uncertain. The industry is characterized by high fixed labor and facilities costs, and an increased regulatory emphasis on reduced costs of care and improved outcomes. Health care delivery companies also face significant competition for patients and resources from private, non-profit, and religious health care systems.

Users of the SASB Standards

The SASB Standards are intended for use by public companies and by investors to inform investment decisions. The standards facilitate disclosure of financially material sustainability-related information in a concise, comparable, cost-effective, decision-useful format.

The SASB Standards are designed for integration into existing reporting mechanisms, such as SEC filings. This keeps the administrative and cost burden to a minimum. SEC filings include Form 10-K for U.S. companies, Form 20-F for foreign issuers, Form 40-F for Canadian issuers, quarterly reports on Form 10-Q, current reports on Form 8-K, and registration statements on Forms S-1 and S-3. The SASB Standards are also recognized by the European Commission as a suitable framework for companies to provide information to investors pursuant to EU Directive 2014/95/EU. See “Guidelines on non-financial reporting (methodology for reporting non-financial information).”⁵ Thus, SASB standards are a cost-effective way to satisfy both U.S. and European reporting requirements.

SASB evaluates the materiality of sustainability-related topics by using the high threshold of financial materiality that is established under the U.S. securities laws.⁶ Although designed to meet the rigorous disclosure requirements of the U.S. capital markets (thereby producing a high-quality set of evidence-based standards focused on material investor-focused topics), the standards represent a best practice that can be used by companies of all types (public and private) to describe their material sustainability-related risks and opportunities.

Guidance for Disclosure of Sustainability Topics in SEC Filings

1. Industry-Level Sustainability Topics

For the Health Care Delivery industry, the SASB has identified the following sustainability disclosure topics:

- Quality of Care and Patient Satisfaction
- Access for Low-Income Patients
- Employee Recruitment, Development, and Retention
- Pricing and Billing Transparency
- Energy and Waste Efficiency
- Climate Change Impacts on Human Health and Infrastructure

⁵ https://ec.europa.eu/info/publications/170626-non-financial-reporting-guidelines_en

⁶ https://library.sasb.org/materiality_bulletin/

- Fraud and Unnecessary Procedures
- Patient Privacy and Electronic Health Records
- [Employee Health and Safety](#)
- [Management of Controlled Substances](#)

2. Determination of Materiality

In the U.S., sustainability disclosures are governed by the same laws and regulations that generally govern disclosures by securities issuers. According to the U.S. Supreme Court, a fact is material if, in the event such fact is omitted from a particular disclosure, there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of the information made available.⁷

Through a rigorous process of research, review of evidence, and public input, the SASB has identified sustainability topics that are reasonably likely to have a material effect on the financial condition or operating performance of companies within each Sustainable Industry Classification System™ (SICS™) industry.⁸ **However, the issuer must determine what information is (or is reasonably likely to be) material to the reasonable investor.** For further information regarding a process that corporations can use to assess the financial materiality of the sustainability-related topics in SASB standards, please see SASB’s Implementation Guide.⁹

3. SEC Requirements Relating to Disclosure of Material Sustainability Information

If a public company determines that certain sustainability information is reasonably likely to be material, it must then determine whether disclosure of some or all of the information under applicable SASB Standards is required under the U.S. federal securities laws. Several provisions of those laws are relevant to sustainability disclosures.

Regulation S-K sets forth certain disclosure requirements associated with Form 10-K and other SEC filings. Item 303 of Regulation S-K requires companies to, among other things, describe in the Management’s Discussion and Analysis of Financial Condition and Results of Operations (MD&A) section of Form 10-K “any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed.”¹⁰

Furthermore, the instructions to Item 303 state that the MD&A “shall focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition.”¹¹

⁷ *TSC Industries v. Northway, Inc.*, 426 U.S. 438 (1976).

⁸ https://library.sasb.org/materiality_bulletin/

⁹ <https://library.sasb.org/implementation-guide>

¹⁰ C.F.R. 229.303(Item 303)(a)(3)(ii).

¹¹ SEC [Release Nos. 33-8056; 34-45321; FR-61] Commission Statement about Management’s Discussion and Analysis of Financial Condition and Results of Operations: “We also want to remind registrants that disclosure must be both useful and understandable. That is, management should provide the most relevant information and provide it using language and formats that investors can be expected to understand. Registrants should be aware also that investors will often find information relating to a particular matter more meaningful if it is disclosed in a single location, rather than presented in a fragmented manner throughout the filing.”

The SEC has provided guidance for companies to use in determining whether a trend or uncertainty should be disclosed. The two-part assessment prescribed by the SEC can be applied to the topics included within this Standard:

- First, a company is not required to make disclosure about a known trend or uncertainty if its management determines that such trend or uncertainty is not reasonably likely to occur.
- Second, if a company's management cannot make a reasonable determination of the likelihood of an event or uncertainty, then disclosure is required "unless management determines that a material effect on the registrant's financial condition or results of operation is not reasonably likely to occur."

Companies should also consider the applicability of other Regulation S-K requirements. Specifically, Item 101 ("Description of Business") requires a company to provide a description of its business and its subsidiaries. Item 103 ("Legal Proceedings") requires a company to describe briefly any material pending or contemplated legal proceedings; instructions to Item 103 provide specific disclosure requirements for administrative or judicial proceedings arising from laws and regulations that target discharge of materials into the environment, or that are primarily for the purpose of protecting the environment. Item 503(c) ("Risk Factors") requires a company to provide discussion of the most significant factors that make an investment in the registrant speculative or risky, clearly stating the risk and specifying how it affects the company.

Finally, as a general matter, Securities Act Rule 408 and Exchange Act Rule 12b-20 require a registrant to disclose, in addition to the information expressly required by law or regulation, "such further material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they are made, not misleading."

4. Where Disclosures Should Be Made in SEC Filings

In using the definition of materiality established under the U.S. federal securities laws, the SASB has identified and developed industry-specific sustainability topics and metrics that are reasonably likely to have a material effect on the financial condition or operating performance of companies within a particular industry. As a general matter, the SASB believes that investors are best served when disclosure of such information is made in SEC filings. An issuer might, for example, make the disclosure in a sub-section of MD&A with a caption, "**Sustainability-Related Information**," with a section that includes the material topics, performance metrics, and management's view with respect to corporate positioning. See SASB's "Mock 10-Ks" for examples of preparing an MD&A using the SASB Standards.¹² Issuers are not precluded from using the Standards elsewhere, such as in stand-alone communications to investors or in sustainability reports (sometimes referred to as corporate social responsibility reports or environmental, social, and governance reports), company websites, or elsewhere. Corporate communication on material topics, including sustainability-related material topics, should be consistent across communication channels. As discussed above, SEC regulations may compel inclusion of material sustainability information in an SEC filing where it is deemed financially material.

The SASB recognizes that sustainability topics are relatively new areas of investor interest, and it may be difficult to determine whether particular sustainability information is material in certain situations. Accordingly, issuers might also consider using the SASB Standards in filings using Form 8-K, Item 8.01 ("Other Events"). This provision states that "The registrant may, at its option, disclose under this Item 8.01 any events, with respect to which information is not

¹² <http://using.sasb.org/mock-10-k-library/>

otherwise called for by this form, that the registrant deems of importance to security holders.” Making a disclosure under Item 8.01 would not require the issuer to make a decision regarding materiality, and might also provide the company with more time to make the disclosure than is permitted under filing rules applicable to Form 10-K, thereby facilitating the completeness and accuracy of the disclosed information.

When using the Standards, issuers should cite or refer to the relevant SASB Standard.

More detailed guidance on preparing disclosures of material information related to sustainability topics and making topic-level materiality determinations can be found in the **SASB Conceptual Framework**, available for download via <http://www.sasb.org/approach/conceptual-framework/>, and the **SASB Implementation Guide for Companies**, available for download via <https://library.sasb.org/implementation-guide/>.

Guidance on Accounting for Sustainability Topics

The SASB has identified accounting metrics for each sustainability topic included in this Standard. The SASB recommends that companies within this industry consider using these sustainability accounting metrics when preparing disclosures on the sustainability topics identified herein.

When disclosing information related to a sustainability topic identified by this Standard, companies should consider including a narrative description of any material factors necessary to ensure completeness, accuracy, and comparability of the data reported, as appropriate. Such a description might in certain circumstances include a discussion of the following:¹³

- The registrant’s **governance** around the risks and opportunities related to the topic, including board oversight of and management’s role in assessing and managing such risks and opportunities.
- The registrant’s **strategic approach** regarding actual and potential impacts of topic-related risks and opportunities on the organization’s **businesses, strategy, and financial planning**, over the **short, medium, and long term**.
- The registrant’s process to **identify, assess, and manage** topic-related risks, and how these risks are integrated into the registrant’s overall risk management process.
- The registrant’s **use of metrics or targets** to assess and manage topic-related risks and opportunities.
- Data for the registrant’s **last three completed fiscal years** (when available).

The SASB recommends that registrants use SASB Standards specific to their primary industry as identified in SICSTM. If a registrant generates significant revenue from multiple industries, the SASB recommends that it also consider sustainability topics that the SASB has identified for those industries, and disclose the associated SASB accounting metrics.

¹³ These areas for possible additional narrative description are generally aligned with the [Recommendations of the Task Force on Climate-related Financial Disclosures](#), which contains a more extensive discussion of such disclosure matters.

Further, the SASB recommends that companies design, implement, and maintain adequate systems of internal control over sustainability performance information to provide reasonable confidence regarding the achievement of related reporting objectives, such as those relating to the reliability of disclosed information.¹⁴

The SASB takes no position as to whether third-party attestation is necessary to enhance the credibility of the disclosed sustainability information, but as a matter of good governance, the SASB suggests that such assurance be considered.¹⁵

Scope of Disclosure

Unless otherwise specified, the SASB recommends:

- That a registrant disclose information on sustainability topics and metrics for itself and for entities that are consolidated for financial reporting purposes, as defined by accounting principles generally accepted in the United States (“US GAAP”), for consistency with other accompanying information within SEC filings;¹⁶
- That for consolidated entities, disclosures be made, and accounting metrics calculated, for the whole entity, regardless of the size of the minority interest; and
- That information from unconsolidated entities not be included in the computation of SASB accounting metrics. However, the registrant should disclose information about unconsolidated entities to the extent that the registrant considers the information necessary for investors to understand the effect of sustainability topics on the company’s financial condition or operating performance. (Typically, this disclosure would be limited to risks and opportunities associated with these entities.)

Reporting Format

Use of Financial Data

In instances where accounting metrics, activity metrics, and technical protocols in this Standard incorporate financial data (e.g., revenues, cost of sales, expenses recorded and disclosed for fines, etc.), such financial data shall be prepared in accordance with US GAAP, and be consistent with the corresponding financial data reported in the registrant’s SEC filings. Should accounting metrics, activity metrics, and technical protocols in this Standard incorporate disclosure of financial data that is not prepared in accordance with US GAAP, the registrant shall disclose such information in accordance with SEC Regulation G.¹⁷

¹⁴ In this regard, companies are referred to the report of a group of experts in this area. Robert H. Herz, Brad J. Monterio, Jeffrey C. Thomson, Leveraging the COSO Internal Control – Integrated Framework to Improve confidence in Sustainability Performance Data (August 2017).

¹⁵ The AICPA’s Guide (see supra note 1) provides guidance to assist accounting practitioners in performing attestation engagements on sustainability information.

¹⁶ See US GAAP consolidation rules (Section 810).

¹⁷ <https://www.sec.gov/rules/final/33-8176.htm>

Activity Metrics and Normalization

The SASB recognizes that normalizing accounting metrics is important for the analysis of SASB disclosures.

The SASB recommends that a registrant disclose any basic business data that may assist in the accurate evaluation and comparability of disclosure, to the extent that they are not already disclosed in Form 10-K (e.g., revenue, EBITDA, etc.).

Such data—termed “activity metrics”—may include high-level business data, including total number of employees, quantity of products produced or services provided, number of facilities, or number of customers. It may also include industry-specific data such as plant capacity utilization (e.g., for specialty chemical companies), number of transactions (e.g., for Internet media and services companies), hospital bed days (e.g., for health care delivery companies), or proven and probable reserves (e.g., for oil and gas exploration and production companies).

Activity metrics disclosed should:

- Convey contextual information that would not otherwise be apparent from SASB accounting metrics.
- Be deemed generally useful for investors relying on SASB accounting metrics to perform their own calculations and create their own ratios.
- Be explained and consistently disclosed from period to period to the extent that they continue to be relevant. However, a decision to make a voluntary disclosure in one period does not obligate a continuation of that disclosure if it is no longer relevant, or if a better metric becomes available.¹⁸

Where relevant, the SASB recommends specific activity metrics that—at a minimum—should accompany SASB accounting metric disclosures.

Table 1. Activity Metrics

<u>ACTIVITY METRIC</u>	<u>CATEGORY</u>	<u>UNIT OF MEASURE</u>	<u>CODE</u>
<u>Number of (1) facilities and (2) beds; by type, including general acute care, psychiatric, rehabilitation, and outpatient</u>	<u>Quantitative</u>	<u>Number</u>	<u>TA01-19-01</u>
<u>Number of (1) inpatient admissions and (2) outpatient visits</u>	<u>Quantitative</u>	<u>Number</u>	<u>TA01-19-02</u>

Units of Measure

Unless specified, disclosures should be reported in International System of Units (SI units).

¹⁸ Improving Business Reporting: Insights into Enhancing Voluntary Disclosures, FASB Business Reporting Research Project, January 29, 2001.

Uncertainty

The SASB recognizes that there may be inherent uncertainty when measuring or disclosing certain sustainability data and information. This uncertainty may be related to variables such as the reliance on data from third-party reporting systems and technologies, or the unpredictable nature of climate events. Where uncertainty around a particular disclosure exists, the SASB recommends that the registrant should consider discussing its nature and likelihood.¹⁹

Estimates

The SASB recognizes that scientifically-based estimates, such as the reliance on certain conversion factors or the exclusion of *de minimis* values, may occur for certain quantitative disclosures. Where appropriate, the SASB does not discourage the use of estimates or ranges. When using an estimate for a particular disclosure, the SASB expects that the registrant discuss its nature and substantiate its basis.

Timing

Unless otherwise specified, disclosure shall be for the registrant's fiscal year.

Limitations

There is no guarantee that SASB Standards address all sustainability impacts or opportunities associated with a sector, industry, or company; therefore, a company must determine for itself the topics that warrant discussion in its SEC filings.

Use of the SASB Standards is voluntary. The Standards are not intended to replace any legal or regulatory requirements that may be applicable to a company's operations. When such laws or regulations address legal or regulatory topics, disclosure under SASB Standards is not meant to supersede those requirements.

Use of the SASB Standards is not required or endorsed by the SEC or various entities governing financial reporting, including the Financial Accounting Standards Board, the Government Accounting Standards Board, or the International Accounting Standards Board.

Forward-Looking Statements

Disclosures on sustainability topics can, in some circumstances, involve discussion of future trends and uncertainties related to the registrant's operations and financial condition, including those influenced by external variables (e.g., environmental, social, regulatory, and political). Companies making these disclosures in SEC filings should familiarize themselves with the safe harbor provisions of Section 27A of the Securities Act, and Section 21E of the Exchange Act, which preclude civil liability for material misstatements or omissions in such statements if the registrant takes certain steps. These include, among other things, identifying the disclosure as "forward-looking," and accompanying such disclosure with "meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statements."

¹⁹ The AICPA's Guide (see *supra* note 1) provides guidance related to measurement uncertainty.

Notes on the Sustainability Accounting Standards

The following sections contain the disclosure guidance associated with each accounting metric, including guidance on definitions, scope, accounting, compilation, and presentation.

The term “shall” is used throughout this document to indicate those elements that reflect requirements of the Standard. The terms “should” and “may” are used to indicate guidance, which, although not required, provides a recommended means of disclosure.

Table 2. Sustainability Disclosure Topics & Accounting Metrics

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
Quality of Care and Patient Satisfaction	Mean 1) Hospital Values-Value-Based Purchasing Total Performance score, broken down by Clinical Process Score, and 2) Domain score, Outcome Domain score, and Patient Experience Domain score., across all facilities.	<u>Quantitative</u>	Number, Mean	HC0301-01- TA01-11-01
	Number of Serious Reportable Events (SREs) as defined by the National Quality Forum.	<u>Quantitative</u>	Number	HC0301-02
	Health care acquired infections, as defined by the CDC's National Healthcare Safety Network, for: (1) Central Line-associated Bloodstream Infections (CLABSIs); (2) Surgical Site Infections (SSIs); (3) Catheter-associated Urinary Tract Infections (CAUTIs). Hospital-Acquired Condition (HAC) Score by facility.	<u>Quantitative</u>	Number	HC0301-03- TA01-12-01
	Excess readmission ratio for pneumonia, acute myocardial infarction, and heart failure, as defined by the Centers for Medicare & Medicaid Services (CMS)- Readmissions Payment Adjustment Amount as part of the Hospital Readmissions Reduction Program, (HRRP). Excess readmission ratio per hospital.	<u>Quantitative</u>	Ratio	HC0301-04 TA01-13-01
	Magnitude of readmissions payment adjustment as part of the Hospital Readmissions Reduction Program (HRRP).	<u>Quantitative</u>	U.S. Dollars (\$)	TA01-13-02
Access for Low-Income Patients	Description of strategy to manage the mix of patient insurance status (i.e., private insurance, government insurance, and uninsured), including a description of alternative pricing mechanisms or programs for the uninsured.	<u>Discussion and Analysis</u>	n/a	HC0301-05
	Amount of Medicare Disproportionate Share Hospital (DSH) adjustment payments received.	<u>Quantitative</u>	U.S. Dollars (\$)	HC0301-06
Employee Recruitment, Development, and Retention	Employee turnover by voluntary and involuntary for: (1) physicians, (2) non-physician health care practitioners, and (3) all others.	<u>Quantitative</u>	Rate	HC0301-07

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
	Description of talent recruitment and retention efforts for health care practitioners, such as mentorship programs, flexible scheduling, and leadership development initiatives. Where applicable, participation or utilization rates for each type of effort.	Discussion and Analysis	n/a	HC0301-08
Pricing and Billing Transparency	Description of policies or initiatives to ensure that patients are adequately informed about price before undergoing a procedure.	Discussion and Analysis	n/a	HC0301-09
	Discussion of how pricing information for services (including inpatient and outpatient) is made publicly available.	Discussion and Analysis	n/a	TA01-14-01
	Description of how pricing information for services (including inpatient and outpatient) is made publicly available, including the number Number of the registrant's 25 most common services for which pricing information is publicly available, and the percentage of total services performed (by volume) that these represent.	Quantitative	Number	HC0301-09 TA01-14-02
Energy and Waste Efficiency	Total annual energy consumed (gigajoules) and percentage renewable (e.g., wind, biomass, solar).	Quantitative	Gigajoules (GJ), Percentage (%)	HC0301-11
	Total weight of Regulated Medical Waste generation (as defined by the Medical Waste Tracking Act of 1988) and total weight by disposition (e.g., on-site incineration, landfill, treatment/storage/disposal facility, etc.).	Quantitative	Kilograms (Kg)	HC0301-12
	Total weight of pharmaceutical waste generation and total weight by disposition (e.g., on-site incineration, landfill, treatment/storage/disposal facility, etc.). Break down by: (1) hazardous waste and (2) non-hazardous (solid) waste.	Quantitative	Kilograms (Kg)	HC0301-13
Climate Change Impacts on Human Health and Infrastructure	Description of the strategy to address the effects of climate change on business operations, physical infrastructure, and facility design. Discussion of specific risks (such as physical risks) presented by policies and practices to address changes in (1) the frequency and intensity of extreme weather events, and changes to and (2) the morbidity and mortality to and rates of illnesses and diseases, associated with climate change.	Discussion and Analysis	n/a	HC0301-14 TA01-18-01

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
	<u>Percentage of health care facilities that comply with CMS's Emergency Preparedness Rule.</u>	<u>Quantitative</u>	Percentage (%)	<u>TA01-18-02</u>
Fraud and Unnecessary Procedures	Description of legal and regulatory fines and settlements associated with Medicare and Medicaid fraud under the False Claims Act. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events.	<u>Quantitative / Discussion and Analysis</u>	U.S. Dollars (\$)	HC0301-15
Patient Privacy and Electronic Health Records	Percentage of patient records that are electronic medical records (EMR) or electronic health records (EHR) meeting the Centers for Medicare and Medicaid Services (CMS) "meaningful use" requirements.	<u>Quantitative</u>	Percentage (%)	HC0301-16
	Description of legal and regulatory fines and settlements associated with Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules violations or The Health Information Technology for Economic and Clinical Health (HITECH) Act violations. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events. <u>Discussion of policies and practices to secure customers' protected health information (PHI) records and other personally identifiable information (PII).</u>	<u>Discussion and Analysis</u>	n/a	HC0301-17 <u>TA01-15-01</u>
	<u>Number of data security breaches, percentage involving (1) only customers' PII and (2) customers' PHI, number of customers affected in each category.</u>	<u>Quantitative</u>	Number	<u>TA01-15-02</u>
	<u>Total amount of losses as a result of legal proceedings associated with data security and privacy.²⁰</u>	<u>Quantitative</u>	U.S. Dollars (\$)	<u>TA01-15-03</u>
Employee Health and Safety	<u>(1) Total recordable case rate and (2) days away from work case rate.</u>	<u>Quantitative</u>	Rate	<u>TA01-16-01</u>
Management of Controlled Substances	<u>Discussion of policies and practices to reduce the number of prescriptions issued for controlled substances.</u>	<u>Discussion and Analysis</u>	n/a	<u>TA01-17-01</u>
	<u>Percentage of controlled substance prescriptions written for which a prescription drug monitoring program (PDMP) database was queried.</u>	<u>Quantitative</u>	Percentage (%)	<u>TA01-17-02</u>

²⁰ Note to **TA01-15-03**—The registrant shall briefly describe the nature, context, and any corrective actions taken as a result of the losses

Quality of Care and Patient Satisfaction

Description

The ability to deliver quality care and ensure patient satisfaction is an essential value driver for health care delivery companies. The link between performance in this area and shareholder value has been strengthened by the Patient Protection and Affordable Care Act (PPACA). Included in the Act's provisions is the establishment of the Hospital Value-Based Purchasing Program, which provides incentive payments, based on performance on a series of health care quality measures. Further, hospitals will be subject to reductions in inpatient payments for excessive readmissions and hospital-acquired conditions.

Accounting Metrics

~~HC0304TA01-11-01. Mean 1) Hospital Values-Value-Based Purchasing Total Performance score, broken down by Clinical Process Score, and 2) Domain score, Outcome Domain score, and Patient Experience Domain score.,, across all facilities~~

~~.01~~ The registrant shall disclose the mean Hospital Values Based Purchasing (HVBP) ~~scores for~~ Total Performance Score (TPS) across all hospitals it operates, where ~~hospitals~~

- ~~Hospitals~~ are defined as in Section 1886(d)(1)(B) of the Social Security Act. ~~Disclosure shall consist of the mean Total Performance score, mean Clinical Process Domain score, mean Outcome Domain score, and mean Patient Experience Domain score for all hospitals it operates.~~
- ~~The registrant shall disclose all scores~~ Total Performance Score (TPS) is calculated according to the HVBP methodology, including achievement points and improvement points. ~~The registrant shall consider the HVBP scoring methodology as a normative reference, thus any updates made year on year shall be considered updates to this guidance.~~
 - For its calculations, the registrant shall use HVBP scores after their weighting has been applied according to ~~the HVBP methodology. Weighting is 45% for Clinical Process Domain scores, 30% for Outcome Domain scores, and 25% for Patient Experience Domain scores.~~ HVBP methodology.

~~.02~~ The registrant shall disclose mean score for each Domain across all hospitals it operates, where

- Domains are defined and calculated according to HVBP methodology

~~.01.03~~ If applicable, the registrant shall indicate if any hospitals it operates have been excluded from the HVBP program for reasons enumerated under Section 1886(o)(1)(C)(ii), including those (i) subject to payment reductions under Hospital Inpatient Quality Reporting, or (ii) cited for deficiencies during the performance period that pose immediate jeopardy to the health or safety of patients, without the minimum number of cases, measures, or surveys.

~~.02.04~~ The registrant may access many of the underlying data in a publicly available database via Hospital Compare, a service of Centers for Medicare & Medicaid Services.

HC0301-02. Number of Serious Reportable Events (SREs) as defined by the National Quality Forum.

- ~~03.05~~ Serious Reportable Events (SREs) are identified by the National Quality Forum in a report entitled Serious Reportable Events in Health Care. There are [29 adverse events](#), classified under one of six categories (surgical, product or device, patient protection, care management, environment, or criminal), occurring in hospitals that are identified as “serious, largely preventable, and of concern to both the public and health care providers.”
- ~~04.06~~ The registrant shall disclose the aggregate number of such events that occurred during the fiscal year at the health care facilities it operates.
- ~~05.07~~ Where necessary to provide an accurate representation, the registrant should disclose SRE figures for individual facilities (e.g., if a small subset of facilities constitutes a disproportionate number of the SREs).
- ~~06.08~~ The registrant shall consider the National Quality Forum’s List of SREs as a normative reference, thus any subsequent updates to the scope or definitions shall be considered updates to this guidance.
- ~~09~~ The registrant shall disclose SREs occurring in any setting under its operation, including hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, and long-term care/skilled nursing facilities.

Additional References

National Quality Forum, “[Serious Reportable Events in Healthcare 2006 Update](#).”

~~HC0301-03. Health care-acquired infections, as defined by the CDC’s National Healthcare Safety Network, for: (1) Central Line-associated Bloodstream Infections (CLABSIs); (2) Surgical Site Infections (SSIs); (3) Catheter-associated Urinary Tract Infections (CAUTIs).~~

- ~~1~~—The registrant shall disclose the number of health care-acquired infections (HAIs) — by type — that occurred during the fiscal year at facilities it operates for each of the following HAIs: CLABSIs, SSIs, and CAUTIs.
- ~~2~~—To identify and disclose HAIs, the registrant shall use methodology developed and maintained by the National Healthcare Safety Network (NHSN), the public health surveillance system operated by the Centers for Disease Control and Prevention’s (CDC) Division of Healthcare Quality Promotion (DHQP).

Additional References

The registrant may use data on CLABSIs, SSIs, and CAUTIs that it currently discloses to meet the requirements of Centers for Medicare and Medicaid Services’ (CMS) Inpatient Quality Reporting Program, state mandated reporting requirements, or otherwise reported directly to NHSN, insofar as they meet the other requirements of ~~HC0301-3~~.

Centers for Disease Control and Prevention (CDC) Division of Health Care Quality Promotion, “[National and State Health Care Associated Infections Standardized Infection Ratio Report](#).”

TA01-12-01. Hospital-Acquired Condition (HAC) Score by facility

~~.10~~ The registrant shall disclose the HAC Score for each of the hospitals it operates, where

- ~~Hospitals are defined as in Section 1886(d)(1)(B) of the Social Security Act~~
- ~~HAC Score is calculated according to the Center for Medicare & Medicaid Services (CMS) FY2017 Inpatient Prospective Payment System / Long-Term Care Hospital Prospective Payment System (IPSS/LCTH PPS) Final Rule²¹~~
 - ~~The registrant shall consider the CMS scoring methodology as a normative reference, thus any updates made year-on-year shall be considered updates to this guidance~~

~~.11~~ If applicable, the registrant shall indicate if any hospitals it operates have been exempted from the HAC Reduction Program by CMS.

~~HC0301-04. TA01-13-01. Excess readmission ratio per hospital ratio for pneumonia, acute myocardial infarction, and heart failure, as defined by the Centers for Medicare & Medicaid Services (CMS). Readmissions Payment Adjustment Amount as part of the Hospital Readmissions Reduction Program.~~

~~.12~~ Readmission shall be defined per the Hospital Readmissions Reduction Program (HRRP) as an admission to a hospital within 30 days of a discharge from the same or another hospital, ~~where hospital~~

- Hospital is defined by Section 1886(d)(1)(B) of the Social Security Act.

~~.07~~ The registrant shall separately disclose the excess readmission ratios for pneumonia, acute myocardial infarction, and heart failure as a mean value for all hospitals it operates.

~~.08~~.13 The excess readmission ratio shall be calculated as is defined by the Centers for Medicare & Medicaid Services (CMS) ~~Centers for Medicare & Medicaid Services (CMS)~~, where the excess readmission ratio = risk-adjusted predicted readmissions/risk-adjusted expected readmissions.

~~.09~~.14 The registrant shall disclose the excess readmission ratio for each hospital it operates.

~~.10~~.15 The registrant shall follow all methodology described by CMS described by CMS, including the use of three years of trailing data to determine excess readmission ratios for the current fiscal year. The registrant shall consider the CMS's IPSS ~~Inpatient Prospective Payment System (IPPS)~~ Final Rules for each fiscal year as normative references, thus each annual update to the adjustment factors, definitions, methodology, and scope shall be considered an update to this requirement.

~~.11~~ The registrant shall disclose the Readmissions Payment Adjustment Amount—a reduction to the inpatient prospective payment system (IPPS) payments the registrant typically receives—in dollars, aggregated for all hospitals it operates.

²¹ The registrant may access many of the underlying data in a publicly available database via Hospital Compare, a service of Centers for Medicare & Medicaid Services

~~.12 The readmission payment adjustment amount shall be calculated as is defined by the CMS, where the Readmissions Payment Adjustment Amount = [Base operating diagnosis-related group (DRG) payment amount x readmissions adjustment factor] – base operating DRG payment amount.~~

TA01-13-02. Magnitude of readmissions payment adjustment as part of the Hospital Readmissions Reduction Program (HRRP).

~~.16 The registrant shall disclose the Readmissions Payment Adjustment Amount aggregated for all hospitals it operates~~

~~.13.17 The readmission payment adjustment amount shall be calculated per the [CMS definition](#) where the Readmissions Payment Adjustment Amount = [Base operating diagnosis-related group (DRG) payment amount x readmissions adjustment factor] – base operating DRG payment amount.~~

Access for Low-Income Patients

Description

~~Although the~~The Patient Protection and Affordable Care Act (PPACA) ~~will increase~~expanded the number of insured individuals, ~~the Congressional Budget Office estimates that 30 million nonelderly people will.~~ However, roughly 11 percent of the adults in the U.S. remain uninsured ~~in 2023.~~ The Health care delivery companies will continue to face challenges associated with serving uninsured and low-income patients ~~will be further.~~ These challenges are likely to be compounded by reductions in Disproportionate Share Hospital (DSH) payments ~~beginning in fiscal year 2014.~~ Disclosure on efforts to extend services to uninsured populations and DSH allocations will allow shareholders to understand how companies in this ~~industry are able to provide access to low income patients and how serving the uninsured affects the business model.~~ industry are incorporating the need to provide services to low-income and uninsured patients into their business models.

Accounting Metrics

HC0301-05. Description of strategy to manage the mix of patient insurance status (i.e., private insurance, government insurance, and uninsured), including a description of alternative pricing mechanisms or programs for the uninsured.

~~14.18~~ The registrant shall describe its strategic approach to managing the impacts and effects of having patients with a mix of insurance statuses at its facilities. Where relevant, the registrant should discuss its approach to managing those patients with private insurance, government insurance, and those without insurance, and the risks and opportunities presented by each group.

~~15.19~~ Alternative pricing mechanisms include, but are not limited to, discounted/sliding fee schedules, care given for charity (as a write-off), or discounts for prompt payment for uninsured customers.

~~16.20~~ The registrant shall describe programs it implements for uninsured individuals including, but not limited to, financial assistance programs or participation in indigent care programs.

Additional References

Definitions: Indigent care programs – Programs typically administered by country or state governments that provide financial discounts for patients who demonstrate an inability to pay for health care services. Eligibility requirements may include proof of residency, an income at a fixed percentage (e.g., 250% or 250%) below the Federal Poverty Level (FPL), and ineligibility for programs such as Medicare, Medicaid, Children’s Health Insurance Programs (CHIP), or state-administered insurance programs.

Financial assistance programs – Programs typically administered by hospitals that provide no-cost or discounted care for patients who demonstrate an inability to pay for health care services. Eligibility requirements may include proof of residency, an income at a fixed percentage (e.g., 250% or 250%) below the Federal Poverty Level (FPL), and ineligibility for programs such as Medicare, Medicaid, Children’s Health Insurance Programs (CHIP), or state-administered insurance programs.

HC0301-06. Amount of Medicare Disproportionate Share Hospital (DSH) adjustment payments received.

.21 The registrant shall disclose the amount of payment adjustment, in dollars, that it received through the Center for Medicare Services' (CMS) Disproportionate Share Hospital program in the form of increases to its basic Medicare Advantage diagnosis-related group (MA-DRG) payment.

.22 The registrant shall disclose its payment adjustment as an aggregate figure for all eligible hospitals it operates.

Additional References

Department of Health and Human Services, "[Medicare Disproportionate Share Hospital – Rural Health Fact Sheet Series](#)."

Employee Recruitment, Development, and Retention

Description

Health care delivery companies will face increased competition for physicians as the Patient Protection and Affordable Care Act increases demand and intensifies current and future shortages. The ongoing ability to recruit, develop, and retain health care practitioners is critical to success in this industry and disclosure on related performance indicators allows shareholders to understand how companies are managing a critical human capital factor in the Health Care Delivery industry.

Accounting Metrics

HC0301-07. Employee turnover by voluntary and involuntary for: (1) physicians, (2) non-physician health care practitioners, and (3) all others.

~~17.23~~ Physicians include specialists and primary care physicians in the 29-1060 group of the Standard Occupation Classification (SOC) system from U.S. Bureau of Labor Statistics (BLS).

~~18.24~~ Non-physician health care practitioners include physician's assistants and nurse practitioners within the following groups of the Healthcare Practitioners and Technical Occupations ([29-0000](#)) Major Group of the SOC system from the BLS:

- 29-1070 Physician Assistants
- 29-1080 Podiatrists
- 29-1120 Therapists
- 29-1140 Registered Nurses
- 29-1150 Nurse Anesthetists
- 29-1160 Nurse Midwives
- 29-1170 Nurse Practitioners
- 29-1180 Audiologists

~~19.25~~ For each category of employees the registrant shall calculate monthly voluntary turnover as = total number of employee-initiated voluntary separation (such as resignation, retirement, etc.) for each month divided by the average number of employees for the month (the sum of the employees on the registrant's payroll at each pay period / number of pay periods). The registrant shall disclose its annual voluntary turnover rate, calculated by adding the 12 monthly turnover figures together and multiplying by 100 to arrive at a percentage.

~~20.26~~ For each category of employees the registrant shall calculate monthly involuntary turnover as = total number of registrant-initiated separation (such as dismissal, downsizing, redundancy, expiry of contract, etc.) for each

month divided by the average number of employees for the month (the sum of the employees on the registrant's payroll at each pay period / number of pay periods). The registrant shall disclose its annual involuntary turnover rate which is calculated by adding the 12 monthly turnover figures together and multiplying by 100 to arrive at a percentage.

Additional References

Society of Human Resources Management, [Executive Brief: Tracking Trends in Employee Turnover](#).

HC0301-08. Description of talent recruitment and retention efforts for health care practitioners, such as mentorship programs, flexible scheduling, and leadership development initiatives—~~22~~. Where applicable, participation or utilization rates for each type of effort.

~~24.27~~ The registrant shall describe its strategy to attract and retain talent, including specific efforts related to mentorship programs, leadership development initiatives, flexible scheduling, part-time employment, "no call" positions, mental and physical health support, and loan repayment programs (e.g., specific to employment in underserved areas).

~~22.28~~ It may be relevant to describe the following elements of programs: overview, implementation, participation, effectiveness (with any quantitative metrics).

~~23.29~~ Health care practitioners include specialists, primary care physicians, physician's assistants, and nurse practitioners with the [29-0000](#) Healthcare Practitioners and Technical Occupations (Major Group) – Standard Occupation Classification (SOC) system from U.S. Bureau of Labor Statistics:

- 29-1060 Physicians and Surgeons
- 29-1070 Physician Assistants
- 29-1080 Podiatrists
- 29-1120 Therapists
- 29-1140 Registered Nurses
- 29-1150 Nurse Anesthetists
- 29-1160 Nurse Midwives
- 29-1170 Nurse Practitioners
- 29-1180 Audiologists

Pricing and Billing Transparency

Description

~~Currently more than half of all~~ Numerous states have legislation that require ~~that~~ hospitals to report pricing information, and legislative trends suggest that a federal mandate is possible. Current and impending legislation, coupled with increased emphasis on health care cost containment, is likely to enhance scrutiny on the pricing and billing practices of companies in this industry. Firms that are able to achieve compliance and transparent pricing structures ~~will be~~ may be better positioned to protect shareholder value.

Accounting Metrics

HC0301-09. Description of policies or initiatives to ensure that patients are adequately informed about price before undergoing a procedure .

- ~~-3.1~~ The registrant shall describe the nature, scope, and implementation of policies and initiatives focused on transparency and clear communication of the price of procedures and/or treatment alternatives insofar as they may be related to the price of a procedure.
- ~~-4.2~~ Initiatives may include providing pricing information to consumers through written communication, posting information to a public website, or providing in-person consultation to consumers prior to services (e.g., during routine services as opposed to in emergency situations).
- ~~-5.3~~ The registrant shall specify how information is provided to consumers paying out-of-pocket versus those with insurance coverage. For those with insurance coverage, this may include coordinating with the consumer's insurer to determine the amount paid out-of-pocket and the amount paid by the insurer.
- ~~-6.4~~ The registrant shall specify if a precise total price, a range of prices, an estimate of price, or some other pricing information is provided to patients, such as the percentage (or amount) of the price for which the patient may be responsible.

~~HC0301-10. Describe~~ **TA01-14-01. Discussion of how pricing information for services (including inpatient and outpatient) is made publicly available, including the number of the registrant's 25 most common services for which pricing information is publicly available, and the percentage of total services performed (by volume) that these represent.**

- ~~-24.30~~ The registrant shall describe the scope, format, and mechanism for making pricing information publicly available, such as via a public website and/or in cooperation with government initiatives to consolidate pricing data.
- ~~-25.31~~ The registrant shall discuss if such information is made available for inpatient services and outpatient services (occurring in any ambulatory setting such as a hospital, clinic, or physician office).
- ~~-26.32~~ The registrant shall specify if ~~it makes~~ the scope of information made available includes precise total price, a range of prices, an estimate of price, or some other pricing information

TA01-14-02. Number of the registrant's 25 most common services for which pricing information is publicly available and the percentage of total services performed (by volume) that these represent

~~.27.33~~ ~~At minimum, the~~The registrant shall identify the number of its 25 most common inpatient services and 25 most common outpatient service services for which it provides public pricing information, where most common services are the registrant's most frequently billed services by count of procedures conducted over the past three years (including the fiscal year).

~~.28.34~~ The registrant shall calculate the percentage of total services for which there is publicly available pricing information by dividing the total number of procedures for which there is publicly available pricing information conducted during the fiscal year by the total number of procedures.

- The registrant shall perform this calculation for both inpatient and outpatient services.

~~.29.35~~ If the registrant makes pricing for more than 25 of its inpatient or outpatient procedures publicly available, it should specify the number it makes available. The registrant may include this additional information ~~in addition,~~ as separate figures, to the data disclosed for ~~.4033~~ and ~~.4134~~.

Energy and Waste Efficiency

Description

The ~~health care delivery~~ Health Care Delivery industry faces significant costs associated with energy use and waste disposal. ~~The Environmental Protection Agency's Energy Star Program estimates that hospitals spend \$8.8 billion~~ As policymakers focus on reducing health care costs, improved efficiencies in energy annually, accounting for 1–3 percent of a hospital's operating budget. Improved energy and waste management and effective waste reduction could be a potential target for cost savings. The use of more efficient equipment, retrocommissioning, and improved waste segregation are among the strategies ~~can~~ that can lead to potential savings for health care facilities. Strong performance and management in this area can lead to lower operating costs and enhance shareholder value.

Accounting Metrics

HC0301-11. Total annual energy consumed (gigajoules) and percentage renewable (e.g., wind, biomass, solar).

~~30.36~~ The registrant shall convert the amount of electricity it purchased from kilowatt hours (kWh) to gigajoules (GJ).

~~31.37~~ The registrant shall disclose fossil fuel consumption in terms of its energy content, using higher heating values (HHV), also known as gross calorific values (GCV), and which are directly measured or taken from the Intergovernmental Panel on Climate Change (IPCC), the U.S. Department of Energy (DOE), or the U.S. Energy Information Administration (EIA).

~~32.38~~ The registrant shall disclose renewable energy consumption as a percentage of its overall energy consumption, in terms of its energy content. For biofuels, the registrant shall use HHVs from the sources mentioned above. For solar or wind energy consumption, the registrant shall convert from electricity production (kWh) to gigajoules (GJ).

~~33.39~~ The registrant shall disclose renewable energy data for renewable energy it either directly produces, or purchases through renewable energy certificates (RECs) that are certified (i.e., through Green-e) or through renewable power purchase agreements (PPAs). It shall not disclose the renewable portion of the energy that is drawn from electricity grids.

HC0301-12. Total weight of Regulated Medical Waste generation (as defined by the Medical Waste Tracking Act of 1988) and total weight by disposition (e.g., on-site incineration, landfill, treatment/storage/disposal facility, etc.).

~~34.40~~ Regulated medical waste (also known as medical waste, infectious waste, biomedical waste, or biohazardous waste), which may be subject to federal or state level regulation, shall be defined here according to the expired [Medical Waste Tracking Act of 1988](#) and includes:

- Cultures and Stocks – Cultures and stocks of infection agents and associated biological cultures, including cultures from medical and pathological laboratories, and stocks of infectious agents from research and industrial laboratories, waste from the production of biological, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures.

- Pathological Wastes – Human pathological wastes, including tissues, organs, body parts, and body fluids that are removed during surgery and autopsy, or other medical procedures, and specimens of body fluids and their containers.
- Human Blood and Blood Products – (1) Liquid waste human blood; (2) products of blood; (3) items saturated and/or dripping with human blood; or (4) items that were saturated and/or dripping with human blood that are now caked with dried human blood, including serum, plasma, and other blood components, and their containers that were used or intended for use in patient care, testing and laboratory analysis, or the development of pharmaceuticals. Intravenous bags are also included in this category.
- Sharps – Sharps that have been used in animal or human patient care or treatment, or in medical research or industrial laboratories, including hypodermic needles, syringes (with or without the attached needle), Pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slide and cover slips.
- Animal waste – Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals, or testing of pharmaceuticals.
- Isolation wastes – Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.
- Unused sharps – The following unused discarded sharps: hypodermic needles, suture needles, syringes, and scalpel blades.

~~35.41~~ The registrant shall disclose the total weight of the waste generated in kilograms, aggregated for all facilities it owns and operates.

~~36.42~~ The disposition shall be identified, taken to mean the final destination of the waste, which may include on-site incineration, landfill, recycling facility, treatment facility, or other (e.g., return to a supplier, commercial composting, etc.).

~~37.43~~ If the registrant utilizes a waste transport service, broker, or intermediary to handle its regulated medical waste, it shall make a good faith effort to determine the final disposition.

HC0301-13. Total weight of pharmaceutical waste generation and total weight by disposition (e.g., on-site incineration, landfill, treatment/storage/disposal facility, etc.). Break down by: (1) hazardous waste and (2) non-hazardous (solid) waste.

~~38.44~~ The registrant shall calculate and disclose the total amount of each type of waste in kilograms that is recycled (or reused), incinerated, and landfilled. If there are other dispositions for the waste (e.g., composting or permanent long-term storage), then the registrant should indicate so.

~~39.45~~ Pharmaceutical waste shall be broken down into two categories: (1) hazardous waste (listed RCRA waste and non-listed, characteristic hazardous waste) and (2) non-hazardous (solid) waste.

~~40.46~~ The registrant shall indicate the final disposition by each category of pharmaceutical waste, where the disposition may include on-site incineration, disposal at a specialized treatment or storage facility, recycling, landfilling, or another disposition.

~~41.47~~ If the registrant utilizes a waste transport service, broker, or intermediary to handle its regulated medical waste, it shall make a good faith effort to determine the final disposition of its waste.

Additional References

Definitions

RCRA hazardous waste – waste that appears on one of the four hazardous wastes lists (F-list, K-list, P-list, or U-list) and found in regulation 40 CFR Part 261.

Non-RCRA hazardous wastes (characteristic wastes) – waste that exhibits at least one of four characteristics: ignitibility, corrosivity, reactivity, or toxicity.

Solid waste – any garbage or refuse, sludge from a wastewater treatment plant, water supply treatment plant, or air pollution control facility and other discarded material, including solid, liquid, semi-solid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations, and from community activities. It may require special handling because it is a controlled substance, or poses an environmental or human health effect.

The U.S. EPA provides a [hazardous waste identification process](#). Should pharmaceuticals be added to an [expanded definition of Universal Waste](#), this requirement will be updated as appropriate.

Climate Change Impacts on Human Health and Infrastructure

Description

An increase in extreme weather events associated with climate change could present physical threats to health care delivery facilities and ~~operations and~~ create challenges in serving affected populations. In addition, these events coupled with the potential spread of infectious diseases, and food and water scarcity, may present material implications for the Health Care Delivery industry. ~~Companies should subsequently disclose strategies to protect value in light of these challenges. As regulators continue to emphasize this issue, company disclosure on policies, practices, and preparedness relating to climate change will help investors understand how value will be protected.~~

Accounting Metrics

~~HC0301-14, TA01-18-01. Description of the strategy to address the effects of climate change on business operations, physical infrastructure, and facility design. Discussion of specific risks (such as physical risks) presented by policies and practices to address changes in (1) the frequency and intensity of extreme weather and changes to events (2) the morbidity and mortality rates of illnesses and diseases, associated with climate change~~

~~48.~~ The registrant shall ~~discuss~~ describe the nature, scope, and implementation of its strategic business approach policies and practices related to addressing significant the risks to physical infrastructure and assets presented by changes in the frequency, severity, type, and geographic location of extreme weather events such as:

- ~~Risks to physical infrastructure that is located in flood prone low-lying and/or hurricane-prone areas.~~
- ~~Risks to physical infrastructure based on facility design, such as having key medical equipment in basements or the availability of backup power.~~

~~42, 49.~~ The registrant shall describe the nature, scope, and implementation of its policies and practices related to addressing the risks presented by the changes in prevalence, geography, and severity of certain diseases that ~~will~~ are likely to be ~~caused~~ impacted by climate change, such as:

- The need for added and/or flexible capacity due to influx of patients ~~from climate related events such as hurricanes, flooding, or due to~~ heat related illness.
- Obtaining the necessary facilities and expertise to identify and treat changing disease profiles in patients, such as for:
 - Malaria, dengue fever, and other vector borne diseases that affect tropical populations, but due to climate change may target non-tropical regions in the future;
 - Heat-related diseases (e.g., lung diseases such as asthma caused by increases in ground level ozone);
 - Waterborne diseases (e.g., cholera due to increased flooding incidence); and
 - Human developmental disorders (e.g., malnutrition due to decreased food availability).

TA01-18-02. Percentage of health care facilities that comply with CMS's Emergency Preparedness Rule

.50 The registrant shall disclose the percentage of the health care facilities that it owns or operates that are in compliance with the Centers for Medicare and Medicaid Services' Emergency Preparedness Rule, where

- The rule and the terms of compliance are defined by the Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers and determined by the Centers for Medicare and Medicaid Services in the Medicare and Medicaid Programs Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers
- The registrant shall consider the Emergency Preparedness Rule as a normative reference, thus any updates made year-on-year shall be considered as updates to this guidance

-.43.51 The registrant shall indicate the number of health care facilities it owns or operates which have been excluded from the Emergency Preparedness Rule

Fraud and Unnecessary Procedures

Description

Health care delivery companies are subject to significant fines and penalties under the Federal False Claims Act and similar state laws. Entities that receive at least \$5 million annually in Medicaid payments must have written policies for all employees and contractors regarding false claims, false statements, and whistleblower protections under these laws. The ability to ensure compliance in this area may have material implications for health delivery companies.

Accounting Metrics

HC0301-15. Description of legal and regulatory fines and settlements associated with Medicare and Medicaid fraud under the False Claims Act. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events.

~~-44.52~~ The registrant shall briefly describe the nature and context of fines and settlements associated with Medicare and Medicaid fraud under the False Claims Act, including civil actions (e.g., civil judgment, settlements, or regulatory penalties) and criminal actions (e.g., criminal judgment, penalties, or restitutions) taken by any entity (government, businesses, or individuals).

~~-45.53~~ The registrant shall disclose the amount of any fine or settlement associated with each incident, not including legal fees.

~~-46.54~~ The registrant shall describe any corrective actions it has implemented as a result of each incident. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

Patient Privacy and Electronic Health Records

Description

The Health Insurance Portability and Accountability Act (HIPAA) requires health care providers to establish administrative, physical, and technical safeguards to protect the integrity, confidentiality, and availability of patient health information. Failure to comply with these regulations can lead to civil and criminal penalties, while the American Recovery and Reinvestment Act (ARRA) has provided for enhanced enforcement and increased fines. The ARRA also established financial incentives for the meaningful use of electronic health records, as well as reduced Medicare payments for companies that fail to demonstrate meaningful use. Disclosure on HIPAA violations and electronic health records adoption will allow shareholders to monitor performance in these areas.

Accounting Metrics

HC0301-16. Percentage of patient records that are electronic medical records (EMR) or electronic health records (EHR) meeting the Centers for Medicare and Medicaid Services (CMS) “meaningful use” requirements.

~~47.55~~ The registrant shall calculate and disclose the percentage of records that are electronic health records (EHR) in “meaningful use,” as defined in [42 CFR \(Public Health\) Part 495 \(Standard for the Electronic Health Record Technology Incentive Program\)](#) and promulgated by the Centers for Medicare and Medicaid Services (CMS) as part of its EHR Incentive Programs.

~~48.56~~ EHR systems that are certified by an authorized testing and certification body according to the Office of the National Coordinator for Health Information Technology (ONC HIT) Certification Criteria shall be considered to meet the “meaningful use” requirements.

~~49.57~~ The registrant shall indicate which edition of the ONC HIT Certification Criteria its EHR systems are certified to, if not the most currently available.

~~50.58~~ Certified EHR systems are those listed on the [Certified Health IT Product List](#) (CHPL).

~~54.59~~ If the registrant does not participate in the Medicare or Medicaid EHR Incentive Program and/or its EHR is not listed on the CHPL, it may demonstrate through an independent audit that its EHR meets the threshold and all of the requirements for “meaningful use.”

~~HC0301-17. TA01-15-01. Description of legal and regulatory fines and settlements associated with Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules violations or The Health Information Technology for Economic and Clinical Health (HITECH) Act violations. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events. Discussion of policies and practices to secure customers’ protected health information (PHI) records and other personally identifiable information (PII)~~

~~60~~ The registrant shall describe the nature, scope, ~~Description of legal and regulatory fines~~ implementation of its policies and settlements associated practices related to securing customer PHI records and other PII, with Health Insurance Portability and Accountability Act of 1996 (HIPAA) a specific focus on how it addresses the collection, usage, and retention of customers’ information, where:

- PHI is defined in 45 CFR 160.103 and referenced in Section 13400 of Subtitle D (“Privacy and Security Rules violations or The”) of the Health Information Technology for Economic and Clinical Health (HITECH) Act violations. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events as information that is a subset of health information, including demographic information collected from an individual, that meets the following criteria: The information (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse and (2) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual; and (i) identifies the individual or (ii) there is a reasonable basis to believe the information can be used to identify the individual.
 - Health information is defined as any information, whether oral or recorded in any form or medium, that (A) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and (B) relates to the past, present, or future physical or mental health or condition of any individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.
 - PHI includes information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium.
 - PHI excludes individually identifiable health information in education records covered by the Family Educational Rights and Privacy Act (20 U.S.C. 1232g), records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a drug retailer in its role as employer.
- PII is defined as any information about an individual that is maintained by an entity, including any information that can be used to distinguish or trace an individual’s identity, such as name, Social Security number, date and place of birth, mother’s maiden name, or biometric records and any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information.²²

.61 The registrant shall briefly describe the nature and context of fines and settlement associated information “lifecycle” (i.e., collection, use, retention, processing, disclosure, and destruction) and how information-handling practices at each stage may affect individuals’ privacy.

- With respect to data collection, it may be relevant for the registrant to discuss which data or types of data are collected without consent of an individual, which require opt-in consent, and which require opt-out action from the individual.
- With respect to usage of data, it may be relevant for the registrant to discuss which data or types of data are used by the registrant internally and under what circumstance the registrant shares, sells, rents, or otherwise distributes data or information to third parties.

²² *Privacy: Alternatives Exist for Enhancing Protection of Personally Identifiable Information*, GAO Report 08-536, May 2008.

- With respect to retention, it may be relevant for the registrant to discuss which data or types of data it retains, the length of time of retention, and practices used to ensure that data is stored securely.

.62 The registrant shall discuss the systems it uses to ensure compliance with the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules and the HITECH Act, including policies and practices related to the collection, usage, storage, and disposal of PHI and PII.

.63 The registrant shall discuss its efforts to ensure compliance in the context of how it implements the following three categories of system security:

- Administrative safeguards, which are defined as documented, formal policies and procedures that are intended to manage the selection and execution of security measures to protect data and manage the conduct of personnel in relation to the protection of data.
- Physical safeguards, which are defined as the protection of physical computer systems and the buildings holding such systems from natural and environmental hazards and inappropriate intrusion or removal.
- Technical safeguards, which are defined as processes put in place to protect information, authenticate users, and control individual access to information.

.64 Relevant practices to discuss include internal monitoring practices, technology and security programs to prevent data breaches, training programs and protocols in place for employees who handle PHI or PII, and disposal methods for paper and electronic PHI records.

.65 The registrant shall disclose if it employs heightened security measures to ensure the security of PHI, including a discussion of those additional measures.

.66 The registrant should not include in its disclosure any information that compromises the security of its systems or its enrollees' PHI or PII.

TA01-15-02. Number of data security breaches, percentage involving (1) only customers' PII and (2) customers' PHI, number of customers affected in each category

.67 The registrant shall disclose the total number of data security breaches, which are defined as instances of unauthorized acquisition, access, use, or disclosure of protected information.

.68 The scope of disclosure shall be limited to data security breaches and incidents that resulted in the registrant's business processes deviating from its expected outcomes for confidentiality, integrity, and availability.

- The scope of disclosure shall include incidents of unauthorized acquisition or acquisition without valid authorization, resulting from deficiencies or failures of people, processes, or technology.
- The scope of disclosure shall exclude disruptions of service due to equipment failures.

.69 Disclosure shall be additional but complementary to the [SEC's CF Disclosure Guidance: Topic No. 2, Cybersecurity](#) violations or The

- At a minimum, this includes instances in which the costs or other consequences associated with one or more known incidents—or the risk of potential incidents—represents a material event, trend, or uncertainty that is reasonably likely to have a material effect on the registrant’s results of operations, liquidity, or financial condition, or would cause reported financial information to not be necessarily indicative of future operating results or financial condition (e.g., theft of intellectual property, reduced revenue, increased cybersecurity protection expenditure, litigation costs, etc.).

.70 The registrant shall disclose the percentage of data security breaches in which only customers’ PII (but not PHI) was breached, where:

- PII is defined as any information about an individual that is maintained by an entity, including (1) any information that can be used to distinguish or trace an individual’s identity, such as name, Social Security number, date and place of birth, mother’s maiden name, or biometric records; and (2) any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information.²³ The scope of disclosure is limited to breaches in which customers were notified of the breach, either as required by state law or voluntarily by the registrant.

.71 The registrant shall disclose the percentage of data security breaches in which customer’s PHI was breached, where:

- PHI is defined in 45 CFR 160.103 and referenced in Section 13400 of Subtitle D (‘Privacy’) of the Health Information Technology for Economic and Clinical Health (HITECH) Act violations, including civil actions (e.g., civil judgment, settlements, or regulatory penalties) and criminal actions (e.g., criminal judgment, penalties, or restitutions) Act (HITECH Act) as information that is a subset of health information, including demographic information collected from an individual, that meets the following criteria: The information (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse and (2) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual; and (i) identifies the individual or (ii) there is a reasonable basis to believe the information can be used to identify the individual.
 - Health information is defined as any information, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present, or future physical or mental health or condition of any individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.
 - PHI includes information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium.
 - PHI excludes individually identifiable health information in education records covered by the Family Educational Rights and Privacy Act (20 U.S.C. 1232g), records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.

²³ *Privacy: Alternatives Exist for Enhancing Protection of Personally Identifiable Information*, GAO Report 08-536, May 2008.

- PHI is a subset of PII.

.72 Disclosure shall include incidents in which encrypted data were acquired with an encryption key that was also acquired.

.73 The registrant may delay disclosure if a law enforcement agency has determined that notification impedes a criminal investigation until the law enforcement agency determines that such notification does not compromise the investigation.

.74 The registrant shall disclose the total number of customers that were affected by data breaches of (a) only PII and (b) PHI, where:

- The number of customers affected includes all those whose personal data (PII or PHI) was compromised in a data breach.

Note to TA01-15-02

~~.52.75~~ The registrant shall describe the corrective actions taken by any entity (government, businesses, or individuals) in response to breaches, such as changes in operations, management, processes, products, business partners, training, or technology.

.76 All disclosure shall be sufficient such that it is specific to the risks the registrant faces, but disclosure itself will not compromise the registrant's ability to maintain data privacy and security.

.77 The registrant ~~shall~~ should disclose ~~the~~its policy for disclosing data breaches to affected customers in a timely manner.

TA01-15-03. Total amount of losses as a result of legal proceedings associated with data security and privacy

.78 The registrant shall disclose the total amount of ~~any fine or settlement~~ losses in U.S. dollars it incurred as a result of legal proceedings associated with data security and privacy

.79 The legal proceedings shall include any adjudicative proceeding, whether before a court, a regulator, an arbitrator, or otherwise, in which the registrant was involved.

.80 The losses shall include all fines, settlements, and other monetary liabilities as a result of civil actions (e.g., civil judgments or settlements), regulatory proceedings (e.g., penalties, disgorgement, or restitution), and criminal actions (e.g., criminal judgment, penalties, or restitution) brought by any entity (governmental, business, or individual).

.81 The losses shall exclude legal fees incurred by the registrant.

.82 The scope of disclosure shall include legal proceedings associated with enforcement of health information privacy and security industry regulations promulgated by U.S. and foreign regulatory authorities. Such regulatory authorities may include, but are not limited to:

- The U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR)

Note to **TA01-15-03**

.53.83 The registrant shall briefly describe the nature (e.g., judgment or order issued after trial, settlement, guilty plea, deferred prosecution agreement, non-prosecution agreement) and context (e.g., data security, data privacy, etc.) of all losses as a result of legal proceedings.

.84 The registrant shall describe any corrective actions it has implemented as a result of each incident. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

Employee Health and Safety

Description

The Health Care Delivery industry is heavily dependent on a skilled workforce, and employees are routinely exposed to injury, illness, and infection during their regular duties. Relative to other industries, Health Care Delivery has one of the highest rates of injury and illness. These risks result from continuous exposure to sick patients and physical demands associated with caring for patients. Although injury and illness are inherent risks for this industry, companies that manage this issue more effectively can reduce costs associated with workers' compensation, productivity, morale, and employee retention. Companies can mitigate risks by implementing proactive health and safety management protocols, developing training requirements for employees, and conducting regular audits of their own practices.

Accounting Metrics

TA01-16-01. (1) Total recordable case rate and (2) days away from work case rate

.85 Registrants whose workforce is entirely U.S.-based shall disclose their total recordable injury rate (TRIR) and fatality rate as calculated and reported in the Occupational Safety and Health Administration's (OSHA) Form 300.

- OSHA guidelines provide details on determining whether an event is a recordable occupational incident and definitions for exemptions for incidents that occur in the work environment but are not occupational.

.86 Registrants whose workforce includes non-U.S.-based employees shall calculate their TRIR and fatality rate according to the U.S. Bureau of Labor Statistics [guidance](#) and/or using the U.S. Bureau of Labor Statistics [calculator](#).

.87 The registrant shall disclose its Total Recordable Case Rate and Days Away from Work Case Rate for all employees, including direct full-time and part-time employees, as well as contract employees.

.88 The scope includes all employees, domestic and foreign.

.89 Rates shall be calculated as: (statistic count / total hours worked) * 200,000.

Management of Controlled Substances

Description

The Health Care Delivery industry is in a unique position with respect to the nation's evolving opioid epidemic. As one of the largest prescribers of opioids, the industry has contributed to an increase in the use of these substances and subsequently to a rise in addiction levels. As the providers of care, the industry also treats individuals who are suffering from addiction and related health concerns. Although health care delivery companies do not typically face direct costs associated with the prescription of opioids, they face significant costs in addressing the health care needs of those suffering from addiction. Companies can address the issue by evaluating their approach to pain management and addressing the number of prescriptions issued. This can be achieved through the development of new policies, training, and oversight.

Accounting Metrics

TA01-17-01. Discussion of policies and practices to reduce the number of prescriptions issued for controlled substances

.90 The registrant shall describe its policies and practices related to the prescription of controlled substances, including the activities required to implement as well as the positions affected by such policies and practices, including, but not limited to:

- Registration and use of state prescription drug monitoring programs
- The scope, positions affected, and percent of workforce covered by training programs related to controlled substances, including the evidence-based treatment of pain
- Programs implemented by the registrant to identify and provide care for patients with substance abuse disorders
- Policies and procedures to ensure the safe storage and disposal of controlled substances
- Policies and programs related to the prescription of opioid antagonists (naloxone, naltrexone, and others) or other drugs that can counter the effects of controlled substances

TA01-17-2. Percentage of controlled substance prescriptions written for which a prescription drug monitoring program (PDMP) database was queried

.91 The registrant shall disclose the percentage of controlled substance prescriptions that it wrote for which a physician or hospital staff queried a PDMP database prior to issuing or filling the prescription, where:

- Controlled substances are defined in §802(6) of Title 21, United States Code (U.S.C.) as drugs that have some potential for abuse or dependence and are regulated by the federal Controlled Substances Act (CSA). Controlled substances exclude distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.

- A PDMP is defined as an electronic database that collects designated data about the dispensing of controlled substances
- PDMPs may be administered by specified statewide regulatory, administrative, or law enforcement agencies, from which data may be distributed by the specified agency to individuals who are authorized under state law to receive the information for purposes of their profession.
 - A PDMP shall be considered queried if an applicable PDMP system was accessed by an authorized individual prior to writing a prescription to review patient prescription history information.
- Patients or circumstances that are excluded from PDMP reporting and querying, based on waiver or exemption established by state law, shall be excluded from the scope of this calculation.

.92 The registrant shall disclose the percentage as the number of controlled substance prescriptions written for which a PDMP was queried divided by the total number of controlled substance prescriptions written.

- Patients or circumstances that are excluded from PDMP reporting and querying based on state exemptions shall not be included in the number of controlled substance prescriptions written where a PDMP was queried or the total number of controlled substance prescriptions written.



HEALTH CARE SECTOR

HEALTH CARE DISTRIBUTORS*

Sustainability Accounting Standard

PROPOSED CHANGES TO PROVISIONAL STANDARDS

EXPOSURE DRAFT

REDLINE OF STANDARD FOR PUBLIC COMMENT

Prepared by the
Sustainability Accounting Standards Board®

October 2017

* Sustainable Industry Classification System™ (SICS™) #HC0302

HEALTH CARE DISTRIBUTORS

Sustainability Accounting Standard

About the SASB

The Sustainability Accounting Standards Board (SASB) was founded in 2011 as an independent standard-setting organization. The SASB issues and maintains sustainability accounting standards for 79 industries, focusing on the subset of industry-specific sustainability factors that are reasonably likely to have material financial impacts on companies within that industry. Companies can use the standards to disclose material information to investors in SEC filings, including Forms 10-K, 20-F, and 8-K, as well as S-1 and S-3, in a cost-effective and decision-useful manner. The standards are designed to help companies better comply with existing disclosure obligations, working within the framework of existing U.S. securities laws.

The SASB Standards Board is responsible for developing and issuing the standards, maintaining technical agendas, proposing updates to the standards, and executing the standard-setting process. The SASB staff is responsible for performing research and engaging in consultation on the standards, supporting the work of the Standards Board.

The SASB Foundation, an independent 501(c)3 non-profit, is responsible for the funding and oversight of the SASB, including safeguarding the SASB's independence and integrity through due process oversight and inquiry resolution. The SASB Foundation Board of Directors appoints members of the SASB.

About this Standard

This Standard is an exposure draft presented for public review and comment. **This version is not intended for implementation.**

The public comment period lasts for 90 days, beginning on October 2, 2017, and ending on December 31, 2017. The Standard is subject to change thereafter. SASB Standards are scheduled to be ratified by the SASB in early 2018.

For instructions on providing comments to SASB, please click [here](https://www.sasb.org/public-comment) (https://www.sasb.org/public-comment).

SUSTAINABILITY ACCOUNTING STANDARDS BOARD

1045 Sansome Street, Suite 450
San Francisco, CA 94111

www.sasb.org

The information, text, and graphics in this publication (the "Content") is owned by the Sustainability Accounting Standards Board. All rights reserved. You may use the Content only for non-commercial and scholarly use, provided that you keep intact all copyright and other proprietary notices related to the Content, and that you make no modifications to the Content. The Content may not be otherwise disseminated, distributed, republished, reproduced, or modified without the prior written permission of the Sustainability Accounting Standards Board. To request permission, please contact us at info@sasb.org.

Purpose & Structure

This document contains the SASB Sustainability Accounting Standard (SASB Standard) for the Health Care Distributors industry.

SASB Sustainability Accounting Standards comprise **(1) disclosure guidance and (2) accounting standards or metrics** for use by U.S. and foreign public companies in their disclosures to investors, such as in annual reports and filings with the U.S. Securities and Exchange Commission (SEC), including Forms 10-K, 20-F, 40-F, 10-Q, 8-K and S-1 and S-3. The Standards facilitate the meaningful disclosure of sustainability information that is useful to investors in making decisions on investments and corporate suffrage.¹ The Standards reflect the fact that certain sustainability information is important for assessing the future financial performance of an issuer, particularly over the long term.

SASB Standards identify sustainability topics that are reasonably likely to constitute material information for a company within a particular industry. Company management is responsible for determining whether those identified topics reflect information that is material to investors and should be disclosed in filings, based on that company's specific circumstances. For further details regarding the use of the SASB Standards, in particular guidance on determinations of materiality, please see SASB's Implementation Guide.²

SASB Standards provide companies with sustainability metrics designed to communicate performance on industry-level sustainability topics in a concise, comparable format using existing reporting mechanisms. Companies can use the Standards to help ensure that disclosure is reliable, decision-useful for investors, and cost-effective for issuers.

SASB Standards are intended to constitute "suitable criteria" for purposes of an attestation engagement as defined by Paragraph .A42 of AT-C section 105³ and referenced in AT-C section 395.⁴ "Suitable criteria" have the following attributes:

- *Relevance*—Criteria are relevant to the subject matter.
- *Objectivity*—Criteria are free from bias.
- *Measurability*—Criteria permit reasonably consistent measurements, qualitative or quantitative, of subject matter.
- *Completeness*—Criteria are complete when subject matter prepared in accordance with them does not omit relevant factors that could reasonably be expected to affect decisions of the intended users made on the basis of that subject matter.

¹ The AICPA defines sustainability information in its Guide, [Attestation Engagements on Sustainability Information \(Including Greenhouse Gas Emissions Information\)](#) (Issued July 2017), as follows: "information about sustainability matters (such as economic, environmental, social and governance performance)." It further explains that "sustainability metrics and sustainability indicators are components of sustainability information. Sustainability information may be nonquantitative (narrative), historical, or forward-looking."

² <https://library.sasb.org/implementation-guide>

³ <https://www.aicpa.org/Research/Standards/AuditAttest/DownloadableDocuments/AT-C-00105.pdf>

⁴ <http://pcaobus.org/Standards/Attestation/Pages/AT701.aspx>

Industry Description

Health care distributors purchase, inventory, and sell pharmaceutical products and medical equipment to hospitals, pharmacies, and physicians. Demand for the industry's services is driven largely by rates of insurance, pharmaceutical spending, illness, and demographics. Increased enrollment in government insurance programs under the Affordable Care Act, electronic health records, and consolidation throughout the health care sector will likely continue to shape the industry. The health care sector continues to face an emphasis on reduced costs and improved efficiencies, which will also impact the Health Care Distributors industry. Companies in this industry face challenges from consolidation and partnerships between pharmacies, payers, and manufacturers.

Users of the SASB Standards

The SASB Standards are intended for use by public companies and by investors to inform investment decisions. The standards facilitate disclosure of financially material sustainability-related information in a concise, comparable, cost-effective, decision-useful format.

The SASB Standards are designed for integration into existing reporting mechanisms, such as SEC filings. This keeps the administrative and cost burden to a minimum. SEC filings include Form 10-K for U.S. companies, Form 20-F for foreign issuers, Form 40-F for Canadian issuers, quarterly reports on Form 10-Q, current reports on Form 8-K, and registration statements on Forms S-1 and S-3. The SASB Standards are also recognized by the European Commission as a suitable framework for companies to provide information to investors pursuant to EU Directive 2014/95/EU. See "Guidelines on non-financial reporting (methodology for reporting non-financial information)."⁵ Thus, SASB standards are a cost-effective way to satisfy both U.S. and European reporting requirements.

SASB evaluates the materiality of sustainability-related topics by using the high threshold of financial materiality that is established under the U.S. securities laws.⁶ Although designed to meet the rigorous disclosure requirements of the U.S. capital markets (thereby producing a high-quality set of evidence-based standards focused on material investor-focused topics), the standards represent a best practice that can be used by companies of all types (public and private) to describe their material sustainability-related risks and opportunities.

Guidance for Disclosure of Sustainability Topics in SEC Filings

1. Industry-Level Sustainability Topics

For the Health Care Distributors industry, the SASB has identified the following sustainability disclosure topics:

- Product Safety
- Counterfeit Drugs
- Fuel Efficiency
- Product Lifecycle Management
- Corruption and Bribery

⁵ https://ec.europa.eu/info/publications/170626-non-financial-reporting-guidelines_en

⁶ https://library.sasb.org/materiality_bulletin/

2. Determination of Materiality

In the U.S., sustainability disclosures are governed by the same laws and regulations that generally govern disclosures by securities issuers. According to the U.S. Supreme Court, a fact is material if, in the event such fact is omitted from a particular disclosure, there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of the information made available.⁷

Through a rigorous process of research, review of evidence, and public input, the SASB has identified sustainability topics that are reasonably likely to have a material effect on the financial condition or operating performance of companies within each Sustainable Industry Classification System™ (SICS™) industry.⁸ **However, the issuer must determine what information is (or is reasonably likely to be) material to the reasonable investor.** For further information regarding a process that corporations can use to assess the financial materiality of the sustainability-related topics in SASB standards, please see SASB’s Implementation Guide.⁹

3. SEC Requirements Relating to Disclosure of Material Sustainability Information

If a public company determines that certain sustainability information is reasonably likely to be material, it must then determine whether disclosure of some or all of the information under applicable SASB Standards is required under the U.S. federal securities laws. Several provisions of those laws are relevant to sustainability disclosures.

Regulation S-K sets forth certain disclosure requirements associated with Form 10-K and other SEC filings. Item 303 of Regulation S-K requires companies to, among other things, describe in the Management’s Discussion and Analysis of Financial Condition and Results of Operations (MD&A) section of Form 10-K “any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed.”¹⁰

Furthermore, the instructions to Item 303 state that the MD&A “shall focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition.”¹¹

The SEC has provided guidance for companies to use in determining whether a trend or uncertainty should be disclosed. The two-part assessment prescribed by the SEC can be applied to the topics included within this Standard:

⁷ *TSC Industries v. Northway, Inc.*, 426 U.S. 438 (1976).

⁸ https://library.sasb.org/materiality_bulletin/

⁹ <https://library.sasb.org/implementation-guide>

¹⁰ C.F.R. 229.303(Item 303)(a)(3)(ii).

¹¹ SEC [Release Nos. 33-8056; 34-45321; FR-61] Commission Statement about Management’s Discussion and Analysis of Financial Condition and Results of Operations: “We also want to remind registrants that disclosure must be both useful and understandable. That is, management should provide the most relevant information and provide it using language and formats that investors can be expected to understand. Registrants should be aware also that investors will often find information relating to a particular matter more meaningful if it is disclosed in a single location, rather than presented in a fragmented manner throughout the filing.”

- First, a company is not required to make disclosure about a known trend or uncertainty if its management determines that such trend or uncertainty is not reasonably likely to occur.
- Second, if a company’s management cannot make a reasonable determination of the likelihood of an event or uncertainty, then disclosure is required “unless management determines that a material effect on the registrant’s financial condition or results of operation is not reasonably likely to occur.”

Companies should also consider the applicability of other Regulation S-K requirements. Specifically, Item 101 (“Description of Business”) requires a company to provide a description of its business and its subsidiaries. Item 103 (“Legal Proceedings”) requires a company to describe briefly any material pending or contemplated legal proceedings; instructions to Item 103 provide specific disclosure requirements for administrative or judicial proceedings arising from laws and regulations that target discharge of materials into the environment, or that are primarily for the purpose of protecting the environment. Item 503(c) (“Risk Factors”) requires a company to provide discussion of the most significant factors that make an investment in the registrant speculative or risky, clearly stating the risk and specifying how it affects the company.

Finally, as a general matter, Securities Act Rule 408 and Exchange Act Rule 12b-20 require a registrant to disclose, in addition to the information expressly required by law or regulation, “such further material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they are made, not misleading.”

4. Where Disclosures Should Be Made in SEC Filings

In using the definition of materiality established under the U.S. federal securities laws, the SASB has identified and developed industry-specific sustainability topics and metrics that are reasonably likely to have a material effect on the financial condition or operating performance of companies within a particular industry. As a general matter, the SASB believes that investors are best served when disclosure of such information is made in SEC filings. An issuer might, for example, make the disclosure in a sub-section of MD&A with a caption, “**Sustainability-Related Information**,” with a section that includes the material topics, performance metrics, and management’s view with respect to corporate positioning. See SASB’s “Mock 10-Ks” for examples of preparing an MD&A using the SASB Standards.¹² Issuers are not precluded from using the Standards elsewhere, such as in stand-alone communications to investors or in sustainability reports (sometimes referred to as corporate social responsibility reports or environmental, social, and governance reports), company websites, or elsewhere. Corporate communication on material topics, including sustainability-related material topics, should be consistent across communication channels. As discussed above, SEC regulations may compel inclusion of material sustainability information in an SEC filing where it is deemed financially material.

The SASB recognizes that sustainability topics are relatively new areas of investor interest, and it may be difficult to determine whether particular sustainability information is material in certain situations. Accordingly, issuers might also consider using the SASB Standards in filings using Form 8-K, Item 8.01 (“Other Events”). This provision states that “The registrant may, at its option, disclose under this Item 8.01 any events, with respect to which information is not otherwise called for by this form, that the registrant deems of importance to security holders.” Making a disclosure

¹² <http://using.sasb.org/mock-10-k-library/>

under Item 8.01 would not require the issuer to make a decision regarding materiality, and might also provide the company with more time to make the disclosure than is permitted under filing rules applicable to Form 10-K, thereby facilitating the completeness and accuracy of the disclosed information.

When using the Standards, issuers should cite or refer to the relevant SASB Standard.

More detailed guidance on preparing disclosures of material information related to sustainability topics and making topic-level materiality determinations can be found in the **SASB Conceptual Framework**, available for download via <http://www.sasb.org/approach/conceptual-framework/>, and the **SASB Implementation Guide for Companies**, available for download via <https://library.sasb.org/implementation-guide/>.

Guidance on Accounting for Sustainability Topics

The SASB has identified accounting metrics for each sustainability topic included in this Standard. The SASB recommends that companies within this industry consider using these sustainability accounting metrics when preparing disclosures on the sustainability topics identified herein.

When disclosing information related to a sustainability topic identified by this Standard, companies should consider including a narrative description of any material factors necessary to ensure completeness, accuracy, and comparability of the data reported, as appropriate. Such a description might in certain circumstances include a discussion of the following:¹³

- The registrant's **governance** around the risks and opportunities related to the topic, including board oversight of and management's role in assessing and managing such risks and opportunities.
- The registrant's **strategic approach** regarding actual and potential impacts of topic-related risks and opportunities on the organization's **businesses, strategy, and financial planning**, over the **short, medium, and long term**.
- The registrant's process to **identify, assess, and manage** topic-related risks, and how these risks are integrated into the registrant's overall risk management process.
- The registrant's **use of metrics or targets** to assess and manage topic-related risks and opportunities.
- Data for the registrant's **last three completed fiscal years** (when available).

The SASB recommends that registrants use SASB Standards specific to their primary industry as identified in SICSTM. If a registrant generates significant revenue from multiple industries, the SASB recommends that it also consider sustainability topics that the SASB has identified for those industries, and disclose the associated SASB accounting metrics.

¹³ These areas for possible additional narrative description are generally aligned with the [Recommendations of the Task Force on Climate-related Financial Disclosures](#), which contains a more extensive discussion of such disclosure matters.

Further, the SASB recommends that companies design, implement, and maintain adequate systems of internal control over sustainability performance information to provide reasonable confidence regarding the achievement of related reporting objectives, such as those relating to the reliability of disclosed information.¹⁴

The SASB takes no position as to whether third-party attestation is necessary to enhance the credibility of the disclosed sustainability information, but as a matter of good governance, the SASB suggests that such assurance be considered.¹⁵

Scope of Disclosure

Unless otherwise specified, the SASB recommends:

- That a registrant disclose information on sustainability topics and metrics for itself and for entities that are consolidated for financial reporting purposes, as defined by accounting principles generally accepted in the United States (“US GAAP”), for consistency with other accompanying information within SEC filings;¹⁶
- That for consolidated entities, disclosures be made, and accounting metrics calculated, for the whole entity, regardless of the size of the minority interest; and
- That information from unconsolidated entities not be included in the computation of SASB accounting metrics. However, the registrant should disclose information about unconsolidated entities to the extent that the registrant considers the information necessary for investors to understand the effect of sustainability topics on the company’s financial condition or operating performance. (Typically, this disclosure would be limited to risks and opportunities associated with these entities.)

Reporting Format

Use of Financial Data

In instances where accounting metrics, activity metrics, and technical protocols in this Standard incorporate financial data (e.g., revenues, cost of sales, expenses recorded and disclosed for fines, etc.), such financial data shall be prepared in accordance with US GAAP, and be consistent with the corresponding financial data reported in the registrant’s SEC filings. Should accounting metrics, activity metrics, and technical protocols in this Standard incorporate disclosure of financial data that is not prepared in accordance with US GAAP, the registrant shall disclose such information in accordance with SEC Regulation G.¹⁷

¹⁴ In this regard, companies are referred to the report of a group of experts in this area. Robert H. Herz, Brad J. Monterio, Jeffrey C. Thomson, Leveraging the COSO Internal Control – Integrated Framework to Improve confidence in Sustainability Performance Data (August 2017).

¹⁵ The AICPA’s Guide (see supra note 1) provides guidance to assist accounting practitioners in performing attestation engagements on sustainability information.

¹⁶ See US GAAP consolidation rules (Section 810).

¹⁷ <https://www.sec.gov/rules/final/33-8176.htm>

Activity Metrics and Normalization

The SASB recognizes that normalizing accounting metrics is important for the analysis of SASB disclosures.

The SASB recommends that a registrant disclose any basic business data that may assist in the accurate evaluation and comparability of disclosure, to the extent that they are not already disclosed in Form 10-K (e.g., revenue, EBITDA, etc.).

Such data—termed “activity metrics”—may include high-level business data, including total number of employees, quantity of products produced or services provided, number of facilities, or number of customers. It may also include industry-specific data such as plant capacity utilization (e.g., for specialty chemical companies), number of transactions (e.g., for Internet media and services companies), hospital bed days (e.g., for health care delivery companies), or proven and probable reserves (e.g., for oil and gas exploration and production companies).

Activity metrics disclosed should:

- Convey contextual information that would not otherwise be apparent from SASB accounting metrics.
- Be deemed generally useful for investors relying on SASB accounting metrics to perform their own calculations and create their own ratios.
- Be explained and consistently disclosed from period to period to the extent that they continue to be relevant. However, a decision to make a voluntary disclosure in one period does not obligate a continuation of that disclosure if it is no longer relevant, or if a better metric becomes available.¹⁸

Where relevant, the SASB recommends specific activity metrics that—at a minimum—should accompany SASB accounting metric disclosures.

Table 1. Activity Metrics

ACTIVITY METRIC	CATEGORY	UNIT OF MEASURE	CODE
<u>Number of pharmaceutical units sold by product category</u>	<u>Quantitative</u>	<u>Number</u>	<u>TA01-21-01</u>
<u>Number of medical devices sold by product category</u>	<u>Quantitative</u>	<u>Number</u>	<u>TA01-21-02</u>

Units of Measure

Unless specified, disclosures should be reported in International System of Units (SI units).

¹⁸ Improving Business Reporting: Insights into Enhancing Voluntary Disclosures, FASB Business Reporting Research Project, January 29, 2001.

Uncertainty

The SASB recognizes that there may be inherent uncertainty when measuring or disclosing certain sustainability data and information. This uncertainty may be related to variables such as the reliance on data from third-party reporting systems and technologies, or the unpredictable nature of climate events. Where uncertainty around a particular disclosure exists, the SASB recommends that the registrant should consider discussing its nature and likelihood.¹⁹

Estimates

The SASB recognizes that scientifically-based estimates, such as the reliance on certain conversion factors or the exclusion of *de minimis* values, may occur for certain quantitative disclosures. Where appropriate, the SASB does not discourage the use of estimates or ranges. When using an estimate for a particular disclosure, the SASB expects that the registrant discuss its nature and substantiate its basis.

Timing

Unless otherwise specified, disclosure shall be for the registrant's fiscal year.

Limitations

There is no guarantee that SASB Standards address all sustainability impacts or opportunities associated with a sector, industry, or company; therefore, a company must determine for itself the topics that warrant discussion in its SEC filings.

Use of the SASB Standards is voluntary. The Standards are not intended to replace any legal or regulatory requirements that may be applicable to a company's operations. When such laws or regulations address legal or regulatory topics, disclosure under SASB Standards is not meant to supersede those requirements.

Use of the SASB Standards is not required or endorsed by the SEC or various entities governing financial reporting, including the Financial Accounting Standards Board, the Government Accounting Standards Board, or the International Accounting Standards Board.

Forward-Looking Statements

Disclosures on sustainability topics can, in some circumstances, involve discussion of future trends and uncertainties related to the registrant's operations and financial condition, including those influenced by external variables (e.g., environmental, social, regulatory, and political). Companies making these disclosures in SEC filings should familiarize themselves with the safe harbor provisions of Section 27A of the Securities Act, and Section 21E of the Exchange Act, which preclude civil liability for material misstatements or omissions in such statements if the registrant takes certain steps. These include, among other things, identifying the disclosure as "forward-looking," and accompanying such

¹⁹ The AICPA's Guide (see *supra* note 1) provides guidance related to measurement uncertainty.

disclosure with “meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statements.”

Notes on the Sustainability Accounting Standards

The following sections contain the disclosure guidance associated with each accounting metric, including guidance on definitions, scope, accounting, compilation, and presentation.

The term “shall” is used throughout this document to indicate those elements that reflect requirements of the Standard. The terms “should” and “may” are used to indicate guidance, which, although not required, provides a recommended means of disclosure.

Table 2. Sustainability Disclosure Topics & Accounting Metrics

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
Product Safety	Description <u>Discussion</u> of legal and regulatory fines and settlements associated with product safety. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events.	Quantitative / Discussion and Analysis	U.S. Dollars (\$)	HC0302-01
	Description <u>Discussion</u> of efforts to minimize health and safety risks of products sold, including those related to toxicity/chemical safety (e.g., REACH substances of very high concern), high abuse potential (e.g., Schedule II controlled substances), or delivery (e.g., incorrect dispensing, mislabeling, transmission of disease through reuse of vials, etc.).	Discussion and Analysis	n/a	HC0302-02
Counterfeit Drugs	Description <u>Discussion</u> of methods and technologies used to maintain traceability of products throughout the distribution chain and prevent counterfeiting.	Discussion and Analysis	n/a	HC0302-03
	Description <u>Discussion</u> of due diligence process to qualify suppliers of drug products and medical equipment and devices.	Discussion and Analysis	n/a	HC0302-04
	Description <u>Discussion</u> of process for alerting customers and business partners of potential or known risks associated with counterfeit products.	Discussion and Analysis	n/a	HC0302-05
Fuel Efficiency	Payload fuel economy = gallons per ton-miles.	Quantitative	Gallons, Tons (U.S.), Miles, U.S. Dollars (\$)	HC0302-06
	Description <u>Discussion</u> of involvement in efforts to reduce the environmental impact of logistics, including involvement in the EPA SmartWay program.	Discussion and Analysis	n/a	HC0302-07

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
Product Lifecycle Management	Description Discussion of initiatives to reduce the environmental impact of packaging, such as use of recycled materials, reductions in the amount of packaging material (i.e., dematerialization), packaging for consolidated shipping, and reduction in packaging waste (e.g., recycling and reuse of packaging, etc.).	Discussion and Analysis	n/a	HC0302-08
	Describe Discussion of product stewardship initiatives to promote take-back (for reprocessing or recycling) of products at the end of their lifecycle. Amount (by weight) of products accepted for take-back.	Discussion and Analysis	n/a	HC0302-09
Corruption and Bribery	Description Discussion of efforts to minimize conflicts of interest and unethical business practices; including mechanisms to ensure compliance.	Discussion and Analysis	n/a	HC0302-10
	Description of legal and regulatory fines and settlements associated with corruption or bribery, including Foreign Corrupt Practices Act and False Claims Act violations. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events. Total amount of losses as a result of legal proceedings associated with bribery, corruption, or other unethical business practices. ²⁰	Quantitative	U.S. Dollars (\$)	HC0302-11-TA01-20-01

²⁰ Note to **TA01-20-01** – Disclosure shall include a description of fines and settlements and corrective actions implemented in response to events.

Product Safety

Description

Health care distributors play an integral role in the delivery of health care products to consumers. The industry therefore has a shared responsibility with manufacturers to ensure safety, labeling, and quality. Health care distributors that limit the incidence of safety or other product claims will be better positioned to protect shareholder value.

Accounting Metrics

HC0302-01—Description, Discussion of legal and regulatory fines and settlements associated with product safety. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events.

- .01 The registrant shall describe the nature and context of fines and settlements related to the safety of products that it distributes, including civil actions (e.g., civil judgment, settlements, or regulatory penalties) and criminal actions (e.g., criminal judgment, penalties, or restitutions) taken by any entity (government, businesses, or individuals).
- .02 In addition to disputes over the safety of the product design and/or manufacturing defects (such as for registrant-branded products or generics), the registrant shall discuss liability lawsuits related to the marketing of products that it distributes insofar as they are related to safety (e.g., directions-for-use labeling, safety warning labeling, etc.).
- .03 The registrant shall disclose the amount of any fine or settlement associated with each incident, not including legal fees.
- .04 The registrant shall describe any corrective actions it has implemented as a result of each incident. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

HC0302-02—Description, Discussion of efforts to minimize health and safety risks of products sold, including those related to toxicity/chemical safety (e.g., REACH substances of very high concern), high abuse potential (e.g., Schedule II controlled substances), or delivery (e.g., incorrect dispensing, mislabeling, transmission of disease through reuse of vials, etc.)-

- .05 The registrant shall describe all relevant aspects, such as the structure, goals, implementation, and scope, of initiatives aimed at minimizing the health and safety risks of the products it distributes.
- .06 Risks may include those related to toxicity of chemicals or materials in the products it distributes, those related to the use of the product (such as high abuse potential or side effects), and those related to delivery of the product to customers (such as ensuring that the correct dosage is dispensed and that the product is appropriately labeled once it is repackaged for the consumer, or that products are not reused on multiple patients when not appropriate).

.07 Relevant initiatives may include labeling, training, education, “right-sizing” of packaged dosages (to minimize unsafe reuse or to minimize the amount of a controlled substance on-site at one time).

Counterfeit Drugs

Description

The World Health Organization estimates that ~~the global market for~~ counterfeit drugs ~~has reached \$431 billion,~~ ~~representing~~ ~~represent~~ one percent of the U.S.'s supply chain, and 10–15 percent of the world's pharmaceuticals market. The issue presents a significant health and safety risk to consumers with an estimated 100,000 annual deaths attributed to substandard or counterfeit drugs worldwide. Health care distributors could face added costs, as the federal government, states, and federal agencies seek to implement pedigree tracking regulations in an effort to prevent counterfeit or mislabeled drugs from entering the pharmaceutical distribution system.

Accounting Metrics

HC0302-03—~~Description. Discussion~~ of methods and technologies used to maintain traceability of products throughout the distribution chain and prevent counterfeiting.

- .08 Traceability refers to the ability to track identifying information (e.g., chemical composition, supplier, production date, production location, processing history, etc.) of a product throughout various stages of manufacturing and distribution (such as raw material source, manufacturing, distribution, and retail). For the biotechnology industry, relevant stages include manufacturing, logistics transportation, drug wholesale and distribution, and pharmacy retail.
- .09 The registrant shall discuss the type and sophistication of technology it uses to maintain traceability and serialization of its products. This may range from the use of a barcode to the use of radio frequency identification (RFID) tagging.
- .10 The registrant may discuss other methods it uses to minimize the risk of counterfeit products entering the supply chain, such as purchasing products directly from the manufacturer.

HC0302-04—~~Description. Discussion~~ of due diligence process to qualify suppliers of drug products and medical equipment and devices.

- .11 The registrant shall describe its process for identifying, screening, and approving product suppliers.
- .12 Where relevant, the registrant should discuss the use of questionnaires, codes of conduct, inspections or audits, or third party certifications for current good manufacturing processes (cGMP) and/or quality management systems (e.g., ISO 9001).
- .13 The registrant may briefly describe its screening requirements related to environmental, social, and governance issues.

HC0302-05—~~Description. Discussion~~ of process for alerting customers and business partners of potential or known risks associated with counterfeit products.

- .14 In addition to providing an overview of its procedures, the registrant shall describe how it communicates potential or known risks with the counterfeit products (such as through maintenance of list of products with a

higher risk of being counterfeited), recommended actions for the respective parties to minimize risks of counterfeiting, and mechanisms for product recall.

.15 Business partners include suppliers, wholesalers, retailers, and hospitals, etc.

Fuel Efficiency

Description

The distribution of health care products and supplies requires significant transportation networks. As concern over climate change and dwindling natural resources continues to impact fuel pricing, health care distributors will be exposed to fluctuations in costs. Firms that are able to improve transportation efficiencies may enhance shareholder value.

Accounting Metrics

HC0302-06. Payload fuel economy = gallons per ton-miles.

- .16 The registrant shall disclose its aggregate payload fuel economy for its transportation fleet.
- .17 The registrant shall calculate payload fuel economy across its delivery fleet, limited to vehicles used for the delivery of products (excluding vehicles used primarily for the transportation of passengers)
- .18 The registrant shall disclose payload fuel economy for vehicles it operates (e.g., owns or long-term lease) and specify if all or portion of its logistics operations are outsourced.
- .19 Payload fuel economy shall be calculated as: total gallons of fuel consumed / revenue tons-miles (RTM), where revenue ton-miles (RTM) = total weight of paid tonnage transported (payload) * total distance in miles goods were transported
 - Payload includes the weight of paid tonnage and excludes the vehicle weight.
- .20 The registrant shall aggregate payload fuel economy for types of transportation (e.g., rail, vehicle, ship)

HC0302-07—~~Description. Discussion~~ of involvement in efforts to reduce the environmental impact of logistics, including involvement in the EPA SmartWay program—~~..~~

- .21 The registrant shall describe the nature, scope, and implementation of its programs and initiatives to reduce the environmental impact, such as non-renewable energy usage, of its logistics operations.
- .22 Relevant efforts to discuss include, but are not limited to, upgrades to fleet (fuel efficiency), usage of alternative fuels, optimized logistics routes, and idling reduction programs.
- .23 If the registrant is a participant in the EPA SmartWay program, it should describe its type of participation:
 - Shipper partner; Truck Carrier Partner; Logistics Company Partner; Multimodal Carrier Partner; Rail Carrier Partner

Additional References

Types of [EPA SmartWay participants](#).

Product Lifecycle Management

Description

Health care distributors have a shared responsibility to reduce the environmental impact of the products that they distribute. Specific opportunities to address these impacts exist in product packaging and take-back programs.

Accounting Metrics

HC0302-08—Description, Discussion of initiatives to reduce the environmental impact of packaging, such as use of recycled materials, reductions in the amount of packaging material (i.e., dematerialization), packaging for consolidated shipping, and reduction in packaging waste (e.g., recycling and reuse of packaging, etc.).

- .24 The registrant shall describe policies, initiatives, designs, or vendor requirements related to reducing the environmental impact of packaging of products it distributes. Where, relevant, it shall indicate the degree of control or influence it has over packaging choices for these products (e.g., clarifying if the registrant has responsibility for primary, secondary, and/or tertiary levels, if any, of packaging).
- .25 Where the registrant has direct control over packaging choices, relevant efforts to discuss may include dematerialization (i.e., reducing the weight or physical amount of packaging), using recycled content materials, using certified paper products (e.g., through the Forest Stewardship Council), designing packaging with materials that can be readily be recycled or composted (e.g., reducing film and foil components in blister packages in favor of paper products), using packaging strategies that allow for consolidated shipping, or shipping products in reusable containers (e.g., in cold chain applications).
- .26 Where the registrant does not have direct control over packaging choices of the products it distributes, it is relevant to discuss vendor requirements which relate to topics listed in .25, above.
- .27 The registrant may choose to include quantitative measures of performance with respect to waste reduction strategies, such as percentage reductions in weight, number of times containers are reused before disposal or recycling, or packing to product weight ratios.

HC0302-09—Describe, Discussion of product stewardship initiatives to promote take-back (for reprocessing or recycling) of products at the end of their lifecycle. Amount (by weight) of products accepted for take-back.

- .28 The registrant shall describe programs and initiatives it implements, funds, or in which it participates related to product take-back for end-of-life management of products it distributes.
- .29 The registrant shall disclose the amount, in tons, of its products that it recovered and which was reused (refurbished), recycled, or donated.
 - This figure shall not include products that were accepted for take-back but were ultimately discarded as waste. The registrant may, however, indicate, if it reclaimed any products for which proper safe

disposal is necessary (e.g., mercury containing, sharps, expired drug products), and for which the registrant is unable to recycle or reuse.

Corruption and Bribery

Description

Health care distributors are subject to various state, federal, and international laws that pertain to their operations, including the False Claims Act and the U.S. Foreign Corrupt Practices Act. The ability of companies to ensure compliance with relevant regulations ~~is likely to have~~may have material implications.

Accounting Metrics

~~HC0302-10. Description. Discussion of efforts to minimize conflicts of interest and unethical business practices including mechanisms to ensure compliance.~~

- ~~.30~~ The registrant shall describe the content (e.g., marketing, interactions with government officials, business competition, and business intelligence) and scope (e.g., type and percentage of staff to which it relates) of any codes of conduct that relates to the corruption, bribery, or other unethical business behavior.
- ~~.31~~ The registrant shall discuss mechanisms to ensure compliance with its code such as education and training (including the degree and frequency) and enforcement (such as inspection, compliance or review committees, and implementing corrective actions when the code is violated).

~~HC0302-11. Description of legal and regulatory fines and settlements associated with corruption or bribery, including Foreign Corrupt Practices Act and False Claims Act violations. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events TA01-20-01. Total amount of losses as a result of legal proceedings associated with bribery, corruption, or other unethical business practices.~~

- ~~.32~~ The registrant shall disclose the total amount of losses in U.S. dollars it incurred as a result of legal proceedings associated with bribery, corruption, or ethical business regulations or other applicable laws or regulations.
- ~~.33~~ The legal proceedings shall include any adjudicative proceeding, whether before a court, a regulator, an arbitrator, or otherwise, in which the registrant was involved.
- ~~.32, .34~~ The losses shall include all fines, settlements, and other monetary liabilities as a result of civil actions (e.g., civil judgment, judgments or settlements, or), regulatory proceedings (e.g., penalties, disgorgement, or restitution), and criminal actions (e.g., criminal judgment, penalties, or restitutions) taken, restitution) brought by any entity (government, businesses governmental, business, or individuals individual).
 - ~~• Disclosure~~ The losses shall exclude legal fees incurred by the registrant.
- ~~.35~~ The scope of disclosure shall include violations of the False Claims Act (such as those related to pricing) legal proceedings associated with enforcement of regulations promulgated by U.S. and Foreign Corrupt Practices Act related to its anti-bribery or accounting provisions and enforced by the foreign regulatory authorities. Such regulatory authorities may include, but are not limited to:
 - ~~The Department of Justice or Securities and Exchange Commission.~~

- Drug Enforcement Administration

Note to **TA01-20-01**

~~33.36~~ The registrant shall ~~disclose~~briefly describe the ~~amount of any fine~~nature (e.g., judgment or order issued after trial, settlement associated with each incident, not including, guilty plea, deferred prosecution agreement, non-prosecution agreement) and context (e.g., controlled substance, bribery, etc.) of all losses as a result of legal fees/proceedings.

~~34.37~~ The registrant shall describe any corrective actions it has implemented as a result of each incident. ~~These~~This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, trainings, or technology.



HEALTH CARE SECTOR

MANAGED CARE*

Sustainability Accounting Standard

PROPOSED CHANGES TO PROVISIONAL STANDARDS

EXPOSURE DRAFT

REDLINE OF STANDARD FOR PUBLIC COMMENT

Prepared by the
Sustainability Accounting Standards Board®

October 2017

* Sustainable Industry Classification System™ (SICS™) #HC0303

MANAGED CARE

Sustainability Accounting Standard

About the SASB

The Sustainability Accounting Standards Board (SASB) was founded in 2011 as an independent standard-setting organization. The SASB issues and maintains sustainability accounting standards for 79 industries, focusing on the subset of industry-specific sustainability factors that are reasonably likely to have material financial impacts on companies within that industry. Companies can use the standards to disclose material information to investors in SEC filings, including Forms 10-K, 20-F, and 8-K, as well as S-1 and S-3, in a cost-effective and decision-useful manner. The standards are designed to help companies better comply with existing disclosure obligations, working within the framework of existing U.S. securities laws.

The SASB Standards Board is responsible for developing and issuing the standards, maintaining technical agendas, proposing updates to the standards, and executing the standard-setting process. The SASB staff is responsible for performing research and engaging in consultation on the standards, supporting the work of the Standards Board.

The SASB Foundation, an independent 501(c)3 non-profit, is responsible for the funding and oversight of the SASB, including safeguarding the SASB's independence and integrity through due process oversight and inquiry resolution. The SASB Foundation Board of Directors appoints members of the SASB.

About this Standard

This Standard is an exposure draft presented for public review and comment. **This version is not intended for implementation.**

The public comment period lasts for 90 days, beginning on October 2, 2017, and ending on December 31, 2017. The Standard is subject to change thereafter. SASB Standards are scheduled to be ratified by the SASB in early 2018.

For instructions on providing comments to SASB, please click [here](https://www.sasb.org/public-comment) (https://www.sasb.org/public-comment).

SUSTAINABILITY ACCOUNTING STANDARDS BOARD

1045 Sansome Street, Suite 450
San Francisco, CA 94111

www.sasb.org

The information, text, and graphics in this publication (the "Content") is owned by the Sustainability Accounting Standards Board. All rights reserved. You may use the Content only for non-commercial and scholarly use, provided that you keep intact all copyright and other proprietary notices related to the Content, and that you make no modifications to the Content. The Content may not be otherwise disseminated, distributed, republished, reproduced, or modified without the prior written permission of the Sustainability Accounting Standards Board. To request permission, please contact us at info@sasb.org.

Purpose & Structure

This document contains the SASB Sustainability Accounting Standard (SASB Standard) for the Managed Care industry.

SASB Sustainability Accounting Standards comprise **(1) disclosure guidance and (2) accounting standards or metrics** for use by U.S. and foreign public companies in their disclosures to investors, such as in annual reports and filings with the U.S. Securities and Exchange Commission (SEC), including Forms 10-K, 20-F, 40-F, 10-Q, 8-K and S-1 and S-3. The Standards facilitate the meaningful disclosure of sustainability information that is useful to investors in making decisions on investments and corporate suffrage.¹ The Standards reflect the fact that certain sustainability information is important for assessing the future financial performance of an issuer, particularly over the long term.

SASB Standards identify sustainability topics that are reasonably likely to constitute material information for a company within a particular industry. Company management is responsible for determining whether those identified topics reflect information that is material to investors and should be disclosed in filings, based on that company's specific circumstances. For further details regarding the use of the SASB Standards, in particular guidance on determinations of materiality, please see SASB's Implementation Guide.²

SASB Standards provide companies with sustainability metrics designed to communicate performance on industry-level sustainability topics in a concise, comparable format using existing reporting mechanisms. Companies can use the Standards to help ensure that disclosure is reliable, decision-useful for investors, and cost-effective for issuers.

SASB Standards are intended to constitute "suitable criteria" for purposes of an attestation engagement as defined by Paragraph .A42 of AT-C section 105³ and referenced in AT-C section 395.⁴ "Suitable criteria" have the following attributes:

- *Relevance*—Criteria are relevant to the subject matter.
- *Objectivity*—Criteria are free from bias.
- *Measurability*—Criteria permit reasonably consistent measurements, qualitative or quantitative, of subject matter.
- *Completeness*—Criteria are complete when subject matter prepared in accordance with them does not omit relevant factors that could reasonably be expected to affect decisions of the intended users made on the basis of that subject matter.

¹ The AICPA defines sustainability information in its Guide, [Attestation Engagements on Sustainability Information \(Including Greenhouse Gas Emissions Information\)](#) (Issued July 2017), as follows: "information about sustainability matters (such as economic, environmental, social and governance performance)." It further explains that "sustainability metrics and sustainability indicators are components of sustainability information. Sustainability information may be nonquantitative (narrative), historical, or forward-looking."

² <https://library.sasb.org/implementation-guide>

³ <https://www.aicpa.org/Research/Standards/AuditAttest/DownloadableDocuments/AT-C-00105.pdf>

⁴ <http://pcaobus.org/Standards/Attestation/Pages/AT701.aspx>

Industry Description

The managed care industry offers health insurance products for individual, commercial, Medicare, and Medicaid members. Companies also provide administrative services and network access for self-funded insurance plans and manage pharmacy benefits. Enrollment in managed care has traditionally been correlated with employment rates, while revenues are driven by the inflation of medical costs. The Patient Protection and Affordable Care Act reduced the percentage of uninsured adults, and created additional demand for the industry's plans. However, legislative uncertainty and a focus on reducing health care costs may create downward pricing pressure and continue to drive consolidation within the industry. In addition, a focus on patient outcomes and plan performance continue to shape the industry's sustainability risks and opportunities.

Users of the SASB Standards

The SASB Standards are intended for use by public companies and by investors to inform investment decisions. The standards facilitate disclosure of financially material sustainability-related information in a concise, comparable, cost-effective, decision-useful format.

The SASB Standards are designed for integration into existing reporting mechanisms, such as SEC filings. This keeps the administrative and cost burden to a minimum. SEC filings include Form 10-K for U.S. companies, Form 20-F for foreign issuers, Form 40-F for Canadian issuers, quarterly reports on Form 10-Q, current reports on Form 8-K, and registration statements on Forms S-1 and S-3. The SASB Standards are also recognized by the European Commission as a suitable framework for companies to provide information to investors pursuant to EU Directive 2014/95/EU. See "Guidelines on non-financial reporting (methodology for reporting non-financial information)."⁵ Thus, SASB standards are a cost-effective way to satisfy both U.S. and European reporting requirements.

SASB evaluates the materiality of sustainability-related topics by using the high threshold of financial materiality that is established under the U.S. securities laws.⁶ Although designed to meet the rigorous disclosure requirements of the U.S. capital markets (thereby producing a high-quality set of evidence-based standards focused on material investor-focused topics), the standards represent a best practice that can be used by companies of all types (public and private) to describe their material sustainability-related risks and opportunities.

Guidance for Disclosure of Sustainability Topics in SEC Filings

1. Industry-Level Sustainability Topics

For the Managed Care industry, the SASB has identified the following sustainability disclosure topics:

- Access to Coverage
- Improved Outcomes
- Plan Performance
- Pricing Transparency and Plan Literacy
- Customer Privacy and Technology Standards
- Climate Change Impacts on Human Health

⁵ https://ec.europa.eu/info/publications/170626-non-financial-reporting-guidelines_en

⁶ https://library.sasb.org/materiality_bulletin/

2. Determination of Materiality

In the U.S., sustainability disclosures are governed by the same laws and regulations that generally govern disclosures by securities issuers. According to the U.S. Supreme Court, a fact is material if, in the event such fact is omitted from a particular disclosure, there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of the information made available.⁷

Through a rigorous process of research, review of evidence, and public input, the SASB has identified sustainability topics that are reasonably likely to have a material effect on the financial condition or operating performance of companies within each Sustainable Industry Classification System™ (SICS™) industry.⁸ **However, the issuer must determine what information is (or is reasonably likely to be) material to the reasonable investor.** For further information regarding a process that corporations can use to assess the financial materiality of the sustainability-related topics in SASB standards, please see SASB’s Implementation Guide.⁹

3. SEC Requirements Relating to Disclosure of Material Sustainability Information

If a public company determines that certain sustainability information is reasonably likely to be material, it must then determine whether disclosure of some or all of the information under applicable SASB Standards is required under the U.S. federal securities laws. Several provisions of those laws are relevant to sustainability disclosures.

Regulation S-K sets forth certain disclosure requirements associated with Form 10-K and other SEC filings. Item 303 of Regulation S-K requires companies to, among other things, describe in the Management’s Discussion and Analysis of Financial Condition and Results of Operations (MD&A) section of Form 10-K “any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed.”¹⁰

Furthermore, the instructions to Item 303 state that the MD&A “shall focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition.”¹¹

The SEC has provided guidance for companies to use in determining whether a trend or uncertainty should be disclosed. The two-part assessment prescribed by the SEC can be applied to the topics included within this Standard:

- First, a company is not required to make disclosure about a known trend or uncertainty if its management determines that such trend or uncertainty is not reasonably likely to occur.

⁷ *TSC Industries v. Northway, Inc.*, 426 U.S. 438 (1976).

⁸ https://library.sasb.org/materiality_bulletin/

⁹ <https://library.sasb.org/implementation-guide>

¹⁰ C.F.R. 229.303(Item 303)(a)(3)(ii).

¹¹ SEC [Release Nos. 33-8056; 34-45321; FR-61] Commission Statement about Management’s Discussion and Analysis of Financial Condition and Results of Operations: “We also want to remind registrants that disclosure must be both useful and understandable. That is, management should provide the most relevant information and provide it using language and formats that investors can be expected to understand. Registrants should be aware also that investors will often find information relating to a particular matter more meaningful if it is disclosed in a single location, rather than presented in a fragmented manner throughout the filing.”

- Second, if a company's management cannot make a reasonable determination of the likelihood of an event or uncertainty, then disclosure is required "unless management determines that a material effect on the registrant's financial condition or results of operation is not reasonably likely to occur."

Companies should also consider the applicability of other Regulation S-K requirements. Specifically, Item 101 ("Description of Business") requires a company to provide a description of its business and its subsidiaries. Item 103 ("Legal Proceedings") requires a company to describe briefly any material pending or contemplated legal proceedings; instructions to Item 103 provide specific disclosure requirements for administrative or judicial proceedings arising from laws and regulations that target discharge of materials into the environment, or that are primarily for the purpose of protecting the environment. Item 503(c) ("Risk Factors") requires a company to provide discussion of the most significant factors that make an investment in the registrant speculative or risky, clearly stating the risk and specifying how it affects the company.

Finally, as a general matter, Securities Act Rule 408 and Exchange Act Rule 12b-20 require a registrant to disclose, in addition to the information expressly required by law or regulation, "such further material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they are made, not misleading."

4. Where Disclosures Should Be Made in SEC Filings

In using the definition of materiality established under the U.S. federal securities laws, the SASB has identified and developed industry-specific sustainability topics and metrics that are reasonably likely to have a material effect on the financial condition or operating performance of companies within a particular industry. As a general matter, the SASB believes that investors are best served when disclosure of such information is made in SEC filings. An issuer might, for example, make the disclosure in a sub-section of MD&A with a caption, "**Sustainability-Related Information**," with a section that includes the material topics, performance metrics, and management's view with respect to corporate positioning. See SASB's "Mock 10-Ks" for examples of preparing an MD&A using the SASB Standards.¹² Issuers are not precluded from using the Standards elsewhere, such as in stand-alone communications to investors or in sustainability reports (sometimes referred to as corporate social responsibility reports or environmental, social, and governance reports), company websites, or elsewhere. Corporate communication on material topics, including sustainability-related material topics, should be consistent across communication channels. As discussed above, SEC regulations may compel inclusion of material sustainability information in an SEC filing where it is deemed financially material.

The SASB recognizes that sustainability topics are relatively new areas of investor interest, and it may be difficult to determine whether particular sustainability information is material in certain situations. Accordingly, issuers might also consider using the SASB Standards in filings using Form 8-K, Item 8.01 ("Other Events"). This provision states that "The registrant may, at its option, disclose under this Item 8.01 any events, with respect to which information is not otherwise called for by this form, that the registrant deems of importance to security holders." Making a disclosure under Item 8.01 would not require the issuer to make a decision regarding materiality, and might also provide the company with more time to make the disclosure than is permitted under filing rules applicable to Form 10-K, thereby facilitating the completeness and accuracy of the disclosed information.

¹² <http://using.sasb.org/mock-10-k-library/>

When using the Standards, issuers should cite or refer to the relevant SASB Standard.

More detailed guidance on preparing disclosures of material information related to sustainability topics and making topic-level materiality determinations can be found in the **SASB Conceptual Framework**, available for download via <http://www.sasb.org/approach/conceptual-framework/>, and the **SASB Implementation Guide for Companies**, available for download via <https://library.sasb.org/implementation-guide/>.

Guidance on Accounting for Sustainability Topics

The SASB has identified accounting metrics for each sustainability topic included in this Standard. The SASB recommends that companies within this industry consider using these sustainability accounting metrics when preparing disclosures on the sustainability topics identified herein.

When disclosing information related to a sustainability topic identified by this Standard, companies should consider including a narrative description of any material factors necessary to ensure completeness, accuracy, and comparability of the data reported, as appropriate. Such a description might in certain circumstances include a discussion of the following:¹³

- The registrant’s **governance** around the risks and opportunities related to the topic, including board oversight of and management’s role in assessing and managing such risks and opportunities.
- The registrant’s **strategic approach** regarding actual and potential impacts of topic-related risks and opportunities on the organization’s **businesses, strategy, and financial planning**, over the **short, medium, and long term**.
- The registrant’s process to **identify, assess, and manage** topic-related risks, and how these risks are integrated into the registrant’s overall risk management process.
- The registrant’s **use of metrics or targets** to assess and manage topic-related risks and opportunities.
- Data for the registrant’s **last three completed fiscal years** (when available).

The SASB recommends that registrants use SASB Standards specific to their primary industry as identified in SICSTM. If a registrant generates significant revenue from multiple industries, the SASB recommends that it also consider sustainability topics that the SASB has identified for those industries, and disclose the associated SASB accounting metrics.

Further, the SASB recommends that companies design, implement, and maintain adequate systems of internal control over sustainability performance information to provide reasonable confidence regarding the achievement of related reporting objectives, such as those relating to the reliability of disclosed information.¹⁴

¹³ These areas for possible additional narrative description are generally aligned with the [Recommendations of the Task Force on Climate-related Financial Disclosures](#), which contains a more extensive discussion of such disclosure matters.

¹⁴ In this regard, companies are referred to the report of a group of experts in this area. Robert H. Herz, Brad J. Monterio, Jeffrey C. Thomson, Leveraging the COSO Internal Control – Integrated Framework to Improve confidence in Sustainability Performance Data (August 2017).

The SASB takes no position as to whether third-party attestation is necessary to enhance the credibility of the disclosed sustainability information, but as a matter of good governance, the SASB suggests that such assurance be considered.¹⁵

Scope of Disclosure

Unless otherwise specified, the SASB recommends:

- That a registrant disclose information on sustainability topics and metrics for itself and for entities that are consolidated for financial reporting purposes, as defined by accounting principles generally accepted in the United States (“US GAAP”), for consistency with other accompanying information within SEC filings;¹⁶
- That for consolidated entities, disclosures be made, and accounting metrics calculated, for the whole entity, regardless of the size of the minority interest; and
- That information from unconsolidated entities not be included in the computation of SASB accounting metrics. However, the registrant should disclose information about unconsolidated entities to the extent that the registrant considers the information necessary for investors to understand the effect of sustainability topics on the company’s financial condition or operating performance. (Typically, this disclosure would be limited to risks and opportunities associated with these entities.)

Reporting Format

Use of Financial Data

In instances where accounting metrics, activity metrics, and technical protocols in this Standard incorporate financial data (e.g., revenues, cost of sales, expenses recorded and disclosed for fines, etc.), such financial data shall be prepared in accordance with US GAAP, and be consistent with the corresponding financial data reported in the registrant’s SEC filings. Should accounting metrics, activity metrics, and technical protocols in this Standard incorporate disclosure of financial data that is not prepared in accordance with US GAAP, the registrant shall disclose such information in accordance with SEC Regulation G.¹⁷

Activity Metrics and Normalization

The SASB recognizes that normalizing accounting metrics is important for the analysis of SASB disclosures.

The SASB recommends that a registrant disclose any basic business data that may assist in the accurate evaluation and comparability of disclosure, to the extent that they are not already disclosed in Form 10-K (e.g., revenue, EBITDA, etc.).

¹⁵ The AICPA’s Guide (see supra note 1) provides guidance to assist accounting practitioners in performing attestation engagements on sustainability information.

¹⁶ See US GAAP consolidation rules (Section 810).

¹⁷ <https://www.sec.gov/rules/final/33-8176.htm>

Such data—termed “activity metrics”—may include high-level business data, including total number of employees, quantity of products produced or services provided, number of facilities, or number of customers. It may also include industry-specific data such as plant capacity utilization (e.g., for specialty chemical companies), number of transactions (e.g., for Internet media and services companies), hospital bed days (e.g., for health care delivery companies), or proven and probable reserves (e.g., for oil and gas exploration and production companies).

Activity metrics disclosed should:

- Convey contextual information that would not otherwise be apparent from SASB accounting metrics.
- Be deemed generally useful for investors relying on SASB accounting metrics to perform their own calculations and create their own ratios.
- Be explained and consistently disclosed from period to period to the extent that they continue to be relevant. However, a decision to make a voluntary disclosure in one period does not obligate a continuation of that disclosure if it is no longer relevant, or if a better metric becomes available.¹⁸

Where relevant, the SASB recommends specific activity metrics that—at a minimum—should accompany SASB accounting metric disclosures.

Table 1. Activity Metrics

<u>ACTIVITY METRIC</u>	<u>CATEGORY</u>	<u>UNIT OF MEASURE</u>	<u>CODE</u>
<u>Number of enrollees by plan type</u>	<u>Quantitative</u>	<u>Number</u>	<u>TA01-23-01</u>

Units of Measure

Unless specified, disclosures should be reported in International System of Units (SI units).

Uncertainty

The SASB recognizes that there may be inherent uncertainty when measuring or disclosing certain sustainability data and information. This uncertainty may be related to variables such as the reliance on data from third-party reporting systems and technologies, or the unpredictable nature of climate events. Where uncertainty around a particular disclosure exists, the SASB recommends that the registrant should consider discussing its nature and likelihood.¹⁹

Estimates

The SASB recognizes that scientifically-based estimates, such as the reliance on certain conversion factors or the exclusion of *de minimis* values, may occur for certain quantitative disclosures. Where appropriate, the SASB does not

¹⁸ Improving Business Reporting: Insights into Enhancing Voluntary Disclosures, FASB Business Reporting Research Project, January 29, 2001.

¹⁹ The AICPA’s Guide (see *supra* note 1) provides guidance related to measurement uncertainty.

discourage the use of estimates or ranges. When using an estimate for a particular disclosure, the SASB expects that the registrant discuss its nature and substantiate its basis.

Timing

Unless otherwise specified, disclosure shall be for the registrant's fiscal year.

Limitations

There is no guarantee that SASB Standards address all sustainability impacts or opportunities associated with a sector, industry, or company; therefore, a company must determine for itself the topics that warrant discussion in its SEC filings.

Use of the SASB Standards is voluntary. The Standards are not intended to replace any legal or regulatory requirements that may be applicable to a company's operations. When such laws or regulations address legal or regulatory topics, disclosure under SASB Standards is not meant to supersede those requirements.

Use of the SASB Standards is not required or endorsed by the SEC or various entities governing financial reporting, including the Financial Accounting Standards Board, the Government Accounting Standards Board, or the International Accounting Standards Board.

Forward-Looking Statements

Disclosures on sustainability topics can, in some circumstances, involve discussion of future trends and uncertainties related to the registrant's operations and financial condition, including those influenced by external variables (e.g., environmental, social, regulatory, and political). Companies making these disclosures in SEC filings should familiarize themselves with the safe harbor provisions of Section 27A of the Securities Act, and Section 21E of the Exchange Act, which preclude civil liability for material misstatements or omissions in such statements if the registrant takes certain steps. These include, among other things, identifying the disclosure as "forward-looking," and accompanying such disclosure with "meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statements."

Notes on the Sustainability Accounting Standards

The following sections contain the disclosure guidance associated with each accounting metric, including guidance on definitions, scope, accounting, compilation, and presentation.

The term "shall" is used throughout this document to indicate those elements that reflect requirements of the Standard. The terms "should" and "may" are used to indicate guidance, which, although not required, provides a recommended means of disclosure.

Table 2. Sustainability Disclosure Topics & Accounting Metrics

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
Access to Coverage	Medical Loss Ratio (MLR) = medical costs as percentage of premium revenue.	Quantitative	Ratio	HC0303-01
	Rebates accrued and rebates paid due to non-compliance with Section 2718 of the Patient Protection and Affordable Care Act for Medical Loss Ratio.	Quantitative	U.S. Dollars (\$)	HC0303-02
	Percentage of proposed rate increases receiving “not unreasonable” designation from Health and Human Services (HHS) review or state review (where it is authorized to conduct the review).	Quantitative	Percentage (%)	HC0303-03
Improved Outcomes	Percentage of enrollees in wellness programs by type: diet & nutrition, exercise, stress management & mental health, smoking or alcohol cessation, or other.	Quantitative	Percentage (%)	HC0303-04
	Coverage of preventive services: (1) Total coverage (\$) for preventive health services with no cost sharing for the enrollees including that which is required by the Patient Protection and Affordable Care Act; (2) Total coverage (\$) for preventive health services requiring cost-sharing by the enrollee, including the percentage of the cost of services covered by the registrant; and (3) Percentage of enrollees receiving Initial Preventive Physical Examination (IPEE) or annual wellness visit (AWV).	Quantitative	U.S. Dollars (\$), Percentage (%)	HC0303-05
	Number of customers receiving care from Accountable Care Organizations or enrolled in Patient-Centered Medical Home programs.	Quantitative	Number	HC0303-06
Plan Performance	Mean Medicare Advantage plan rating (1–5 stars) for each of the following plan types: HMO, local PPO, regional PPO, PFFS, and SNP.	Quantitative	Number	HC0303-07
	Enrollee retention rate by plan type, including HMO, local PPO, regional PPO, PFFS, and SNP.	Quantitative	Rate	HC0303-08
	Percentage of claims denied that were appealed by customers and ultimately reversed.	Quantitative	Percentage (%)	HC0303-09
	Grievance rate per 10,000 enrollees.	Quantitative	Rate	HC0303-10

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
Pricing Transparency and Plan Literacy	JD Power & Associates members' rating on "Information and Communication."	Quantitative	Number	HC0303-11
	Description of policies and practices related to clarity in pricing and coverage, including health care literacy programs.	Discussion and Analysis	n/a	HC0303-12
Customer Privacy and Technology Standards	Description of legal and regulatory fines and settlements related to Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules violations or The Health Information Technology for Economic and Clinical Health (HITECH) Act violations. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events. Discussion of policies and practices to secure customers' protected health information (PHI) records and other personally identifiable information (PII)	Quantitative Discussion and Analysis	U.S. Dollars (\$) n/a	HC0303-13 TA01-22-01
	Discussion of implementation of technology and management standards to maintain security, privacy, and availability of customer data. Number of breaches of customer data security, including the number of HIPAA-mandated breach notifications. Number of data security breaches, percentage involving (1) only customers' PII and (2) customers' PHI, and number of customers affected in each category	Discussion and Analysis Quantitative	n/a Number	HC0303-14 TA01-22-02
	Total amount of losses as a result of legal proceedings associated with data security and privacy²⁰	Quantitative	U.S. Dollars (\$)	TA01-22-03
Climate Change Impacts on Human Health	Description of the strategy to address the effects of climate change on business operations and how climate change is incorporated into risk models. Discussion of specific risks presented by changes in the geographic incidence, morbidity, and mortality of illnesses and diseases.	Discussion and Analysis	n/a	HC0303-15

²⁰ Note to **TA01-22-03**— The registrant shall briefly describe the nature, context, and any corrective actions taken as a result of the losses.

Access to Coverage

Description

~~Although The percentage of uninsured adults in the Patient Protection and Affordable Care Act (PPACA) will increase the number of insured individuals, the Congressional Budget Office estimates that 30 million nonelderly people will~~ United States has decreased in recent years, however millions remain uninsured in 2023. The PPACA will require that managed. Managed care companies can play a role in providing additional access by limiting plan costs. Companies must also comply with regulations relating to medical loss ratios and continue to cover all applicants regardless of health status, gender, or pre-existing conditions. Increased demand will pressure firms to address their medical cost ratio, while maintaining access to coverage regulatory focus on health care costs and the need to comply with new regulations continue to present challenges for the industry.

Accounting Metrics

HC0303-01. Medical Loss Ratio (MLR) = medical costs as percentage of premium revenue.

- .01 The registrant shall disclose its MLR as defined by the U.S. Department of Health and Human Services (HHS) in Title 45: Public Welfare Part 158 – Issuer Use of Premium Revenue: Reporting and Rebate Requirements (45 CFR Part 158), [Section § 158.221](#) Formula for calculating an issuer’s medical loss ratio.
- .02 As necessary, disclosure shall be subject to the aggregation of data requirements and credibility adjustment, as specified by HHS in 45 CFR Part 158.
- .03 The registrant shall disclose MLR consolidated for all business lines and for each of the registrant’s business segments (e.g., small employer group, large employer group, individual retail) according its disaggregation of financial information, as outlined by US GAAP Topic 280 (Segment Reporting).

HC0303-02. Rebates accrued and rebates paid due to non-compliance with Section 2718 of the Patient Protection and Affordable Care Act for Medical Loss Ratio.

- .04 The registrant shall disclose rebates, in dollar amount, owed to policyholders and as calculated by Title 45: Public Welfare Part 158 – Issuer Use of Premium Revenue: Reporting and Rebate Requirements (45 CFR Part 158), [Section § 158.240 Rebating premium if the applicable medical loss ratio standard is not met](#).
- .05 The registrant shall disclose the aggregate dollar amount of all forms of rebate, whether it was in the form of a premium credit, lump-sum check, or reimbursement to credit card or bank account.
- .06 The registrant shall disclose the rebate amount accrued for the fiscal year, as well as the amount paid during the fiscal year for rebate liabilities from the previous year.
- .07 The registrant should explain any differences between the amount paid during the fiscal year and the amount accrued during the previous fiscal year.

HC0303-03. Percentage of proposed rate increases receiving “not unreasonable” designation from Health and Human Services (HHS) review or state review (where it is authorized to conduct the review) ~~)-1~~.

- .08 The registrant shall disclose “not unreasonable” rate increase requests as a percentage of all rate increase requests made by the registrant during the fiscal period.
- .09 The registrant shall disclose only for requests for which review has been completed during the fiscal year and conducted as per Title 45: Public Welfare Part 154 – Health Insurance Issuer Rate Increases: Disclosure and Review Requirements.
- .10 The registrant may access the publicly available, searchable [database](#) of rate increase requests, which includes reviews conducted by the U.S. Department of Health and Human Services (HHS) and state designees.

Additional References:-

~~A current list of state programs that have designated effective rate review programs is here:-~~

Improved Outcomes

Description

Managed care companies ~~have the opportunity to create shareholder and societal value by working to improve~~ can play a critical role in maintaining and improving the health of enrollees. ~~The Patient Protection and Affordable Care Act (PPACA) places increased emphasis on health~~ In addition, legislation continues to emphasize improved outcomes through provisions, including those that require health plans to provide coverage for preventive services without cost to members. ~~Further, the Act established~~ The development of the Five Star Quality Rating System for Medicare Advantage Plans. ~~This rating system ties federal~~ further strengthens the relationship between enrollee health and value by linking reimbursement rates ~~for Medicare Advantage carriers~~ and bonus payments to performance in five ~~domain areas~~ domains, including specific outcome-based measures. ~~Subsequently, managed care companies~~ Companies that are able to improve the health of enrollees ~~will~~ may be better positioned to protect shareholder value.

Accounting Metrics

HC0303-04. Percentage of enrollees in wellness programs by type: diet & nutrition, exercise, stress management & mental health, smoking or alcohol cessation, or other.

- .11 Broadly, wellness programs are defined as those that foster:
 - Primary prevention by promoting health-related behaviors (e.g., immunizations), healthy body mass index, or healthy lifestyle (e.g., exercise or smoking cessation);
 - Secondary prevention by promoting early-stage disease detection and management.
- .12 The registrant shall disclose enrollee participation in wellness programs as a percentage, where the numerator is the number of unique, individual enrollees participating in a wellness program and the denominator is the monthly average number of enrollees.
- .13 The monthly average enrollees is calculated as the total number of member months (one member being enrolled in a registrant's plan for one month) divided by 12 months.
- .14 The registrant shall disclose the percentage of participation for each of the following types of wellness program: diet & nutrition, exercise, stress management & mental health, smoking or alcohol cessation, or other.

HC0303-05. Coverage of preventive services: (1) Total coverage (\$) for preventive health services with no cost sharing for the enrollees including that which is required by the Patient Protection and Affordable Care Act; (2) Total coverage (\$) for preventive health services requiring cost-sharing by the enrollee, including the percentage of the cost of services covered by the registrant; and (3) Percentage of enrollees receiving Initial Preventive Physical Examination (IPEE) or annual wellness visit (AWV).

- .15 The registrant shall disclose the total value, in dollar amount, of claims paid for preventative services covered under Section 2713 of the PPACA. These include services rated "A" or "B" by the US Preventive Services Task Force (USPSTF) as posted annually on the Agency for Health Care Research and Quality's [website](#):

- Immunizations for routine use in children, adolescents, and adults as recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention;
- Preventive care and screenings for children as recommended by Bright Futures (American Academy of Pediatrics) and Newborn Testing (American College of Medical Genetics) as supported by the Health Resources and Services Administration; and
- Preventive care and screenings provided for women in the comprehensive guidelines supported by the Health Resources and Services Administration.

- .16 The registrant shall disclose the total value, in dollar amount, of claims paid for preventive services outside the scope of Section 2713 of the PPACA, and for which it may require cost-sharing from enrollees. The registrant shall disclose the percentage of the total cost of these services that its coverage constituted.
- .17 Services are considered preventive if they: a) are coded with a Current Procedural Terminology (CPT®) code that contains the modifier “33,” denoting a preventive service, b) are specifically identified as preventive, or c) are inherently preventive in nature, such as a screening mammography.
- .18 The registrant shall not include in its calculation those services that are conducted in response to a symptom, even if it is the same service that can be administered as a preventive measure (e.g., a colonoscopy can be a preventive screening service when the patient is asymptomatic but is non-preventive when the patient is symptomatic).
- .19 The registrant shall disclose the percentage of enrollees receiving wellness screenings, as CPT®/HCPCS coded for Initial Preventive physical examination (G0402, G0403, G0404, G0450) or Annual Wellness Visit (G0438, G0439).

Additional References:

Definitions: Preventive services – encounters with health services that are not for the treatment of illness or injury. These are often classified with an International Classification of Disease (ICD) Z code (in the ICD-10-CM) representing the diagnosis. The ICD diagnosis code is then accompanied by a Current Procedural Terminology (CPT®) code that represents the services performed.

~~[United Healthcare’s example list of preventive services is located here.](#) [Cigna Corp’s example list of preventive services and FAQs is located here.](#)~~

HC0303-06. Number of customers receiving care from Accountable Care Organizations or enrolled in Patient-Centered Medical Home programs.

- .20 The registrant shall include in its calculation enrollees in ACOs that meet the eligibility requirements of, and participate in, Medicare’s Shared Savings Program for Fee-For-Service beneficiaries. It may, however, include enrollees in ACOs not participating in the Medicare program, provided that such ACO includes, at a minimum, the coordination of care from a variety of health care providers (including primary care physicians, specialists, and a hospital), and has the ability to administer payments, set benchmarks and measure outcome-based performance, and distribute shared savings.

.21 The registrant shall include in its calculation enrollees receiving care from Patient-Centered Medical Homes (PCMH) that meet the recognition and accreditation [guidelines](#) published by the American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP), American College of Physicians (ACP), and American Osteopathic Association (AOA).

Additional References

Definitions: Patient-Centered Medical Home – a reimbursement model founded on an outcome-based care delivery, “pay for coordination,” system in which payment is based on the coordination of services and comprehensive care that is coordinated through a physician (or physician assistant or registered nurse).

Accountable Care Organization defined in the PPACA: Sec. 2707 Pediatric Accountable Care Organization Demonstration Project and Sec. 3022 Medicare Shared Saving Program.

~~A Deloitte Center for Health Solutions [report](#) provides an overview and characteristics of ACOs.~~

~~The Center for Medicare & Medicaid Services (CMS) defines quality metrics for ACOs in its “Accountable Care Organizations 2013 Program Analysis” [report](#)~~

Plan Performance

Description

Managed care companies must manage performance in areas such as responsiveness, complaints, voluntary disenrollment, and customer service in order to maintain competitiveness. Under the Five Star Quality Rating System for Medicare Advantage Plans, performance on key plan performance metrics will be factored into federal reimbursement rates and bonus payments for Medicare Advantage carriers. Disclosure on key indicators related to plan performance will allow shareholders to understand how managed care companies are ensuring corporate value.

Accounting Metrics

HC0303-07. Mean Medicare Advantage plan rating (1–5 stars) for each of the following plan types: HMO, local PPO, regional PPO, PFFS, and SNP.

- .22 The registrant shall disclose the arithmetic mean Overall Plan Rating for each of the following plan types that it offers: Health Maintenance Organization (HMO) plans, Preferred Provider Organization (PPO) plans, Private Fee-for-Service (PFFS) plans, and Special Needs Plans (SNP).
- .23 The registrant shall include in the calculation all plans of each type receiving a Medicare Advantage plan rating.
- .24 The mean rating shall be disclosed rounded to the nearest tenth (one place after the decimal point).
- .25 Plan ratings are publicly available on Medicare’s “Medicare Plan Finder” [website](#).
- .26 The registrant may choose to disclose the percentage of its plans, by type, that are “Five Star Plans” – those plans that receive the highest Medicare Advantage plan rating.

Additional References

~~Definitions: HMO—health maintenance organization; PPO—preferred provider organization; PFFS—private fee for service; SNP—special needs plan~~

HC0303-08. Enrollee retention rate by plan type, including HMO, local PPO, regional PPO, PFFS, and SNP .

- .27 The registrant shall disclose its enrollee retention rate using the following the calculation: (Total number of enrollees at close of fiscal year – new enrollees added during the fiscal year) / (enrollees at the close of the previous fiscal year – enrollees involuntarily terminated during the fiscal year – attrition of employees in employee sponsored plans).
 - Involuntarily terminated enrollees – those whose plans were terminated by the registrant due to fraud or intentional misrepresentation of material facts – shall be excluded from the calculation.
 - Attrition of enrollees in employer sponsored group plans due to turnover (voluntary or involuntary) shall be excluded from the calculation.
- .28 The registrant shall disclose retention rates by plan type, which may include HMO, local PPO, regional PPO, PFFS, and SNP.

Additional References

~~The Kaiser Family Foundation provides an [overview of Medicare Advantage Plans quality ratings](#).~~

HC0303-09. Percentage of claims denied that were appealed by customers and ultimately reversed.

- .29 The registrant shall calculate the number of claims it denied that enrollees appealed and which the registrant reversed its decision having determined the denial to be invalid.
- .30 To calculate the percentage of reversed claims denials, the registrant shall divide the figure calculated in .31 above by the total number of enrollee appeals to claims denials that were made during the fiscal year.
- .31 The registrant shall not consider ongoing claims appeals – only those that were resolved during the fiscal year.
- .32 Coverage for medical services can be denied before or after the service has been provided, either through denial of preauthorization requests or denial of claims for payment. Therefore, the scope of this metric includes both appeals of denials at preauthorization and denials at the time of payment.
- .33 Claims that were denied for a billing error by the provider, appealed and resubmitted, and ultimately paid shall be considered outside of the scope of this metric (both numerator and denominator).
- .34 For the purposes of this metric, if the appeal relates to denial of a portion of a claim, the registrant shall consider it in the same manner as an appeal to an entire claim denial.
- .35 For the purposes of this metric, complaints, such as those with a state department of insurance which can also result in a reversal of denial, shall be considered in the same manner as an appeal. Complaints in this context shall only include those related to denial of coverage.
- .36 Multiple appeals to the same claim shall not be counted separately for calculations.

Additional References

Preauthorization denials occur when a determination is made that: (1) the consumer is not eligible to receive the requested service because, for example, the service is not covered under the individual's policy, or (2) the service is not appropriate, meaning that it is not medically necessary or is experimental or investigational.

~~US Government Accountability Office report, "Private Health Insurance — Data on Application and Coverage Denials."~~

HC0303-10. Grievance rate per 10,000 enrollees.

- .37 The registrant shall calculate the grievance rate as: the number of grievances reported during the fiscal year / (monthly average enrollees / 10,000)
- .38 Monthly average enrollees is calculated as the total number of member months (one member being enrolled for in a registrants plan for one month) divided by 12 months.
- .39 As adapted from the Medicare definition, a grievance is any complaint or dispute, other than a registrant determination, expressing dissatisfaction with the manner in which the registrant or delegated entity provides

health care services, regardless of whether any remedial action can be taken. An enrollee or his/her representative may make the complaint or dispute, either orally or in writing, to the registrant. In addition, grievances may include complaints regarding the timeliness, appropriateness, access to, and/or setting of a provided health service, procedure, or item. Grievance issues may also include complaints that a covered health service procedure or item during a course of treatment did not meet accepted standards for delivery of health care.

Additional References

[California reporting guidelines](#)

Pricing Transparency and Plan Literacy

Description

Managed care companies can create value through effective communication and transparency. ~~The Patient Protection and Affordable Care Act~~ Current legislation strengthens that link by requiring that all health plans provide a uniform summary of benefits and coverage for enrollees and applicants. ~~Companies will also be required to provide two examples of typical out-of-pocket costs for common medical events.~~ Performance in this area will contribute to value as companies compete for ~~new applicants in state-based exchanges~~ individual and commercial enrollees.

Accounting Metrics

HC0303-11. JD Power & Associates members' rating on "Information and Communication."

- .40 The registrant shall disclose the Member Health Plan Rating for the fiscal year as a mean rating of plans across all regions (currently 17)
- .41 The Information and Communication Rating shall be disclosed rounded to the nearest tenth (one place after the decimal point).
- .42 If the registrant is not ranked by JD Power & Associates, it shall disclose such information and may choose to disclose the reason that it did not receive a ranking (e.g., the sample size of enrollees was too small).

HC0303-12. Description of policies and practices related to clarity in pricing and coverage, including health care literacy programs.

- .43 The registrant shall describe the nature, scope, and implementation of its policies and practices to ensure that enrollees have a clear understanding of their coverage and associated pricing.
- .44 Relevant policies and practices may relate to communication tools and strategies (e.g., targeted reading level for written communications, policy to write in plain English, translated services), customer support mechanisms, enrollees' surveys, and cross-cultural training of key staff.
- .45 The registrant may choose to disclose the efficacy of its initiatives by disclosing, for example, the number of participants in its programs or other performance-based metrics.

Customer Privacy and Technology Standards

Description

The Health Insurance Portability and Accountability Act (HIPAA) requires health plans to comply with various requirements relating to the use, disclosure, storage, and transmission of patient health information. Further, companies in this industry are required to develop policies and technical safeguards to protect patient health information. A failure to comply with these evolving standards, which include ~~new~~ provisions established under the Health Information Technology for Economic and Clinical Health (HITECH) Act, can lead to significant civil and criminal penalties.

Accounting Metrics

HC0303-13. Description **TA01-22-01. Discussion of legal policies and regulatory fines/practices to secure customers' protected health information (PHI) records and ~~settlements~~ other personally identifiable information (PII)**

.46 The registrant shall describe the nature, scope, and implementation of its policies and practices related to securing customer PHI records and other PII, with a specific focus on how it addresses the collection, usage, and retention of customers' information, where:

- PHI is defined in 45 CFR 160.103 and referenced in Section 13400 of Subtitle D ("Privacy") of the Health Information Technology for Economic and Clinical Health (HITECH) Act as information that is a subset of health information, including demographic information collected from an individual, that meets the following criteria: The information (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse and (2) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual; and (i) identifies the individual or (ii) there is a reasonable basis to believe the information can be used to identify the individual.
 - Health information is defined as any information, whether oral or recorded in any form or medium, that (A) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and (B) relates to the past, present, or future physical or mental health or condition of any individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.
 - PHI includes information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium.
 - PHI excludes individually identifiable health information in education records covered by the Family Educational Rights and Privacy Act (20 U.S.C. 1232g), records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a drug retailer in its role as employer.
- PII is defined as any information about an individual that is maintained by an entity, including any information that can be used to distinguish or trace an individual's identity, such as name, Social

Security number, date and place of birth, mother's maiden name, or biometric records and any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information.²¹

47 The registrant shall describe the information "lifecycle" (i.e., collection, use, retention, processing, disclosure, and destruction) and how information-handling practices at each stage may affect individuals' privacy.

- With respect to data collection, it may be relevant for the registrant to discuss which data or types of data are collected without consent of an individual, which require opt-in consent, and which require opt-out action from the individual.
- With respect to usage of data, it may be relevant for the registrant to discuss which data or types of data are used by the registrant internally and under what circumstance the registrant shares, sells, rents, or otherwise distributes data or information to third parties.
- With respect to retention, it may be relevant for the registrant to discuss which data or types of data it retains, the length of time of retention, and practices used to ensure that data is stored securely.

~~46.48~~ The registrant shall discuss the systems it uses to ensure compliance with the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules ~~violations or The Health Information Technology for Economic and Clinical Health (HITECH) Act violations. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events and the HITECH Act,~~ including policies and practices related to the collection, usage, storage, and disposal of PHI and PII.

49 The registrant shall ~~briefly described~~ discuss its efforts to ensure compliance in the ~~nature and~~ context of proceedings related to HIPAA Act ~~how it implements the following three categories of system security:~~

- Administrative safeguards, which are defined as documented, formal policies and procedures that are intended to manage the selection and execution of security measures to protect data and manage the conduct of personnel in relation to the protection of data.
- Physical safeguards, which are defined as the protection of physical computer systems and the buildings holding such systems from natural and environmental hazards and inappropriate intrusion or HITECH Act violations. ~~Proceedings~~ removal.
- Technical safeguards, which are defined as processes put in place to protect information, authenticate users, and control individual access to information.

~~47.50~~ Relevant practices to discuss include ~~civil actions (e.g., civil judgment, settlements) internal monitoring practices, technology and security programs to prevent data breaches, training programs and protocols in place for employees who handle PHI or regulatory penalties) and~~ PII, and disposal methods for paper and electronic PHI records.

²¹ *Privacy: Alternatives Exist for Enhancing Protection of Personally Identifiable Information*, GAO Report 08-536, May 2008.

.51 The registrant shall disclose if it employs heightened security measures to ensure the security of PHI, including a discussion of those additional measures.

.52 The registrant should not include in its disclosure any information that compromises the security of its systems or its enrollees' PHI or PII.

TA01-22-02. Number of data security breaches, percentage involving (1) only customers' PII and (2) customers' PHI, number of customers affected in each category

.53 The registrant shall disclose the total number of data security breaches, which are defined as instances of unauthorized acquisition, access, use, or disclosure of protected information.

.54 The scope of disclosure shall be limited to data security breaches and incidents that resulted in the registrant's business processes deviating from its expected outcomes for confidentiality, integrity, and availability.

- The scope of disclosure shall include incidents of unauthorized acquisition or acquisition without valid authorization, resulting from deficiencies or failures of people, processes, or technology.
- The scope of disclosure shall exclude disruptions of service due to equipment failures.

.55 Disclosure shall be additional but complementary to the [SEC's CF Disclosure Guidance: Topic No. 2, Cybersecurity](#)the amount of any fine or settlement.

- At a minimum, this includes instances in which the costs or other consequences associated with each incident, not including one or more known incidents—or the risk of potential incidents—represents a material event, trend, or uncertainty that is reasonably likely to have a material effect on the registrant's results of operations, liquidity, or financial condition, or would cause reported financial information to not be necessarily indicative of future operating results or financial condition (e.g., theft of intellectual property, reduced revenue, increased cybersecurity protection expenditure, litigation costs, etc.).

.56 The registrant shall disclose the percentage of data security breaches in which only customers' PII (but not PHI) was breached, where:

- PII is defined as any information about an individual that is maintained by an entity, including (1) any information that can be used to distinguish or trace an individual's identity, such as name, Social Security number, date and place of birth, mother's maiden name, or biometric records; and (2) any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information.²² The scope of disclosure is limited to breaches in which customers were notified of the breach, either as required by state law or voluntarily by the registrant.

.57 The registrant shall disclose the percentage of data security breaches in which customer's PHI was breached, where:

²² *Privacy: Alternatives Exist for Enhancing Protection of Personally Identifiable Information*, GAO Report 08-536, May 2008.

- PHI is defined in 45 CFR 160.103 and referenced in Section 13400 of Subtitle D ('Privacy') of the Health Information Technology for Economic and Clinical Health Act (HITECH Act) as information that is a subset of health information, including demographic information collected from an individual, that meets the following criteria: The information (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse and (2) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual; and (i) identifies the individual or (ii) there is a reasonable basis to believe the information can be used to identify the individual.
 - Health information is defined as any information, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present, or future physical or mental health or condition of any individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.
 - PHI includes information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium.
 - PHI excludes individually identifiable health information in education records covered by the Family Educational Rights and Privacy Act (20 U.S.C. 1232g), records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.
 - PHI is a subset of PII.

.58 Disclosure shall include incidents in which encrypted data were acquired with an encryption key that was also acquired.

.59 The registrant may delay disclosure if a law enforcement agency has determined that notification impedes a criminal investigation until the law enforcement agency determines that such notification does not compromise the investigation.

.60 The registrant shall disclose the total number of customers that were affected by data breaches of (a) only PII and (b) PHI, where:

- The number of customers affected includes all those whose personal data (PII or PHI) was compromised in a data breach.

Note to TA01-22-02

.61 The registrant shall describe the corrective actions taken in response to breaches, such as changes in operations, management, processes, products, business partners, training, or technology.

.62 All disclosure shall be sufficient such that it is specific to the risks the registrant faces, but disclosure itself will not compromise the registrant's ability to maintain data privacy and security.

.63 The registrant should disclose its policy for disclosing data breaches to affected customers in a timely manner.

TA01-22-03. Total amount of losses as a result of legal proceedings associated with data security and privacy

.64 The registrant shall disclose the total amount of losses in U.S. dollars it incurred as a result of legal proceedings associated with data security and privacy

.65 The legal proceedings shall include any adjudicative proceeding, whether before a court, a regulator, an arbitrator, or otherwise, in which the registrant was involved.

.66 The losses shall include all fines, settlements, and other monetary liabilities as a result of civil actions (e.g., civil judgments or settlements), regulatory proceedings (e.g., penalties, disgorgement, or restitution), and criminal actions (e.g., criminal judgment, penalties, or restitution) brought by any entity (governmental, business, or individual).

~~.48.~~.67 The losses shall exclude legal fees incurred by the registrant.

.68 The scope of disclosure shall include legal proceedings associated with enforcement of health information privacy and security industry regulations promulgated by U.S. and foreign regulatory authorities. Such regulatory authorities may include, but are not limited to:

- Th U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR)

Note to TA01-22-03

~~.49.~~.69 The registrant shall briefly describe the nature (e.g., judgment or order issued after trial, settlement, guilty plea, deferred prosecution agreement, non-prosecution agreement) and context (e.g., data security, data privacy, etc.) of all losses as a result of legal proceedings.

.70 The registrant shall describe any corrective actions it has implemented as a result of each incident. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

~~HC0303-14 . Discuss implementation of technology and management standards to maintain security, privacy, and availability of customer data. Number of significant breaches of customer data security, defined as "Notice to Media" breaches by 45 CFR 164.406.~~

~~.18 The registrant shall describe its mechanisms to protect customer data that it creates, receives, maintains, or transmits from reasonably anticipated threats, hazards, and impermissible uses and/or disclosures. It shall include an overview of how it meets the standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules.~~

~~.19 Customer data includes, but is not limited to, electronic protected health information (ePHI) and personally identifiable information (PII).~~

~~.20 The registrant should not include in its disclosure any information that compromises the security of its systems, its enrollees' ePHI, or PII.~~

~~.21.18 The registrant shall disclose the number of breaches that occurred during the fiscal year and affected more than 500 individuals and thus required notification to the media. (Title 45: Public Welfare, Part 164 Security and Privacy, Subpart D Notification in the Case of Breach of Unsecured Protected Health Information, -):~~

Additional References

~~Breach—A breach is, generally, an impermissible use or disclosure under the Privacy Rule that compromises the security or privacy of the protected health information such that the use or disclosure poses a significant risk of financial, reputational, or other harm to the affected individual. (U.S. Department of Health and Human Services)~~

~~Confidentiality—the property that data or information is not made available or disclosed to unauthorized persons or processes.” (Department of Health and Human Services)~~

~~Integrity—the property that data or information have not been altered or destroyed in an unauthorized manner. (U.S. Department of Health and Human Services)~~

~~Availability—the property that data or information is accessible and useable upon demand by an authorized person.— (U.S. Department of Health and Human Services)~~

Climate Change Impacts on Human Health

Description

An increase in extreme weather events associated with climate change could have significant health impacts. These events, coupled with the potential spread of infectious diseases and food and water scarcity, may present material implications for the managed care industry through an increase in encounters with the health care system.

Accounting Metrics

HC0303-15. Description of the strategy to address the effects of climate change on business operations and how climate change is incorporated into risk models. Discussion of specific and opportunities presented by changes in the geographic incidence, morbidity, and mortality of illnesses and diseases.

~~50.71~~ The registrant shall discuss its strategic business approach to addressing significant risks related to the effects of climate change. The effects may include changes in geography, morbidity, and mortality of illnesses and disease, such as:

- Increases in allergic responses, asthma rates, and heat-induced illness;
- Migration of tropical diseases such as malaria, dengue fever, and other vector-borne tropical diseases to non-tropical regions;
- Increases in waterborne diseases, such as cholera, due to increased natural disaster incidence; and
- Increased rates of human developmental diseases such as malnutrition due to decreased food availability.

~~51.72~~ The registrant shall discuss any projected impacts on revenue, costs, or plan affordability.

~~52.73~~ The registrant should discuss it how it incorporates the effects of climate change into its risk assessment and risk adjustment activities.



HEALTH CARE SECTOR

DRUG RETAILERS*

Sustainability Accounting Standard

PROPOSED CHANGES TO PROVISIONAL STANDARDS

EXPOSURE DRAFT

REDLINE OF STANDARD FOR PUBLIC COMMENT

Prepared by the
Sustainability Accounting Standards Board®

October 2017

* Sustainable Industry Classification System™ (SICS™) #HC0304

DRUG RETAILERS

Sustainability Accounting Standard

About the SASB

The Sustainability Accounting Standards Board (SASB) was founded in 2011 as an independent standard-setting organization. The SASB issues and maintains sustainability accounting standards for 79 industries, focusing on the subset of industry-specific sustainability factors that are reasonably likely to have material financial impacts on companies within that industry. Companies can use the standards to disclose material information to investors in SEC filings, including Forms 10-K, 20-F, and 8-K, as well as S-1 and S-3, in a cost-effective and decision-useful manner. The standards are designed to help companies better comply with existing disclosure obligations, working within the framework of existing U.S. securities laws.

The SASB Standards Board is responsible for developing and issuing the standards, maintaining technical agendas, proposing updates to the standards, and executing the standard-setting process. The SASB staff is responsible for performing research and engaging in consultation on the standards, supporting the work of the Standards Board.

The SASB Foundation, an independent 501(c)3 non-profit, is responsible for the funding and oversight of the SASB, including safeguarding the SASB's independence and integrity through due process oversight and inquiry resolution. The SASB Foundation Board of Directors appoints members of the SASB.

About this Standard

This Standard is an exposure draft presented for public review and comment. **This version is not intended for implementation.**

The public comment period lasts for 90 days, beginning on October 2, 2017, and ending on December 31, 2017. The Standard is subject to change thereafter. SASB Standards are scheduled to be ratified by the SASB in early 2018.

For instructions on providing comments to SASB, please click [here](https://www.sasb.org/public-comment) (https://www.sasb.org/public-comment).

SUSTAINABILITY ACCOUNTING STANDARDS BOARD

1045 Sansome Street, Suite 450
San Francisco, CA 94111

www.sasb.org

The information, text, and graphics in this publication (the "Content") is owned by the Sustainability Accounting Standards Board. All rights reserved. You may use the Content only for non-commercial and scholarly use, provided that you keep intact all copyright and other proprietary notices related to the Content, and that you make no modifications to the Content. The Content may not be otherwise disseminated, distributed, republished, reproduced, or modified without the prior written permission of the Sustainability Accounting Standards Board. To request permission, please contact us at info@sasb.org.

Purpose & Structure

This document contains the SASB Sustainability Accounting Standard (SASB Standard) for the Drug Retailers industry.

SASB Sustainability Accounting Standards comprise **(1) disclosure guidance and (2) accounting standards or metrics** for use by U.S. and foreign public companies in their disclosures to investors, such as in annual reports and filings with the U.S. Securities and Exchange Commission (SEC), including Forms 10-K, 20-F, 40-F, 10-Q, 8-K and S-1 and S-3. The Standards facilitate the meaningful disclosure of sustainability information that is useful to investors in making decisions on investments and corporate suffrage.¹ The Standards reflect the fact that certain sustainability information is important for assessing the future financial performance of an issuer, particularly over the long term.

SASB Standards identify sustainability topics that are reasonably likely to constitute material information for a company within a particular industry. Company management is responsible for determining whether those identified topics reflect information that is material to investors and should be disclosed in filings, based on that company's specific circumstances. For further details regarding the use of the SASB Standards, in particular guidance on determinations of materiality, please see SASB's Implementation Guide.²

SASB Standards provide companies with sustainability metrics designed to communicate performance on industry-level sustainability topics in a concise, comparable format using existing reporting mechanisms. Companies can use the Standards to help ensure that disclosure is reliable, decision-useful for investors, and cost-effective for issuers.

SASB Standards are intended to constitute "suitable criteria" for purposes of an attestation engagement as defined by Paragraph .A42 of AT-C section 105³ and referenced in AT-C section 395.⁴ "Suitable criteria" have the following attributes:

- *Relevance*—Criteria are relevant to the subject matter.
- *Objectivity*—Criteria are free from bias.
- *Measurability*—Criteria permit reasonably consistent measurements, qualitative or quantitative, of subject matter.
- *Completeness*—Criteria are complete when subject matter prepared in accordance with them does not omit relevant factors that could reasonably be expected to affect decisions of the intended users made on the basis of that subject matter.

¹ The AICPA defines sustainability information in its Guide, [Attestation Engagements on Sustainability Information \(Including Greenhouse Gas Emissions Information\)](#) (Issued July 2017), as follows: "information about sustainability matters (such as economic, environmental, social and governance performance)." It further explains that "sustainability metrics and sustainability indicators are components of sustainability information. Sustainability information may be nonquantitative (narrative), historical, or forward-looking."

² <https://library.sasb.org/implementation-guide>

³ <https://www.aicpa.org/Research/Standards/AuditAttest/DownloadableDocuments/AT-C-00105.pdf>

⁴ <http://pcaobus.org/Standards/Attestation/Pages/AT701.aspx>

Industry Description

The Drug Retailers & Convenience Stores industry comprises companies that operate retail pharmacies, ~~convenience stores~~, and distribution centers that supply retail stores. Stores may be company-owned or franchised. Large companies operate mainly in the U.S. and source drugs and other merchandise through wholesalers and distributors. The majority of the industry's revenues are derived from consumer sales of prescription and over-the-counter pharmaceutical products; other goods sold include household goods, personal care products, and a limited selection of groceries. Additionally, the pharmacy retailer segment is expanding its health-focused services by offering clinics at various retail locations, which adds to the industry's shifting sustainability landscape.

Users of the SASB Standards

The SASB Standards are intended for use by public companies and by investors to inform investment decisions. The standards facilitate disclosure of financially material sustainability-related information in a concise, comparable, cost-effective, decision-useful format.

The SASB Standards are designed for integration into existing reporting mechanisms, such as SEC filings. This keeps the administrative and cost burden to a minimum. SEC filings include Form 10-K for U.S. companies, Form 20-F for foreign issuers, Form 40-F for Canadian issuers, quarterly reports on Form 10-Q, current reports on Form 8-K, and registration statements on Forms S-1 and S-3. The SASB Standards are also recognized by the European Commission as a suitable framework for companies to provide information to investors pursuant to EU Directive 2014/95/EU. See "Guidelines on non-financial reporting (methodology for reporting non-financial information)."⁵ Thus, SASB standards are a cost-effective way to satisfy both U.S. and European reporting requirements.

SASB evaluates the materiality of sustainability-related topics by using the high threshold of financial materiality that is established under the U.S. securities laws.⁶ Although designed to meet the rigorous disclosure requirements of the U.S. capital markets (thereby producing a high-quality set of evidence-based standards focused on material investor-focused topics), the standards represent a best practice that can be used by companies of all types (public and private) to describe their material sustainability-related risks and opportunities.

Guidance for Disclosure of Sustainability Topics in SEC Filings

1. Industry-Level Sustainability Topics

For the Drug Retailers & Convenience Stores industry, the SASB has identified the following sustainability disclosure topics:

- Energy Management in Retail
- Data Security & Privacy
- Management of Controlled Substances
- Patient Health Outcomes
- Drug Supply Chain Integrity

⁵ https://ec.europa.eu/info/publications/170626-non-financial-reporting-guidelines_en

⁶ https://library.sasb.org/materiality_bulletin/

2. Determination of Materiality

In the U.S., sustainability disclosures are governed by the same laws and regulations that generally govern disclosures by securities issuers. According to the U.S. Supreme Court, a fact is material if, in the event such fact is omitted from a particular disclosure, there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of the information made available.⁷

Through a rigorous process of research, review of evidence, and public input, the SASB has identified sustainability topics that are reasonably likely to have a material effect on the financial condition or operating performance of companies within each Sustainable Industry Classification System™ (SICS™) industry.⁸ **However, the issuer must determine what information is (or is reasonably likely to be) material to the reasonable investor.** For further information regarding a process that corporations can use to assess the financial materiality of the sustainability-related topics in SASB standards, please see SASB’s Implementation Guide.⁹

3. SEC Requirements Relating to Disclosure of Material Sustainability Information

If a public company determines that certain sustainability information is reasonably likely to be material, it must then determine whether disclosure of some or all of the information under applicable SASB Standards is required under the U.S. federal securities laws. Several provisions of those laws are relevant to sustainability disclosures.

Regulation S-K sets forth certain disclosure requirements associated with Form 10-K and other SEC filings. Item 303 of Regulation S-K requires companies to, among other things, describe in the Management’s Discussion and Analysis of Financial Condition and Results of Operations (MD&A) section of Form 10-K “any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed.”¹⁰

Furthermore, the instructions to Item 303 state that the MD&A “shall focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition.”¹¹

The SEC has provided guidance for companies to use in determining whether a trend or uncertainty should be disclosed. The two-part assessment prescribed by the SEC can be applied to the topics included within this Standard:

- First, a company is not required to make disclosure about a known trend or uncertainty if its management determines that such trend or uncertainty is not reasonably likely to occur.

⁷ *TSC Industries v. Northway, Inc.*, 426 U.S. 438 (1976).

⁸ https://library.sasb.org/materiality_bulletin/

⁹ <https://library.sasb.org/implementation-guide>

¹⁰ C.F.R. 229.303(Item 303)(a)(3)(ii).

¹¹ SEC [Release Nos. 33-8056; 34-45321; FR-61] Commission Statement about Management’s Discussion and Analysis of Financial Condition and Results of Operations: “We also want to remind registrants that disclosure must be both useful and understandable. That is, management should provide the most relevant information and provide it using language and formats that investors can be expected to understand. Registrants should be aware also that investors will often find information relating to a particular matter more meaningful if it is disclosed in a single location, rather than presented in a fragmented manner throughout the filing.”

- Second, if a company’s management cannot make a reasonable determination of the likelihood of an event or uncertainty, then disclosure is required “unless management determines that a material effect on the registrant’s financial condition or results of operation is not reasonably likely to occur.”

Companies should also consider the applicability of other Regulation S-K requirements. Specifically, Item 101 (“Description of Business”) requires a company to provide a description of its business and its subsidiaries. Item 103 (“Legal Proceedings”) requires a company to describe briefly any material pending or contemplated legal proceedings; instructions to Item 103 provide specific disclosure requirements for administrative or judicial proceedings arising from laws and regulations that target discharge of materials into the environment, or that are primarily for the purpose of protecting the environment. Item 503(c) (“Risk Factors”) requires a company to provide discussion of the most significant factors that make an investment in the registrant speculative or risky, clearly stating the risk and specifying how it affects the company.

Finally, as a general matter, Securities Act Rule 408 and Exchange Act Rule 12b-20 require a registrant to disclose, in addition to the information expressly required by law or regulation, “such further material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they are made, not misleading.”

4. Where Disclosures Should Be Made in SEC Filings

In using the definition of materiality established under the U.S. federal securities laws, the SASB has identified and developed industry-specific sustainability topics and metrics that are reasonably likely to have a material effect on the financial condition or operating performance of companies within a particular industry. As a general matter, the SASB believes that investors are best served when disclosure of such information is made in SEC filings. An issuer might, for example, make the disclosure in a sub-section of MD&A with a caption, “**Sustainability-Related Information**,” with a section that includes the material topics, performance metrics, and management’s view with respect to corporate positioning. See SASB’s “Mock 10-Ks” for examples of preparing an MD&A using the SASB Standards.¹² Issuers are not precluded from using the Standards elsewhere, such as in stand-alone communications to investors or in sustainability reports (sometimes referred to as corporate social responsibility reports or environmental, social, and governance reports), company websites, or elsewhere. Corporate communication on material topics, including sustainability-related material topics, should be consistent across communication channels. As discussed above, SEC regulations may compel inclusion of material sustainability information in an SEC filing where it is deemed financially material.

The SASB recognizes that sustainability topics are relatively new areas of investor interest, and it may be difficult to determine whether particular sustainability information is material in certain situations. Accordingly, issuers might also consider using the SASB Standards in filings using Form 8-K, Item 8.01 (“Other Events”). This provision states that “The registrant may, at its option, disclose under this Item 8.01 any events, with respect to which information is not otherwise called for by this form, that the registrant deems of importance to security holders.” Making a disclosure under Item 8.01 would not require the issuer to make a decision regarding materiality, and might also provide the company with more time to make the disclosure than is permitted under filing rules applicable to Form 10-K, thereby facilitating the completeness and accuracy of the disclosed information.

¹² <http://using.sasb.org/mock-10-k-library/>

When using the Standards, issuers should cite or refer to the relevant SASB Standard.

More detailed guidance on preparing disclosures of material information related to sustainability topics and making topic-level materiality determinations can be found in the **SASB Conceptual Framework**, available for download via <http://www.sasb.org/approach/conceptual-framework/>, and the **SASB Implementation Guide for Companies**, available for download via <https://library.sasb.org/implementation-guide/>.

Guidance on Accounting for Sustainability Topics

The SASB has identified accounting metrics for each sustainability topic included in this Standard. The SASB recommends that companies within this industry consider using these sustainability accounting metrics when preparing disclosures on the sustainability topics identified herein.

When disclosing information related to a sustainability topic identified by this Standard, companies should consider including a narrative description of any material factors necessary to ensure completeness, accuracy, and comparability of the data reported, as appropriate. Such a description might in certain circumstances include a discussion of the following:¹³

- The registrant's **governance** around the risks and opportunities related to the topic, including board oversight of and management's role in assessing and managing such risks and opportunities.
- The registrant's **strategic approach** regarding actual and potential impacts of topic-related risks and opportunities on the organization's **businesses, strategy, and financial planning**, over the **short, medium, and long term**.
- The registrant's process to **identify, assess, and manage** topic-related risks, and how these risks are integrated into the registrant's overall risk management process.
- The registrant's **use of metrics or targets** to assess and manage topic-related risks and opportunities.
- Data for the registrant's **last three completed fiscal years** (when available).

The SASB recommends that registrants use SASB Standards specific to their primary industry as identified in SICSTM. If a registrant generates significant revenue from multiple industries, the SASB recommends that it also consider sustainability topics that the SASB has identified for those industries, and disclose the associated SASB accounting metrics.

Further, the SASB recommends that companies design, implement, and maintain adequate systems of internal control over sustainability performance information to provide reasonable confidence regarding the achievement of related reporting objectives, such as those relating to the reliability of disclosed information.¹⁴

¹³ These areas for possible additional narrative description are generally aligned with the [Recommendations of the Task Force on Climate-related Financial Disclosures](#), which contains a more extensive discussion of such disclosure matters.

¹⁴ In this regard, companies are referred to the report of a group of experts in this area. Robert H. Herz, Brad J. Monterio, Jeffrey C. Thomson, Leveraging the COSO Internal Control – Integrated Framework to Improve confidence in Sustainability Performance Data (August 2017).

The SASB takes no position as to whether third-party attestation is necessary to enhance the credibility of the disclosed sustainability information, but as a matter of good governance, the SASB suggests that such assurance be considered.¹⁵

Scope of Disclosure

Unless otherwise specified, the SASB recommends:

- That a registrant disclose information on sustainability topics and metrics for itself and for entities that are consolidated for financial reporting purposes, as defined by accounting principles generally accepted in the United States (“US GAAP”), for consistency with other accompanying information within SEC filings;¹⁶
- That for consolidated entities, disclosures be made, and accounting metrics calculated, for the whole entity, regardless of the size of the minority interest; and
- That information from unconsolidated entities not be included in the computation of SASB accounting metrics. However, the registrant should disclose information about unconsolidated entities to the extent that the registrant considers the information necessary for investors to understand the effect of sustainability topics on the company’s financial condition or operating performance. (Typically, this disclosure would be limited to risks and opportunities associated with these entities.)

Reporting Format

Use of Financial Data

In instances where accounting metrics, activity metrics, and technical protocols in this Standard incorporate financial data (e.g., revenues, cost of sales, expenses recorded and disclosed for fines, etc.), such financial data shall be prepared in accordance with US GAAP, and be consistent with the corresponding financial data reported in the registrant’s SEC filings. Should accounting metrics, activity metrics, and technical protocols in this Standard incorporate disclosure of financial data that is not prepared in accordance with US GAAP, the registrant shall disclose such information in accordance with SEC Regulation G.¹⁷

Activity Metrics and Normalization

The SASB recognizes that normalizing accounting metrics is important for the analysis of SASB disclosures.

The SASB recommends that a registrant disclose any basic business data that may assist in the accurate evaluation and comparability of disclosure, to the extent that they are not already disclosed in Form 10-K (e.g., revenue, EBITDA, etc.).

¹⁵ The AICPA’s Guide (see supra note 1) provides guidance to assist accounting practitioners in performing attestation engagements on sustainability information.

¹⁶ See US GAAP consolidation rules (Section 810).

¹⁷ <https://www.sec.gov/rules/final/33-8176.htm>

Such data—termed “activity metrics”—may include high-level business data, including total number of employees, quantity of products produced or services provided, number of facilities, or number of customers. It may also include industry-specific data such as plant capacity utilization (e.g., for specialty chemical companies), number of transactions (e.g., for Internet media and services companies), hospital bed days (e.g., for health care delivery companies), or proven and probable reserves (e.g., for oil and gas exploration and production companies).

Activity metrics disclosed should:

- Convey contextual information that would not otherwise be apparent from SASB accounting metrics.
- Be deemed generally useful for investors relying on SASB accounting metrics to perform their own calculations and create their own ratios.
- Be explained and consistently disclosed from period to period to the extent that they continue to be relevant. However, a decision to make a voluntary disclosure in one period does not obligate a continuation of that disclosure if it is no longer relevant, or if a better metric becomes available.¹⁸

Where relevant, the SASB recommends specific activity metrics that—at a minimum—should accompany SASB accounting metric disclosures.

Table 1. Activity Metrics

ACTIVITY METRIC	CATEGORY	UNIT OF MEASURE	CODE
Number of pharmacy locations	Quantitative	Number	CN0402 <u>HC0304-A</u>
Total area of retail space	Quantitative	Square meters (m ²)	CN0402 <u>HC0304-B</u>
Number of prescriptions filled, percentage for controlled substances	Quantitative	Number, Percentage (%)	CN0402 <u>HC0304-C</u>
Number of pharmacists ¹⁹	Quantitative	Number	CN0402 <u>HC0304-D</u>

Units of Measure

Unless specified, disclosures should be reported in International System of Units (SI units).

Uncertainty

¹⁸ Improving Business Reporting: Insights into Enhancing Voluntary Disclosures, FASB Business Reporting Research Project, January 29, 2001.

¹⁹ Note to ~~CN0402~~HC0304-D—Pharmacists are employees in the 29-1051 group of the EEO-1 Job Classification Guide who dispense drugs prescribed by physicians and other health practitioners and provide information to patients about medications and their use. Pharmacists may advise physicians and other health practitioners on the selection, dosage, interactions, and side effects of medications.

The SASB recognizes that there may be inherent uncertainty when measuring or disclosing certain sustainability data and information. This uncertainty may be related to variables such as the reliance on data from third-party reporting systems and technologies, or the unpredictable nature of climate events. Where uncertainty around a particular disclosure exists, the SASB recommends that the registrant should consider discussing its nature and likelihood.²⁰

Estimates

The SASB recognizes that scientifically-based estimates, such as the reliance on certain conversion factors or the exclusion of *de minimis* values, may occur for certain quantitative disclosures. Where appropriate, the SASB does not discourage the use of estimates or ranges. When using an estimate for a particular disclosure, the SASB expects that the registrant discuss its nature and substantiate its basis.

Timing

Unless otherwise specified, disclosure shall be for the registrant's fiscal year.

Limitations

There is no guarantee that SASB Standards address all sustainability impacts or opportunities associated with a sector, industry, or company; therefore, a company must determine for itself the topics that warrant discussion in its SEC filings.

Use of the SASB Standards is voluntary. The Standards are not intended to replace any legal or regulatory requirements that may be applicable to a company's operations. When such laws or regulations address legal or regulatory topics, disclosure under SASB Standards is not meant to supersede those requirements.

Use of the SASB Standards is not required or endorsed by the SEC or various entities governing financial reporting, including the Financial Accounting Standards Board, the Government Accounting Standards Board, or the International Accounting Standards Board.

Forward-Looking Statements

Disclosures on sustainability topics can, in some circumstances, involve discussion of future trends and uncertainties related to the registrant's operations and financial condition, including those influenced by external variables (e.g., environmental, social, regulatory, and political). Companies making these disclosures in SEC filings should familiarize themselves with the safe harbor provisions of Section 27A of the Securities Act, and Section 21E of the Exchange Act, which preclude civil liability for material misstatements or omissions in such statements if the registrant takes certain steps. These include, among other things, identifying the disclosure as "forward-looking," and accompanying such disclosure with "meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statements."

Notes on the Sustainability Accounting Standards

²⁰ The AICPA's Guide (see *supra* note 1) provides guidance related to measurement uncertainty.

The following sections contain the disclosure guidance associated with each accounting metric, including guidance on definitions, scope, accounting, compilation, and presentation.

The term “shall” is used throughout this document to indicate those elements that reflect requirements of the Standard. The terms “should” and “may” are used to indicate guidance, which, although not required, provides a recommended means of disclosure.

Table 2. Sustainability Disclosure Topics & Accounting Metrics

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
Energy Management in Retail	Total energy consumed, percentage grid electricity, percentage renewable energy	Quantitative	Gigajoules (GJ), Percentage (%)	CN0402 HC0304-01
Data Security & Privacy	Discussion of policies and practices to secure customers’ protected health information (PHI) records and other personally identifiable information (PII)	Discussion and Analysis	n/a	CN0402 HC0304-02
	Number of data security breaches, percentage involving (1) only customers’ PII and (2) customers’ PHI, number of customers affected in each category ²¹	Quantitative	Number, Percentage (%)	CN0402 HC0304-03
	Amount of legal and regulatory fines and settlements associated with data security and privacy ²²	Quantitative	U.S. Dollars (\$)	CN0402 HC0304-04
Management of Controlled Substances	Percentage of controlled substance prescriptions dispensed for which a prescription drug monitoring program (PDMP) database was queried ²³	Quantitative	Percentage (%)	CN0402 HC0304-05
	Amount of legal and regulatory fines and settlements associated with controlled substances ²⁴	Quantitative	U.S. Dollars (\$)	CN0402 HC0304-06
Patient Health Outcomes	First fill adherence rate ²⁵	Quantitative	Percentage (%)	CN0402 HC0304-07
	Description of policies and practices to prevent prescription dispensing errors	Discussion and Analysis	n/a	CN0402 HC0304-08

²¹ Note to [CN0402HC0304-03](#)—Disclosure shall include a description of corrective actions implemented in response to data security breaches.

²² Note to [CN0402HC0304-04](#)—Disclosure shall include a description of fines and settlements and corrective actions implemented in response to events.

²³ Note to [CN0402HC0304-05](#)—Disclosure shall include a description of additional verification procedures the registrant uses when dispensing controlled substances prescriptions to prevent controlled substance abuse.

²⁴ Note to [CN0402HC0304-06](#)—Disclosure shall include a description of fines and settlements and corrective actions implemented in response to events.

²⁵ Note to [CN0402HC0304-07](#)—Disclosure shall include a description of strategies used to increase medication adherence.

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
	Amount of legal and regulatory fines and settlements associated with prescription dispensing errors ²⁶	Quantitative	U.S. Dollars (\$)	CN0402 HC0304-09
	Percentage of gender and racial/ethnic group representation for pharmacists	Quantitative	Percentage (%)	CN0402 HC0304-10
Drug Supply Chain Integrity	Discussion of efforts to reduce the occurrence of compromised drugs within the supply chain	Discussion and Analysis	n/a	CN0402 HC0304-11
	Number of drug recalls, total units recalled, percentage for private-label products ²⁷	Quantitative	Number, Percentage (%)	CN0402 HC0304-12

²⁶ Note to ~~CN0402HC0304-09~~—Disclosure shall include a description of fines and settlements and corrective actions implemented in response to events.

²⁷ Note to ~~CN0402HC0304-12~~—The registrant shall discuss notable recalls such as those that affected a significant number of units of one product or those related to serious injury or fatality.

Energy Management in Retail

Description

Chain drug retailers ~~and convenience store companies~~ operate thousands of locations that consume large quantities of energy. Energy, in the form of electricity, is used primarily for lighting and refrigeration purposes. Refrigeration is necessary to cool fresh foods and beverages, as well as some pharmaceutical products. Furthermore, some ~~retailer convenience stores~~ are open around the clock, which increases total energy demands. Energy efficiency in operation and diversifying their energy portfolio across a range of sources can mitigate exposure to rising energy costs and limit a company's contribution to indirect GHG emissions.

Accounting Metrics

CN0402HC0304-01. Total energy consumed, percentage grid electricity, percentage renewable energy

- .01 The registrant shall disclose total energy consumption from all sources as an aggregate figure in gigajoules or their multiples.
 - The scope includes energy purchased from sources external to the organization or produced by the organization itself (self-generated).
 - The scope includes only energy consumed by entities owned or controlled by the organization.
 - The scope includes energy from all sources, including direct fuel usage, purchased electricity, and heating, cooling, and steam energy.
- .02 In calculating energy consumption from fuels and biofuels, the registrant shall use higher heating values (HHV), also known as gross calorific values (GCV), which are directly measured or taken from the Intergovernmental Panel on Climate Change (IPCC), the U.S. Department of Energy (DOE), or the U.S. Energy Information Administration (EIA).
- .03 The registrant shall disclose purchased grid electricity consumption as a percentage of its total energy consumption.
- .04 The registrant shall disclose renewable energy consumption as a percentage of its total energy consumption.
- .05 The scope of renewable energy includes renewable fuel the registrant consumes and renewable energy the registrant directly produces, purchases through a renewable power purchase agreement (PPA) that explicitly includes renewable energy certificates (RECs), or for which Green-e Energy Certified RECs are paired with grid electricity.
 - For any renewable electricity generated on-site, any RECs must be retained (i.e., not sold) and retired on behalf of the registrant in order for the registrant to claim them as renewable energy.
 - For renewable PPAs, the agreement must explicitly include and convey that RECs be retained and retired on behalf of the registrant in order for the registrant to claim them as renewable energy.

- The renewable portion of the electricity grid mix that is outside of the control or influence of the registrant is excluded from disclosure.²⁸
- Renewable energy is defined as energy from sources that are capable of being replenished in a short time through ecological cycles, such as geothermal, wind, solar, hydro, and biomass.

.06 For the purposes of this disclosure, the scope of renewable energy from hydro and biomass sources is limited to the following:

- Energy from hydro sources that are certified by the Low Impact Hydropower Institute or that are eligible for a state Renewable Portfolio Standard.
- Energy from biomass sources is limited to that from materials certified to a third-party standard (e.g., Forest Stewardship Council, Sustainable Forest Initiative, Programme for the Endorsement of Forest Certification, or American Tree Farm System), materials considered “eligible renewables” according to the Green-e Energy National Standard Version 2.5 (2014), and materials that are eligible for a state Renewable Portfolio Standard.

.07 The registrant shall apply conversion factors consistently for all data reported under this disclosure, such as the use of HHVs for fuel usage (including biofuels) and conversion of kWh to gigajoules (including for electricity from solar or wind energy).

²⁸ SASB recognizes that RECs reflect the environmental attributes of renewable energy that have been introduced to the grid.

Data Security & Privacy

Description

Drug retailers, as distributors of prescription medication and operators of retail health clinics, have access to and manage protected health information. Companies have a legal obligation to safeguard their customers' information, a task that includes the proper handling of sensitive information by staff in pharmacies and clinics, as well as the safe storage of information on physical and electronic media. Cyber-attacks may compromise data stored electronically, which is increasingly the medium of choice. In addition to health information, industry players also have access to their customers' financial and personal data; credit cards and debit cards have steadily eclipsed cash and checks as consumers' preferred payment methods. Customer information should be adequately protected by retailers in order to maintain customer trust and brand reputation. Strong internal controls are essential to protect customer information. Retailers that prevent major data breaches, including point-of-sales breaches and cyber-attacks, can avoid harming brand value, reduce contingent liabilities, and maintain market share.

Accounting Metrics

CN0402HC0304-02. Discussion of policies and practices to secure customers' protected health information (PHI) records and other personally identifiable information (PII)

.08 The registrant shall describe the nature, scope, and implementation of its policies and practices related to securing customer PHI records and other PII, with a specific focus on how it addresses the collection, usage, and retention of customers' information, where:

- PHI is defined in 45 CFR 160.103 and referenced in Section 13400 of Subtitle D ("Privacy") of the Health Information Technology for Economic and Clinical Health (HITECH) Act as information that is a subset of health information, including demographic information collected from an individual, that meets the following criteria: The information (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse and (2) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual; and (i) identifies the individual or (ii) there is a reasonable basis to believe the information can be used to identify the individual.
 - Health information is defined as any information, whether oral or recorded in any form or medium, that (A) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and (B) relates to the past, present, or future physical or mental health or condition of any individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.
 - PHI includes information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium.

- PHI excludes individually identifiable health information in education records covered by the Family Educational Rights and Privacy Act (20 U.S.C. 1232g), records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a drug retailer in its role as employer.
 - PII is defined as any information about an individual that is maintained by an entity, including any information that can be used to distinguish or trace an individual's identity, such as name, Social Security number, date and place of birth, mother's maiden name, or biometric records and any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information.²⁹
- .09 The registrant shall describe the information "lifecycle" (i.e., collection, use, retention, processing, disclosure, and destruction) and how information-handling practices at each stage may affect individuals' privacy.
- With respect to data collection, it may be relevant for the registrant to discuss which data or types of data are collected without consent of an individual, which require opt-in consent, and which require opt-out action from the individual.
 - With respect to usage of data, it may be relevant for the registrant to discuss which data or types of data are used by the registrant internally and under what circumstance the registrant shares, sells, rents, or otherwise distributes data or information to third parties.
 - With respect to retention, it may be relevant for the registrant to discuss which data or types of data it retains, the length of time of retention, and practices used to ensure that data is stored securely.
- .10 The registrant shall discuss the systems it uses to ensure compliance with the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules and the HITECH Act, including policies and practices related to the collection, usage, storage, and disposal of PHI and PII.
- .11 The registrant shall discuss its efforts to ensure compliance in the context of how it implements the following three categories of system security:
- Administrative safeguards, which are defined as documented, formal policies and procedures that are intended to manage the selection and execution of security measures to protect data and manage the conduct of personnel in relation to the protection of data.
 - Physical safeguards, which are defined as the protection of physical computer systems and the buildings holding such systems from natural and environmental hazards and inappropriate intrusion or removal.
 - Technical safeguards, which are defined as processes put in place to protect information, authenticate users, and control individual access to information.

²⁹ *Privacy: Alternatives Exist for Enhancing Protection of Personally Identifiable Information*, GAO Report 08-536, May 2008.

- .12 Relevant practices to discuss include internal monitoring practices, technology and security programs to prevent data breaches, training programs and protocols in place for employees who handle PHI or PII, and disposal methods for paper and electronic PHI records.
- .13 The registrant shall disclose if it employs heightened security measures to ensure the security of PHI, including a discussion of those additional measures.
- .14 The registrant should not include in its disclosure any information that compromises the security of its systems or its enrollees' PHI or PII.

CN0402HC0304-03. Number of data security breaches, percentage involving (1) only customers' PII and (2) customers' PHI, number of customers affected in each category

- .15 The registrant shall disclose the total number of data security breaches, which are defined as instances of unauthorized acquisition, access, use, or disclosure of protected information.
- .16 The scope of disclosure shall be limited to data security breaches, cybersecurity risks, and incidents that resulted in the registrant's business processes deviating from its expected outcomes for confidentiality, integrity, and availability.
 - The scope of disclosure shall include incidents of unauthorized acquisition or acquisition without valid authorization, resulting from deficiencies or failures of people, processes, or technology.
 - The scope of disclosure shall exclude disruptions of service due to equipment failures.
- .17 Disclosure shall be additional but complementary to the [SEC's CF Disclosure Guidance: Topic No. 2, Cybersecurity](#).
 - At a minimum, this includes instances in which the costs or other consequences associated with one or more known incidents—or the risk of potential incidents—represents a material event, trend, or uncertainty that is reasonably likely to have a material effect on the registrant's results of operations, liquidity, or financial condition, or would cause reported financial information to not be necessarily indicative of future operating results or financial condition (e.g., theft of intellectual property, reduced revenue, increased cybersecurity protection expenditure, litigation costs, etc.).
- .18 The registrant shall disclose the percentage of data security breaches in which only customers' PII (but not PHI) was breached, where:
 - PII is defined as any information about an individual that is maintained by an entity, including (1) any information that can be used to distinguish or trace an individual's identity, such as name, Social Security number, date and place of birth, mother's maiden name, or biometric records; and (2) any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information.³⁰ The scope of disclosure is limited to breaches in which customers were notified of the breach, either as required by state law or voluntarily by the registrant.

³⁰ *Privacy: Alternatives Exist for Enhancing Protection of Personally Identifiable Information*, GAO Report 08-536, May 2008.

.19 The registrant shall disclose the percentage of data security breaches in which customer's PHI was breached, where:

- PHI is defined in 45 CFR 160.103 and referenced in Section 13400 of Subtitle D ('Privacy') of the Health Information Technology for Economic and Clinical Health Act (HITECH Act) as information that is a subset of health information, including demographic information collected from an individual, that meets the following criteria: The information (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse and (2) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual; and (i) identifies the individual or (ii) there is a reasonable basis to believe the information can be used to identify the individual.
 - Health information is defined as any information, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present, or future physical or mental health or condition of any individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.
 - PHI includes information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium.
 - PHI excludes individually identifiable health information in education records covered by the Family Educational Rights and Privacy Act (20 U.S.C. 1232g), records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.
 - PHI is a subset of PII.

.20 Disclosure shall include incidents in which encrypted data were acquired with an encryption key that was also acquired.

.21 The registrant may delay disclosure if a law enforcement agency has determined that notification impedes a criminal investigation until the law enforcement agency determines that such notification does not compromise the investigation.

.22 The registrant shall disclose the total number of customers that were affected by data breaches of (a) only PII and (b) PHI, where:

- The number of customers affected includes all those whose personal data (PII or PHI) was compromised in a data breach.

Note to **CN0402HC0304-03**

.23 The registrant shall describe the corrective actions taken in response to breaches, such as changes in operations, management, processes, products, business partners, training, or technology.

- .24 All disclosure shall be sufficient such that it is specific to the risks the registrant faces, but disclosure itself will not compromise the registrant's ability to maintain data privacy and security.
- .25 The registrant should disclose its policy for disclosing data breaches to affected customers in a timely manner.

CN0402HC0304-04. Amount of legal and regulatory fines and settlements associated with data security and privacy

- .26 The registrant shall disclose the amount (excluding legal fees), in U.S. dollars, of all fines or settlements associated with data security and privacy, including, but not limited to, violations of HIPPA, the HITECH Act, Directive 2002/58/EC (ePrivacy Directive) of the Federal Trade Commission Privacy Act, and the US-EU Safe Harbor Program.
- .27 Disclosure shall include civil actions (e.g., civil judgment, settlements, or regulatory penalties) and criminal actions (e.g., criminal judgment, penalties, or restitutions) taken by any entity (government, businesses, or individuals).

Note to **CN0402HC0304-04**

- .28 The registrant shall briefly describe the nature (e.g., guilty plea, deferred agreement, or non-prosecution agreement) and context (e.g., unauthorized monitoring, sharing of data, improper disposal of health information, etc.) of fines and settlements.
- .29 The registrant shall describe any corrective actions it has implemented as a result of each incident. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.
- .29 All disclosure shall be sufficient such that it is specific to the risks the registrant faces, but disclosure itself will not compromise the registrant's ability to maintain data security.

Management of Controlled Substances

Description

Drug retailers are distributors and sellers of a wide variety of controlled substances. The Controlled Substance Act (CSA) defines requirements for record keeping, distribution, dispensing, disposal, and security of controlled substances. Within this industry, the high volumes of drugs processed and dispensed, along with the extensive retail and distribution networks of larger companies, heighten the risk of theft, loss, and illegal drug dispensing. These actions may result in adverse social externalities, including public health consequences related to drug abuse and the illicit drug trade, which are on the rise in the U.S. Drug retailers are participating in statewide drug-monitoring programs to help mitigate some of the social issues associated with dispensing controlled substances. Furthermore, regulatory enforcement of the CSA requirements can result in fines and license suspensions. Strong internal management of controlled substances can mitigate these risks and help protect shareholder value in the long term.

Accounting Metrics

CN0402HC0304-05. Percentage of controlled substance prescriptions dispensed for which a prescription drug monitoring program (PDMP) database was queried

.30 The registrant shall disclose the percentage of controlled substance prescriptions that it dispensed for which a pharmacist queried a PDMP database prior to dispensing the prescription, where:

- Controlled substances are defined in §802(6) of Title 21, United States Code (U.S.C.) as drugs that have some potential for abuse or dependence and are regulated by the federal Controlled Substances Act (CSA). Controlled substances exclude distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.
- A PDMP is defined as an electronic database that collects designated data about controlled substances dispensed, typically on a statewide level. PDMPs are housed by specified statewide regulatory, administrative, or law enforcement agencies, and this housing agency distributes data from the database to individuals who are authorized under state law to receive the information for purposes of their profession.
- A PDMP shall be considered queried if the registrant has a record that an authorized individual accessed the applicable PDMP system prior to dispensing a prescription in an effort to locate patient prescription history information.
- Patients and circumstances of a type that are excluded from PDMP reporting and querying, based on waiver or exemption established by state law, shall be excluded from the scope of this calculation.

.31 The registrant shall disclose the percentage as the number of controlled substance prescriptions dispensed for which a PDMP was queried divided by the total number of controlled substance prescriptions dispensed.

- Patients and circumstances that are excluded from PDMP reporting and querying based on state exemptions shall not be included in the number of controlled substance prescriptions dispensed where a PDMP was queried or the total number of controlled substance prescriptions dispensed.

Note to **CN0402HC0304-05**

- .32 The registrant shall describe any additional verification procedures it uses when dispensing controlled substance prescriptions in order to prevent controlled substance abuse.
- .33 Relevant strategies to discuss include:
- Practices to identify physicians and prescribers who exhibit extreme patterns of prescribing “high-risk drugs.”
 - Identification of “red flags” in customers, such as their age, payment methods, the prescriber of the medication, how long the customer has been taking the medication, and the geographic proximity of the prescriber.

CN0402HC0304-06. Amount of legal and regulatory fines and settlements associated with controlled substances

- .34 The registrant shall disclose the amount (excluding legal fees), in U.S. dollars, of all fines or settlements associated with controlled substances, including, but not limited to, violations of the CSA and other state regulations that monitor controlled substances.
- Controlled substances are drugs that have some potential for abuse or dependence and are regulated by the CSA. A controlled substance is defined in §802(6) of Title 21, U.S.C. as a drug or other substance, or immediate precursor of such a substance, that is included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.
- .35 Disclosure shall include civil actions (e.g., civil judgment, settlements, or regulatory penalties) and criminal actions (e.g., criminal judgment, penalties, or restitutions) taken by any entity (government, businesses, or individuals).

Note to **CN0402HC0304-06**

- .36 The registrant shall briefly describe the nature (e.g., guilty plea, deferred agreement, or non-prosecution agreement) and context (e.g., failure to report specific drug orders, selling a controlled substance above the legal quantity, or other inappropriate dispensing practices, etc.) of fines and settlements and any significant results of violations (including loss of DEA license to sell certain products).
- .37 The registrant shall describe any corrective actions it has implemented as a result of each incident. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

Patient Health Outcomes

Description

Drug retailers and pharmacists play an important role in the healthcare delivery system, as they provide patients with medications and are often the last healthcare professionals to interact and engage with patients before medications are consumed. Therefore, to provide the best level of care, drug retailers can enhance patient outcomes by improving communication, avoiding dispensing errors, and raising patients' drug-adherence rates (i.e., the degree to which patients follow their physician-specified drug regimens). Patients' failure to adhere to drug medication schedules can lead to suboptimal health outcomes and result in social externalities in the form of increased hospital visits and avoidable healthcare costs. Pharmacies have the opportunity to engage and educate patients on the importance of adhering to prescriptions, which provides beneficial outcomes for patients as well as for businesses, as more prescriptions are refilled. These close interactions make employee diversity an important factor in customer satisfaction and may provide companies with additional insight into consumer preferences and needs, better helping them service their customers. Pharmacies occasionally have errors in dispensing medications that can result in harm to consumers and create financial liabilities. While these occur infrequently, relative to the number of prescriptions filled every year, they still present risks to customer satisfaction and drug retailers' reputations.

Accounting Metrics

CN0402HC0304-07. First fill adherence rate

.38 The registrant shall disclose its customers' first fill adherence rate, where the rate is calculated as:

- The percentage of customer prescriptions that are required by the prescriber to have one or more refill and were refilled by the registrant at least once after the initial fill divided by the total number of customer prescriptions that were initially filled by the registrant and were required by the prescriber to have at least one additional refill, regardless of whether the prescription was refilled.

.39 The scope includes prescriptions that were initially filled in the registrant's pharmacies and excludes prescriptions that were transferred into the registrant's pharmacy from another pharmacy, and out of the registrant's pharmacy after the initial fill.

Note to **CN0402HC0304-07**

.40 The registrant shall describe the strategies it uses to increase medication adherence in its pharmacies, where:

- Medication adherence is defined as the patient's conformance with the health care provider's recommendation with respect to timing, dosage, and frequency of medication-taking during the prescribed length of time.

.41 Relevant practices to discuss include programs to communicate prescription information, directions, and reminders with customers, technology and systems used to track prescriptions and place refill orders, refill reminders, research to identify customers most at-risk for non-adherence, cultural, language, or other engagement training programs for pharmacists, programs that provide educational resources to patients,

efforts to increase diversity of pharmacy staff, and any other programs aimed at improving adherence that are in place.

- .42 The registrant may choose to disclose its performance on other relevant metrics it uses to measure progress on medication adherence
- Where the registrant discloses additional metrics related to medication adherence, it shall disclose the methodology used to calculate each such metric.

~~CN0402~~HC0304-08. Description of policies and practices to prevent prescription dispensing errors

- .43 The registrant shall discuss its policies and practices to prevent prescription dispensing errors in its pharmacies and for any mail order dispensing activities, where:
- A dispensing error is defined as a discrepancy between the medicine indicated on a prescription and the medicine that the pharmacy delivers to the patient, including the dispensing of a medicine with inferior pharmaceutical or informational quality.³¹
- .44 Relevant policies and practices to discuss include, but are not limited to, implementation of quality assurance protocols, use of bar coding, automation of processes, use of data verification systems, training of key employees, and improvements to the accuracy of recordkeeping.
- .45 The registrant may also choose to discuss observed trends or high-risk practices that could lead to dispensing errors as well the number of dispensing errors identified.

~~CN0402~~HC0304-09. Amount of legal and regulatory fines and settlements associated with prescription dispensing errors

- .46 The registrant shall disclose the amount (excluding legal fees), in U.S. dollars, of all fines or settlements associated with dispensing errors in pharmacies.
- .47 A dispensing error is a discrepancy between a prescription and the medicine that the pharmacy delivers to the patient, including the dispensing of a medicine with inferior pharmaceutical or informational quality.
- .48 Disclosure shall include civil actions (e.g., civil judgment, settlements, or regulatory penalties) and criminal actions (e.g., criminal judgment, penalties, or restitutions) taken by any entity (government, businesses, or individuals).

Note to **~~CN0402~~HC0304-09**

- .49 The registrant shall briefly describe the nature (e.g., guilty plea, deferred agreement, or non-prosecution agreement) and context (e.g., dispensing the incorrect dose or incorrect medicine, etc.) of fines and settlements.

³¹ ACG Egberts and PMLA van den Bemt, "Drug-related problems: definitions and classification," *EJHP Practice*, Vol. 13, 2007, pp. 62–64.

.50 The registrant shall describe any corrective actions it has implemented as a result of each incident. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

CN0402HC0304-10. Percentage of gender and racial/ethnic group representation for pharmacists

.51 The registrant shall classify its pharmacists according to the following definition from the U.S. Equal Employment Opportunity Commission [EEO-1 Job Classification Guide](#):

- Pharmacists (29-1051) dispense drugs prescribed by physicians and other health practitioners and provide information to patients about medications and their use. Pharmacists may advise physicians and other health practitioners on the selection, dosage, interactions, and side effects of medications.

.52 The registrant shall categorize the gender of its employees as male, female, or not disclosed/available.

.53 The registrant shall classify the racial/ethnic group of its employees in the following categories, using the same definitions employed for the registrant’s [EEO-1 Report](#): White, Black or African American, Hispanic or Latino, Asian, and Other (which includes American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, and “two or more races” classifications), or not disclosed/available.

.54 Where racial/ethnic group and/or gender representation percentages are significantly influenced by the country or region where the workforce is located, the registrant shall provide contextual disclosure to ensure proper interpretation of results.

.55 Where relevant, the registrant may provide supplemental breakdown of gender and racial/ethnic group representation by country or region.

.56 The registrant should summarize and disclose employee representation by employee category in the following table format:

EMPLOYEE CATEGORY	GENDER			RACE AND ETHNICITY					
	Male	Female	NA*	White	Black or African American	Hispanic or Latino	Asian	Other**	NA*
Pharmacists									

*NA = not available/not disclosed

**Other includes American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, and “two or more races” classifications.

Drug Supply Chain Integrity

Description

The industry's supply chain is long and complex, consisting of distribution networks between manufacturers and retailers. Drugs are intended for human consumption, which means that the quality and safety of pharmaceutical and healthcare products is of great importance. Compromised drugs include those that are counterfeit or are recalled or withdrawn for various consumer health and safety reasons. These drugs may enter the supply chain, presenting business and social safety risks. When there is a lack of quality control in a drug retailer's supply chain, it can raise the potential for human consumption of dangerous products. This can lead to costly recalls, some of which are outside the direct control of the drug retailers but still present significant consumer health and business risks. The importance of this issue is elevated by the prevalence of store-brand products, which constitute a growing portion of drugstore sales.

Accounting Metrics

CN0402HC0304-11. Discussion of efforts to reduce the occurrence of compromised drugs within the supply chain

- .57 The registrant shall describe any practices or policies it has implemented to mitigate the introduction of counterfeit or compromised drugs into its supply chain, including, but not limited to, implementation of or updates to internal controls and updates to operations, management, processes, products, business partners, training, or technology.
- .58 Compromised drugs include counterfeit drugs and other drugs that are recalled or that are of substandard quality because of a health or other safety hazard, mislabeling or improper packaging, potential contamination, or poor manufacturing.
 - Counterfeit drugs are defined by the U.S. law as drugs sold under a product name without proper authorization. Counterfeiting can apply to both brand name and generic products, where the identity of the source is mislabeled in a way that suggests that it is the authentic, approved product. Counterfeit products may include products that lack the active ingredient, contain an insufficient or excessive quantity of the active ingredient, contain the wrong active ingredient, or have fake packaging.
- .59 Relevant processes to discuss include:
 - Vendor inspection and supply chain audits
 - Traceability and bar code systems (including those related to Drug Supply Chain Security Act (DSCSA) compliance)
 - Participation in industry partnerships and initiatives, such as audit sharing programs
 - Implementation of alert systems
 - Training programs for pharmacists and other supply chain employees

- Coordination with law enforcement
 - Customer feedback tools
- .60 The registrant shall discuss whether its practices to identify compromised drugs in the supply chain differ between its private-label products and national brand products.
- .61 The registrant shall specifically discuss its plan for achieving complete implementation of the DSCSA within the DSCSA-mandated timeframe, including implementation of measures as they align with requirements of [Title II of the Drug Quality and Security Act](#), which outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.
- .62 The registrant shall describe its implementation of the DSCSA provisions across its operations, including any measures it has implemented to meet requirements for product identification, product tracing, product verification, detection and response, notification, and licensing.

CN0402HC0304-12. Number of drug recalls, total units recalled, percentage for private-label products

- .63 The registrant shall disclose the total number of recalls for drug products that the registrant retails, where:
- Drugs are defined by the FD&C Act sec. 201(g)(1) as articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and articles (other than food) intended to affect the structure or any function of the body of man or other animals.
 - Drugs include pharmaceutical prescription products as well as over-the-counter medications. Recalls are defined as actions taken by a firm to remove a product from the market, including those conducted on the registrant's own initiative, by FDA request, or by FDA order under statutory authority.
 - A recall is defined as removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action.
 - Removal means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.
 - Correction means repair, modification, adjustment, relabeling, destruction, or inspection of a product without its physical removal to some other location.
 - The scope includes all recalls of drugs for sale by the registrant, whether initiated by the FDA or voluntarily by the registrant.
 - The scope of recalls excludes market withdrawals, which are defined as a registrant's removal or correction of a distributed product that involves a minor violation that would not be subject to legal action by the FDA or that involves no violation (e.g., normal stock rotation practices).
- .64 The scope of disclosure includes voluntary recalls initiated by the registrant and recalls requested or mandated by the FDA (or other relevant government agency).

- .65 The registrant shall disclose the total number of drug product units available for sale by the registrant that were subject to a recall.
- .66 The registrant shall disclose the percentage of the total number of units recalled that were for private-label products.
- Private-label is defined as a product containing the registrant’s brand name and label, whether manufactured by a third-party vendor or by the registrant’s own facilities.
- .67 The registrant may choose to disclose, in addition to the total number of drug recalls, the percentage of recalls that were (1) voluntarily, (2) FDA requested and (3) FDA mandated.
- .68 The registrant may choose to disclose the percentage of the total number of units recalled that were part of Class I recalls, where Class I recalls is defined as a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

Note to **CN0402HC0304-12**

- .69 The registrant shall discuss notable recalls such as those that affected a significant number of units of one product or those related to serious injury or fatality.
- .70 For such recalls the registrant should provide:
- Description and cause of the recall issue
 - The total number of units recalled
 - The cost to remedy the issue (in U.S. dollars)
 - Whether the recall was initiated voluntarily or at the request of the FDA
 - Corrective actions
 - Any other significant outcomes (e.g., legal proceedings, customer fatalities, etc.)

Additional References

U.S. FDA [Backgrounds and Definitions](#)

U.S. FDA [Drug Supply Chain Integrity](#) and [Counterfeit Drugs Questions and Answers](#)