



SUSTAINABILITY ACCOUNTING STANDARD | HEALTH CARE SECTOR

BIOTECHNOLOGY

Sustainability Accounting Standard

Sustainable Industry Classification System™ (SICS™)# HC0101

Prepared by the
Sustainability Accounting Standards Board®

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BIOTECHNOLOGY

Sustainability Accounting Standard

About SASB

The Sustainability Accounting Standards Board (SASB) provides sustainability accounting standards for use by publicly-listed corporations in the U.S. in disclosing material sustainability issues for the benefit of investors and the public. SASB standards are designed for disclosure in mandatory filings to the Securities and Exchange Commission (SEC), such as the Form 10-K and 20-F. SASB is an independent 501(c)3 non-profit organization and is accredited to set standards by the American National Standards Institute (ANSI).

SASB is developing standards for more than 80 industries in 10 sectors. SASB's standards-setting process includes evidence-based analysis with in-depth industry research and engagement with a broad range of stakeholders. The end result of this process is the creation of a complete, industry-specific accounting standard which accurately reflects the material issues for each industry.

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INTRODUCTION

Purpose and Structure

This document contains the SASB Sustainability Accounting Standards (SASB Standards) for Biotechnology.

SASB Standards are comprised of **(1) disclosure guidance and (2) accounting standards on sustainability topics** for use by U.S. and foreign public companies in their annual filings (Form 10-K or 20-F) with the U.S. Securities and Exchange Commission (SEC). To the extent relevant, SASB Standards may also be applicable to other periodic mandatory filings with the SEC, such as the Form 10-Q, Form S-1, and Form 8-K.

SASB's **disclosure guidance** identifies sustainability topics at an industry level and—depending on the specific operating context of a company—may be material to a company within that industry. Each company is ultimately responsible for determining which information is material, and which such company is therefore required to include in its Form 10-K or 20-F and other periodic SEC filings.

SASB's **accounting standards** provide companies with standardized accounting metrics to account for performance on industry-level sustainability topics. When making disclosure on sustainability topics, companies adopting SASB's accounting standards will help to ensure that disclosure is standardized and therefore useful, relevant, comparable and auditable.

Guidance for Disclosure of Material Sustainability Topics in SEC filings

1. Industry-Level Material Sustainability Topics

For the Biotechnology Industry, SASB has identified the following material sustainability topics:

- **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**

NOTE: A description of each topic is provided alongside standard accounting metrics in the rest of this document.

2. Company-Level Determination and Disclosure of Material Sustainability Topics

Sustainability disclosures are governed by the same laws and regulations that govern disclosures by securities issuers generally. 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”.¹

SASB has attempted to identify those sustainability topics (above) that it believes may be material for all companies within the Biotechnology Industry. SASB recognizes, however, that each company is ultimately responsible for determining what is material to it.

Regulation S-K, which sets forth certain disclosure requirements associated with Form 10-K and other SEC filings, requires companies, among other things, to 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.”²

Furthermore, 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.”

In determining whether a trend or uncertainty should be disclosed, the SEC has stated that management should use a two-part assessment based on probability and magnitude:

- 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.
- 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.

3. Sustainability Accounting Standard Disclosures in Form 10-K

a. Management’s Discussion and Analysis

Companies should consider making disclosure on sustainability topics as a complete set in the MD&A, in a sub-section titled **“Sustainability Accounting Standards Disclosures.”**³

b. Other Relevant Sections of Form 10-K

¹ TSC Industries v. Northway, Inc., 426 U.S. 438 (1976).

² 17 C.F.R. 229.303(Item 3030)(a)(3)(ii).

³ 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.”

In addition to the MD&A section, companies should consider disclosing sustainability information in other sections of Form 10-K, as relevant, including:

- **Description of business**—Item 101 of Regulation S-K requires a company to provide a description of its business and its subsidiaries. Specifically Item 101(c)(1)(xii) expressly requires disclosure regarding certain costs of complying with environmental laws:

Appropriate disclosure also shall be made as to the material effects that compliance with Federal, State and local provisions which have been enacted or adopted regulating the discharge of materials into the environment, or otherwise relating to the protection of the environment, may have upon the capital expenditures, earnings and competitive position of the registrant and its subsidiaries.

- **Legal proceedings**—Item 103 of Regulation S-K requires companies 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 targeting discharge of materials into the environment or primarily for the purpose of protecting the environment.
- **Risk factors**—Item 503(c) of Regulation S-K requires filing companies to provide a discussion of the most significant factors that make an investment in the registrant speculative or risky, clearly stating the risk and specifying how a particular risk affects the particular filing company.
- **Rule 12b-20**—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.”

More detailed guidance on disclosure of material sustainability topics can be found in the **SASB Conceptual Framework**, available for download via <http://www.sasb.org/approach/conceptual-framework/>

Guidance on Accounting of Material Sustainability Topics

For material sustainability topics in the Biotechnology Industry, SASB identified the accounting metrics below in **Table 1. Material Sustainability Topics & Accounting Metrics.**

SASB recommends that each company consider using these sustainability accounting metrics when disclosing their performance with respect to each of the sustainability topics it has identified as material.

As appropriate—and consistent with Rule 12b-20⁴—for each sustainability topic, companies should consider including a narrative description of any material factors necessary to ensure completeness, accuracy and comparability of the data reported. Where not addressed by the specific accounting metrics, but relevant, the registrant should discuss the following related to the topic:

⁴ SEC Rule 12b-20: “In addition to the information expressly required to be included in a statement or report, there shall be added such further material information, if any, as may be necessary to make the required statements, in the light of the circumstances under which they are made not misleading.”

- the registrant's **strategic approach** to managing performance on material sustainability issues;
- the registrant's **competitive positioning**;
- the **degree of control** the registrant has;
- any **measures the registrant has undertaken** or **plans to undertake** to improve performance; and
- data for registrant's **last three completed fiscal years** (when available).

SASB recommends that registrants use SASB Standards specific to their primary industry as identified in the [Sustainability Industry Classification System \(SICS™\)](#). If a registrant generates significant revenue from multiple industries, SASB recommends that it consider the materiality of the sustainability issues that SASB has identified for those industries and disclose the associated SASB accounting metrics.

Users of the SASB Standards

The SASB Standards are intended for companies that engage in public offerings of securities registered under the Securities Act of 1933 (the Securities Act) and those that issue securities registered under the Securities Exchange Act of 1934 (the Exchange Act)⁵, for use in SEC filings, including, without limitation, annual reports on Form 10-K (Form 20-F for foreign issuers), quarterly reports on Form 10-Q, current reports on Form 8-K, and registration statements on Forms S-1 and S-3. Nevertheless, disclosure with respect to the SASB Standards is not required or endorsed by the SEC or other entities governing financial reporting, such as FASB, GASB, or IASB.

Scope of Disclosure

Unless otherwise specified, SASB recommends:

- That a registrant disclose on sustainability issues and metrics for itself and for entities in which the registrant has a controlling interest and therefore are consolidated for financial reporting purposes (controlling interest is generally defined as ownership of 50% or more of voting shares);⁶
- 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. A registrant should disclose, however, information about unconsolidated entities to the extent that such registrant considers the information necessary for investors to understand its performance with respect to sustainability issues (typically this disclosure would be limited to risks and opportunities associated with these entities).

⁵ Registration under the Securities Exchange Act of 1934 is required (1) for securities to be listed on a national securities exchange such as the New York Stock Exchange, the NYSE Amex and the NASDAQ Stock Market or (2) if (A) the securities are equity securities and are held by more than 2,000 persons (or 500 persons who are not accredited investors) and (B) the company has more than \$10 million in assets.

⁶ See US GAAP consolidation rules (Section 810).

Reporting Format

Normalization

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

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

Such data may include high-level operating data such as 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).

Any operational data provided should:

- Convey contextual information that would not otherwise be apparent from SASB accounting metric
- Be deemed generally useful for users of SASB accounting metrics (e.g., investors) in performing their own calculations and creating their own ratios.

Units of Measure

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

Uncertainty

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

Estimates

SASB recognizes that scientifically-based estimates, such as the reliance on certain conversion factors or the exclusion of *de minimis* values, may be necessary for certain quantitative disclosures. Where appropriate, SASB does not discourage the use of such estimates. When using an estimate for a particular disclosure, 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 to address all sustainability impacts or opportunities associated with a sector, industry, or company and, therefore, a company must determine for itself the topics—sustainability-related or otherwise—that warrant discussion in a registrant’s SEC filings.

Disclosure under SASB Standards is voluntary. It is not intended to replace any legal or regulatory requirements that may be applicable to user operations. Where such laws or regulations address legal or regulatory topics, disclosure under SASB Standards is not meant to supersede those requirements. Disclosure according to SASB Standards shall not be construed as demonstration of compliance with any law, regulation, or other requirement.

SASB Standards are intended to be aligned with the principles of materiality enforced by the SEC. However, SASB is not affiliated with or endorsed by the SEC or other entities governing financial reporting, such as FASB, GASB, or IASB.

Forward Looking Statements

Disclosures on sustainability topics can 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 such disclosures 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, including, 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.”

Assurance

In reporting on SASB Standards, it is expected that registrants report with the same level of rigor, accuracy, and responsibility as all other information contained in their SEC filings.

SASB recommends registrants use a higher level of assurance (attestation), such as an Examination Engagement to AT Section 701.

The following sections contain the technical protocols associated with each accounting metric such as guidance on definitions, scope, accounting guidance, compilation, and presentation.

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

Table 1. Material Sustainability Topics & Accounting Metrics

TOPIC	CODE	ACCOUNTING METRIC
Access to Medicines	HC0101-01	Description of initiatives to promote access to health care products in priority countries as defined by the Access to Medicine Index.
	HC0101-02	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP).
Drug Safety and Side Effects	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).
	HC0101-04	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System.
	HC0101-05	List of products recalled.
	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.
Safety of Clinical Trial Participants	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.
	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 (VAI) and (2) Official Action Indicated (OAI).
	HC0101-09	Description of legal and regulatory fines and settlements 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.
Affordability and Fair Pricing	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.
	HC0101-11	Ratio of weighted average rate of net price increases (for all products) to the annual increase in the U.S. Consumer Price Index.
Ethical Marketing	HC0101-12	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.
	HC0101-13	Description of code of ethics governing promotion of off-label use of products, including mechanisms to ensure compliance.
Employee Recruitment, Development, and Retention	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.
	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.
	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).

Table 1. Material Sustainability Topics & Accounting Metrics (cont.)

TOPIC	CODE	ACCOUNTING METRIC
Employee Health and Safety	HC0101-17	Total Injury Rate – (Number of recordable injuries and illnesses / Hours Worked)*200,000.
	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.
	HC0101-19	Laboratory-acquired infection (LAI) rate – LAIs per 1000 employees in human and animal diagnostic laboratories.
Counterfeit Drugs	HC0101-20	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting.
	HC0101-21	Description of process for alerting end customers and business partners of potential or known risks associated with counterfeit products.
	HC0101-22	Number (and description) of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products.
Energy, Water, and Waste Efficiency	HC0101-23	Total annual energy consumed (gigajoules) and percentage renewable (e.g., wind, biomass, solar).
	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.
	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).
	HC0101-26	Amount of waste (metric tons); percentage that is recycled, incinerated (including for energy recovery), and landfilled
Corruption and Bribery	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.
	HC0101-28	Description of code of ethics governing interactions with health care professionals, including mechanisms to ensure employee compliance.
Manufacturing and Supply Chain Quality Management	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.
	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.).

Access to Medicines

Description

Biotechnology 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 Methodology 2012](#).

NOTES

HC0101-1 – 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).

- .06 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).
- .07 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.
- .08 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.
- .09 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 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).

- .10 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](#).
- .11 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.
- .12 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.
- .13 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](#).

NOTES

HC0101-03 – 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.

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)

- .14 Products are listed by “active ingredient and trade name (if applicable)” or by “product class.”
- .15 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.
- .16 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.

- .17 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](#).
- .18 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.
- .19 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.
- .20 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. 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 (“.”).
- .21 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.
- .22 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.
- .23 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

- .24 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.
- .25 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](#).
- .26 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. national regulatory authority) and/or are not listed in an FDA Enforcement Report.
- .27 For FDA-initiated recalls, the registrant may choose to disclose the FDA classification of each recall: Class I, Class II, or Class III.
- .28 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.
- .29 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.
- .30 The registrant should list recalls associated with all drugs and biologic products manufactured by the registrant and its subsidiaries.

NOTES

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.

Additional references:

- [Chapter 7 Recall Procedures \(FDA Regulatory Procedures – July 2012\)](#)

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.

- .31 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.
- .32 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).
- .33 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.
- .34 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 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 companies that effectively manage clinical trials will 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.

- .35 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.
- .36 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.
- .37 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.
- .38 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.
- .39 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.
- .40 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.
- .41 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.
- .42 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).
- .43 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.
- .44 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.

- .45 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](#).
- .46 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 (CLILL) is organized by individual investigators (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.
- .47 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).
- .48 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.
- .49 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. Description of legal and regulatory fines and settlements 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.

- .50 The registrant shall briefly describe the nature and context of fines and 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).
- .51 The registrant shall disclose the amount of any fine or settlement associated with each incident, not including legal fees.
- .52 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.
- .53 The scope of countries comprises those that meet the following definition: (1) Low-income and Lowermiddle-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 [Access to Medicine Index Methodology 2012](#).

NOTES

HC0101-08

Definitions

[Voluntary Action Indicated](#) – 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](#) – Official Action Indicated. Objectionable conditions were found and regulatory and/or administrative sanctions by FDA are indicated.

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 biotechnology products. As a result, companies that have relied on 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 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

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.

- .54 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.
- .55 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.
- .56 The registrant should indicate if it entered multiple settlements for the same product.

HC0101-11. Ratio of weighted average rate of net price increases (for all products) to the annual increase in the U.S. Consumer Price Index.

- .57 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.
- .58 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](#).

NOTES

HC0101-10

Additional References:

[Pharmaceutical Agreement filings](#) with the FTC under The Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Ethical Marketing

Description

Biotechnology 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

HC0101-12. 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.

- .59 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).
- .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 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.
- .63 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 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 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 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.

NOTES

HC0101-13

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.

[Off-label use](#) – 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 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 will 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 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 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 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 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 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 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 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.

NOTES

HC0101-16

Additional References:

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

Employee Health and Safety

Description

The biotechnology 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 could 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 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 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 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 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 Laboratory-acquired infections include all infections acquired through laboratory or laboratory-related activities, regardless whether they are symptomatic or asymptomatic in nature.
- .79 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 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 companies subsequently face material risks associated with the potential loss of public confidence and reduced revenue.

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

- .80 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.
- .81 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.

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

- .82 Business partners include suppliers, wholesalers, retailers, hospitals, etc.
- .83 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.

NOTES

HC0101-20

Additional References:

[Prescription Drug Marketing Act pedigree requirements.](#)

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

- .84 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 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 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 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 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 enhance shareholder value.

Accounting Metrics

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

- .87 The registrant shall convert the amount of electricity it consumed from kilowatt hours (kWh) to gigajoules (GJ).
- .88 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 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 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 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 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 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.

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HC0101-24

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

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

- .96 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 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 Waste shall be limited to that which is produced during the manufacturing process.
- .99 Non-hazardous waste includes both municipal and solid waste.

NOTES

HC0101-25

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

Additional References:
[40 CFR – Title 40 – Protection of the Environment, Parts 239 – 282](#)

Corruption and Bribery

Description

Biotechnology 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 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.

- .100 The registrant shall briefly describe the nature and context of fines and settlements (e.g., non-prosecution agreement) associated with bribery, corruption, or other unethical business practices (e.g., indirect enticements such as kick-backs). These 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).
- .101 Disclosure shall include violations of the Foreign Corrupt Practices Act related to its anti-bribery or accounting provisions and enforced by the Department of Justice or the Securities and Exchange Commission.
- .102 The registrant shall disclose the amount of any fine or settlement associated with each incident, not including legal fees.
- .103 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.

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

- .104 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).
- .105 "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).
- .106 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.
- .107 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).
- .108 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 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.

- .109 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.
- .110 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.
- .111 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.).

- .112 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.
- .113 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).
- .114 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.
- .115 **Scope:** Facilities discussed shall be those recognized by the registrant as physical assets under Property, Plant, and Equipment (Topic 360).

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SUSTAINABILITY ACCOUNTING STANDARD | HEALTH CARE SECTOR

PHARMACEUTICALS

Sustainability Accounting Standard

Sustainable Industry Classification System™ (SICS™)# HC0102

Prepared by the
Sustainability Accounting Standards Board®

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PHARMACEUTICALS

Sustainability Accounting Standard

About SASB

The Sustainability Accounting Standards Board (SASB) provides sustainability accounting standards for use by publicly-listed corporations in the U.S. in disclosing material sustainability issues for the benefit of investors and the public. SASB standards are designed for disclosure in mandatory filings to the Securities and Exchange Commission (SEC), such as the Form 10-K and 20-F. SASB is an independent 501(c)3 non-profit organization and is accredited to set standards by the American National Standards Institute (ANSI).

SASB is developing standards for more than 80 industries in 10 sectors. SASB's standards-setting process includes evidence-based analysis with in-depth industry research and engagement with a broad range of stakeholders. The end result of this process is the creation of a complete, industry-specific accounting standard which accurately reflects the material issues for each industry.

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INTRODUCTION

Purpose and Structure

This document contains the SASB Sustainability Accounting Standards (SASB Standards) for Pharmaceuticals.

SASB Standards are comprised of **(1) disclosure guidance and (2) accounting standards on sustainability topics** for use by U.S. and foreign public companies in their annual filings (Form 10-K or 20-F) with the U.S. Securities and Exchange Commission (SEC). To the extent relevant, SASB Standards may also be applicable to other periodic mandatory filings with the SEC, such as the Form 10-Q, Form S-1, and Form 8-K.

SASB's **disclosure guidance** identifies sustainability topics at an industry level and—depending on the specific operating context of a company—may be material to a company within that industry. Each company is ultimately responsible for determining which information is material, and which such company is therefore required to include in its Form 10-K or 20-F and other periodic SEC filings.

SASB's **accounting standards** provide companies with standardized accounting metrics to account for performance on industry-level sustainability topics. When making disclosure on sustainability topics, companies adopting SASB's accounting standards will help to ensure that disclosure is standardized and therefore useful, relevant, comparable and auditable.

Guidance for Disclosure of Material Sustainability Topics in SEC filings

1. Industry-Level Material Sustainability Topics

For the Pharmaceuticals Industry, SASB has identified the following material sustainability topics:

- **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**

NOTE: A description of each topic is provided alongside standard accounting metrics in the rest of this document.

2. Company-Level Determination and Disclosure of Material Sustainability Topics

Sustainability disclosures are governed by the same laws and regulations that govern disclosures by securities issuers generally. 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”.¹

SASB has attempted to identify those sustainability topics (above) that it believes may be material for all companies within the Pharmaceuticals Industry. SASB recognizes, however, that each company is ultimately responsible for determining what is material to it.

Regulation S-K, which sets forth certain disclosure requirements associated with Form 10-K and other SEC filings, requires companies, among other things, to 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.”²

Furthermore, 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.”

In determining whether a trend or uncertainty should be disclosed, the SEC has stated that management should use a two-part assessment based on probability and magnitude:

- 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.
- 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.

3. Sustainability Accounting Standard Disclosures in Form 10-K

a. Management’s Discussion and Analysis

Companies should consider making disclosure on sustainability topics as a complete set in the MD&A, in a sub-section titled “**Sustainability Accounting Standards Disclosures.**”³

b. Other Relevant Sections of Form 10-K

¹ TSC Industries v. Northway, Inc., 426 U.S. 438 (1976).

² 17 C.F.R. 229.303(Item 3030)(a)(3)(ii).

³ 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.”

In addition to the MD&A section, companies should consider disclosing sustainability information in other sections of Form 10-K, as relevant, including:

- **Description of business**—Item 101 of Regulation S-K requires a company to provide a description of its business and its subsidiaries. Specifically Item 101(c)(1)(xii) expressly requires disclosure regarding certain costs of complying with environmental laws:

Appropriate disclosure also shall be made as to the material effects that compliance with Federal, State and local provisions which have been enacted or adopted regulating the discharge of materials into the environment, or otherwise relating to the protection of the environment, may have upon the capital expenditures, earnings and competitive position of the registrant and its subsidiaries.

- **Legal proceedings**—Item 103 of Regulation S-K requires companies 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 targeting discharge of materials into the environment or primarily for the purpose of protecting the environment.
- **Risk factors**—Item 503(c) of Regulation S-K requires filing companies to provide a discussion of the most significant factors that make an investment in the registrant speculative or risky, clearly stating the risk and specifying how a particular risk affects the particular filing company.
- **Rule 12b-20**—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.”

More detailed guidance on disclosure of material sustainability topics can be found in the **SASB Conceptual Framework**, available for download via <http://www.sasb.org/approach/conceptual-framework/>

Guidance on Accounting of Material Sustainability Topics

For material sustainability topics in the Pharmaceuticals Industry, SASB identified the accounting metrics below in **Table 1. Material Sustainability Topics & Accounting Metrics.**

SASB recommends that each company consider using these sustainability accounting metrics when disclosing their performance with respect to each of the sustainability topics it has identified as material.

As appropriate—and consistent with Rule 12b-20⁴—for each sustainability topic, companies should consider including a narrative description of any material factors necessary to ensure completeness, accuracy and comparability of the data reported. Where not addressed by the specific accounting metrics, but relevant, the registrant should discuss the following related to the topic:

⁴ SEC Rule 12b-20: “In addition to the information expressly required to be included in a statement or report, there shall be added such further material information, if any, as may be necessary to make the required statements, in the light of the circumstances under which they are made not misleading.”

- the registrant's **strategic approach** to managing performance on material sustainability issues;
- the registrant's **competitive positioning**;
- the **degree of control** the registrant has;
- any **measures the registrant has undertaken** or **plans to undertake** to improve performance; and
- data for registrant's **last three completed fiscal years** (when available).

SASB recommends that registrants use SASB Standards specific to their primary industry as identified in the [Sustainability Industry Classification System \(SICS™\)](#). If a registrant generates significant revenue from multiple industries, SASB recommends that it consider the materiality of the sustainability issues that SASB has identified for those industries and disclose the associated SASB accounting metrics.

Users of the SASB Standards

The SASB Standards are intended for companies that engage in public offerings of securities registered under the Securities Act of 1933 (the Securities Act) and those that issue securities registered under the Securities Exchange Act of 1934 (the Exchange Act)⁵, for use in SEC filings, including, without limitation, annual reports on Form 10-K (Form 20-F for foreign issuers), quarterly reports on Form 10-Q, current reports on Form 8-K, and registration statements on Forms S-1 and S-3. Nevertheless, disclosure with respect to the SASB Standards is not required or endorsed by the SEC or other entities governing financial reporting, such as FASB, GASB, or IASB.

Scope of Disclosure

Unless otherwise specified, SASB recommends:

- That a registrant disclose on sustainability issues and metrics for itself and for entities in which the registrant has a controlling interest and therefore are consolidated for financial reporting purposes (controlling interest is generally defined as ownership of 50% or more of voting shares);⁶
- 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. A registrant should disclose, however, information about unconsolidated entities to the extent that such registrant considers the information necessary for investors to understand its performance with respect to sustainability issues (typically this disclosure would be limited to risks and opportunities associated with these entities).

⁵ Registration under the Securities Exchange Act of 1934 is required (1) for securities to be listed on a national securities exchange such as the New York Stock Exchange, the NYSE Amex and the NASDAQ Stock Market or (2) if (A) the securities are equity securities and are held by more than 2,000 persons (or 500 persons who are not accredited investors) and (B) the company has more than \$10 million in assets.

⁶ See US GAAP consolidation rules (Section 810).

Reporting Format

Normalization

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

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

Such data may include high-level operating data such as 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).

Any operational data provided should:

- Convey contextual information that would not otherwise be apparent from SASB accounting metric
- Be deemed generally useful for users of SASB accounting metrics (e.g., investors) in performing their own calculations and creating their own ratios.

Units of Measure

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

Uncertainty

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

Estimates

SASB recognizes that scientifically-based estimates, such as the reliance on certain conversion factors or the exclusion of *de minimis* values, may be necessary for certain quantitative disclosures. Where appropriate, SASB does not discourage the use of such estimates. When using an estimate for a particular disclosure, 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 to address all sustainability impacts or opportunities associated with a sector, industry, or company and, therefore, a company must determine for itself the topics—sustainability-related or otherwise—that warrant discussion in a registrant’s SEC filings.

Disclosure under SASB Standards is voluntary. It is not intended to replace any legal or regulatory requirements that may be applicable to user operations. Where such laws or regulations address legal or regulatory topics, disclosure under SASB Standards is not meant to supersede those requirements. Disclosure according to SASB Standards shall not be construed as demonstration of compliance with any law, regulation, or other requirement.

SASB Standards are intended to be aligned with the principles of materiality enforced by the SEC. However, SASB is not affiliated with or endorsed by the SEC or other entities governing financial reporting, such as FASB, GASB, or IASB.

Forward Looking Statements

Disclosures on sustainability topics can 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 such disclosures 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, including, 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.”

Assurance

In reporting on SASB Standards, it is expected that registrants report with the same level of rigor, accuracy, and responsibility as all other information contained in their SEC filings.

SASB recommends registrants use a higher level of assurance (attestation), such as an Examination Engagement to AT Section 701.

The following sections contain the technical protocols associated with each accounting metric such as guidance on definitions, scope, accounting guidance, compilation, and presentation.

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

Table 1. Material Sustainability Topics & Accounting Metrics

TOPIC	CODE	ACCOUNTING METRIC
Access to Medicines	HC0102-01	Description of initiatives to promote access to health care products in priority countries as defined by the Access to Medicine Index.
	HC0102-02	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP).
Drug Safety and Side Effects	HC0102-03	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).
	HC0102-04	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System.
	HC0102-05	List of products recalled.
	HC0102-06	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.
Safety of Clinical Trial Participants	HC0102-07	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.
	HC0102-08	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).
	HC0102-09	Description of legal and regulatory fines and settlements 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.
Affordability and Fair Pricing	HC0102-10	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.
	HC0102-11	Ratio of weighted average rate of net price increases (for all products) to the annual increase in the U.S. Consumer Price Index.
Ethical Marketing	HC0102-12	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.
	HC0102-13	Description of code of ethics governing promotion of off-label use of products, including mechanisms to ensure compliance.
Employee Recruitment, Development, and Retention	HC0102-14	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.
	HC0102-15	Training and development expenditures per full time employee by: (1) expenditures for industry or professional qualification and advanced industry education; (2) all other.
	HC0102-16	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).

Table 1. Material Sustainability Topics & Accounting Metrics (cont.)

TOPIC	CODE	ACCOUNTING METRIC
Employee Health and Safety	HC0102-17	Total Injury Rate – (Number of recordable injuries and illnesses / Hours Worked)*200,000.
	HC0102-18	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.
	HC0102-19	Laboratory-acquired infection (LAI) rate – LAIs per 1000 employees in human and animal diagnostic laboratories
Counterfeit Drugs	HC0102-20	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting.
	HC0102-21	Description of process for alerting end customers and business partners of potential or known risks associated with counterfeit products.
	HC0102-22	Number (and description) of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products.
Energy, Water, and Waste Efficiency	HC0102-23	Total annual energy consumed (gigajoules) and percentage renewable (e.g., wind, biomass, solar).
	HC0102-24	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.
	HC0102-25	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).
	HC0102-26	Amount of waste (metric tons); percentage that is recycled, incinerated (including for energy recovery), and landfilled.
Corruption and Bribery	HC0102-27	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.
	HC0102-28	Description of code of ethics governing interactions with health care professionals, including mechanisms to ensure employee compliance.
Manufacturing and Supply Chain Quality Management	HC0102-29	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.
	HC0102-30	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.).

Access to Medicines

Description

Pharmaceutical 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

HC0102-01. 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 Methodology 2012](#).

NOTES

HC0102-1 – 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](#).

HC0102-02. List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP).

- .06 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).
- .07 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.
- .08 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.
- .09 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. Pharmaceutical 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

HC0102-03. 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).

- .10 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](#).
- .11 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.
- .12 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.
- .13 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](#).

NOTES

HC0102-03 – 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.

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)

- .14 Products are listed by “active ingredient and trade name (if applicable)” or by “product class.”
- .15 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.
- .16 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.

HC0102-04. Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System.

- .17 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](#).
- .18 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.
- .19 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.
- .20 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. 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 (“.”).
- .21 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.
- .22 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.
- .23 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.

HC0102-5. List of products recalled

- .24 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.
- .25 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.
- .26 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.
- .27 For FDA-initiated recalls, the registrant may choose to disclose the FDA classification of each recall: Class I, Class II, or Class III.
- .28 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.
- .29 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.
- .30 The registrant should list recalls associated with all drugs and biologic products manufactured by the registrant and its subsidiaries.

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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 \(FDA Regulatory Procedures – July 2012\)](#)

HC0102-06. 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.

- .31 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.
- .32 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).
- .33 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.
- .34 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 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. Pharmaceutical companies that effectively manage clinical trials will be positioned to enhance shareholder value through the revenue associated with new products.

Accounting Metrics

HC0102-07. 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.

- .35 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.
- .36 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.
- .37 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.
- .38 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.
- .39 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.
- .40 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.
- .41 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.

- .42 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).
- .43 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.
- .44 **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.

HC0102-08. 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.

- .45 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](#).
- .46 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 (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.
- .47 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).
- .48 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.
- .49 **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.

HC0102-09. Description of legal and regulatory fines and settlements 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.

- .50 The registrant shall briefly describe the nature and context of fines and 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).
- .51 The registrant shall disclose the amount of any fine or settlement associated with each incident, not including legal fees.

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Definitions: [Voluntary Action Indicated](#) – 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](#) – Official Action Indicated. Objectionable conditions were found and regulatory and/or administrative sanctions by FDA are indicated.

- .52 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.
- .53 The scope of countries comprises those that meet the following definition: (1) Low-income and Lowermiddle-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 [Access to Medicine Index Methodology 2012](#).

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 pharmaceutical products. As a result, companies that have relied on 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 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

HC0102-10. 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.

- .54 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.
- .55 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.
- .56 The registrant should indicate if it entered multiple settlements for the same product.

HC0102-11. Ratio of weighted average rate of net price increases (for all products) to the annual increase in the U.S. Consumer Price Index.

- .57 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.
- .58 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](#).

NOTES

HC0102-10

Additional References:

[Pharmaceutical Agreement filings](#) with the FTC under The Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Ethical Marketing

Description

Pharmaceutical 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

HC0102-12. 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.

- .59 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).
- .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 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.
- .63 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.

HC0102-13. Description of code of ethics governing promotion of off-label use of products, including mechanisms to ensure compliance.

- .64 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 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 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.

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HC0102-13

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.

[Off-label use](#) – 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

Pharmaceutical 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 will be better positioned to protect and enhance shareholder value.

Accounting Metrics

HC0102-14. 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 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 Discussion shall focus on scientists and other personnel that are directly involved in research and development of activities for new biopharmaceutical products.

HC0102-15. Training and development expenditures per full-time employee by: (1) expenditures for industry or professional qualification and advanced industry education; (2) all other.

- .69 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 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).

HC0102-16. 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 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 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 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.

NOTES

HC0102-16

Additional References:

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

Employee Health and Safety

Description

The pharmaceutical 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 could result in negative material impacts through litigation, fines, and penalties.

Accounting Metrics

HC0102-17. Total Injury Rate – (Number of recordable injuries and illnesses / Hours Worked)*200,000.

- .74 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 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](#).

HC0102-18. 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 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 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](#).

HC0102-19. Laboratory-acquired infection (LAI) rate – LAIs per 1000 employees in human and animal diagnostic laboratories.

- .78 Laboratory-acquired infections include all infections acquired through laboratory or laboratory-related activities, regardless whether they are symptomatic or asymptomatic in nature.
- .79 The registrant shall disclose the number of laboratory-acquired infections per 1000 employees, even if these incidents are included in data for HC0102-17 and/or HC0102-18.

Counterfeit Drugs

Description

The World Health Organization estimates that the global market for counterfeit drugs has reached \$431 billion, representing 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. Pharmaceutical companies subsequently face material risks associated with the potential loss of public confidence and reduced revenue.

Accounting Metrics

HC0102-20. Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting.

- .80 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 pharmaceutical industry, relevant stages include manufacturing, logistics transportation, drug wholesale and distribution, and pharmacy retail.
- .81 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.

HC0102-21. Description of process for alerting end customers and business partners of potential or known risks associated with counterfeit products.

- .82 Business partners include suppliers, wholesalers, retailers, hospitals, etc.
- .83 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.

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HC0102-20

Additional References:

[Prescription Drug Marketing Act pedigree requirements.](#)

HC0102-22. Number (and description) of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products.

- .84 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 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 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 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, pharmaceutical 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 enhance shareholder value.

Accounting Metrics

HC0102-23. Total annual energy consumed (gigajoules) and percentage renewable (e.g., wind, biomass, solar).

- .87 The registrant shall convert the amount of electricity it consumed from kilowatt hours (kWh) to gigajoules (GJ).
- .88 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 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 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.

HC0102-24. 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 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 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 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.

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HC0102-24

Additional References:

[Corporate Water Disclosure Guidelines](#): Toward a Common Approach to Reporting Water Issues, CEO Water Mandate, August 2012.

HC0102-25. 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 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 The registrant should disclose total PMI for all raw material inputs, as well as separate PMI figures for water inputs and organic solvent inputs.

HC0102-26. Amount of waste (metric tons); percentage that is recycled, incinerated (including for energy recovery), and landfilled.

- .96 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 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 Waste shall be limited to that which is produced during the manufacturing process.
- .99 Non-hazardous waste includes both municipal and solid waste.

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HC0102-25

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

HC0102-26

Additional References:

[40 CFR – Title 40 – Protection of the Environment, Parts 239 – 282](#)

Corruption and Bribery

Description

Pharmaceutical 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 have material implications.

Accounting Metrics

HC0102-27. 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.

- .100 The registrant shall briefly describe the nature and context of fines and settlements (e.g., non-prosecution agreement) associated with bribery, corruption, or other unethical business practices (e.g., indirect enticements such as kick-backs). These 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).
- .101 Disclosure shall include violations of the Foreign Corrupt Practices Act related to its anti-bribery or accounting provisions and enforced by the Department of Justice or the Securities and Exchange Commission.
- .102 The registrant shall disclose the amount of any fine or settlement associated with each incident, not including legal fees.
- .103 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.

HC0102-28. Description of code of ethics governing interactions with health care professionals including mechanisms to ensure employee compliance.

- .104 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).

- .105 “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).
- .106 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.
- .107 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).
- .108 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. Pharmaceutical 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

HC0102-29. 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.

- .109 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.
- .110 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.
- .111 Scope: Facilities discussed shall be those recognized by the registrant as physical assets under Property, Plant, and Equipment (Topic 360).

HC0102-30. 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.).

- .112 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.
- .113 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).
- .114 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.
- .115 **Scope:** Facilities discussed shall be those recognized by the registrant as physical assets under Property, Plant, and Equipment (Topic 360).

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SUSTAINABILITY ACCOUNTING STANDARD | HEALTH CARE SECTOR

MEDICAL EQUIPMENT AND SUPPLIES

Sustainability Accounting Standard

Sustainable Industry Classification System™ (SICS™)# HC0201

Prepared by the
Sustainability Accounting Standards Board®

August 2013
Version 1.0

MEDICAL EQUIPMENT AND SUPPLIES

Sustainability Accounting Standard

About SASB

The Sustainability Accounting Standards Board (SASB) provides sustainability accounting standards for use by publicly-listed corporations in the U.S. in disclosing material sustainability issues for the benefit of investors and the public. SASB standards are designed for disclosure in mandatory filings to the Securities and Exchange Commission (SEC), such as the Form 10-K and 20-F. SASB is an independent 501(c)3 non-profit organization and is accredited to set standards by the American National Standards Institute (ANSI).

SASB is developing standards for more than 80 industries in 10 sectors. SASB's standards-setting process includes evidence-based analysis with in-depth industry research and engagement with a broad range of stakeholders. The end result of this process is the creation of a complete, industry-specific accounting standard which accurately reflects the material issues for each industry.

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INTRODUCTION

Purpose and Structure

This document contains the SASB Sustainability Accounting Standards (SASB Standards) for Medical Equipment and Supplies.

SASB Standards are comprised of **(1) disclosure guidance and (2) accounting standards on sustainability topics** for use by U.S. and foreign public companies in their annual filings (Form 10-K or 20-F) with the U.S. Securities and Exchange Commission (SEC). To the extent relevant, SASB Standards may also be applicable to other periodic mandatory filings with the SEC, such as the Form 10-Q, Form S-1, and Form 8-K.

SASB's **disclosure guidance** identifies sustainability topics at an industry level and—depending on the specific operating context of a company—may be material to a company within that industry. Each company is ultimately responsible for determining which information is material, and which such company is therefore required to include in its Form 10-K or 20-F and other periodic SEC filings.

SASB's **accounting standards** provide companies with standardized accounting metrics to account for performance on industry-level sustainability topics. When making disclosure on sustainability topics, companies adopting SASB's accounting standards will help to ensure that disclosure is standardized and therefore useful, relevant, comparable and auditable.

Guidance for Disclosure of Material Sustainability Topics in SEC filings

1. Industry-Level Material Sustainability Topics

For the Medical Equipment and Supplies Industry, SASB has identified the following material sustainability topics:

- **Product Safety**
- **Ethical Marketing**
- **Affordability and Fair Pricing**
- **Energy, Water, and Waste Efficiency**
- **Product Design and Lifecycle Management**
- **Corruption and Bribery**
- **Manufacturing and Supply Chain Quality Management**

NOTE: A description of each topic is provided alongside standard accounting metrics in the rest of this document.

2. Company-Level Determination and Disclosure of Material Sustainability Topics

Sustainability disclosures are governed by the same laws and regulations that govern disclosures by securities issuers generally. 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”.¹

SASB has attempted to identify those sustainability topics (above) that it believes may be material for all companies within the Medical Equipment and Supplies Industry. SASB recognizes, however, that each company is ultimately responsible for determining what is material to it.

Regulation S-K, which sets forth certain disclosure requirements associated with Form 10-K and other SEC filings, requires companies, among other things, to 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.”²

Furthermore, 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.”

In determining whether a trend or uncertainty should be disclosed, the SEC has stated that management should use a two-part assessment based on probability and magnitude:

- 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.
- 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.

3. Sustainability Accounting Standard Disclosures in Form 10-K

a. Management’s Discussion and Analysis

Companies should consider making disclosure on sustainability topics as a complete set in the MD&A, in a sub-section titled **“Sustainability Accounting Standards Disclosures.”**³

b. Other Relevant Sections of Form 10-K

¹ TSC Industries v. Northway, Inc., 426 U.S. 438 (1976).

² 17 C.F.R. 229.303(Item 3030)(a)(3)(ii).

³ 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.”

In addition to the MD&A section, companies should consider disclosing sustainability information in other sections of Form 10-K, as relevant, including:

- **Description of business**—Item 101 of Regulation S-K requires a company to provide a description of its business and its subsidiaries. Specifically Item 101(c)(1)(xii) expressly requires disclosure regarding certain costs of complying with environmental laws:

Appropriate disclosure also shall be made as to the material effects that compliance with Federal, State and local provisions which have been enacted or adopted regulating the discharge of materials into the environment, or otherwise relating to the protection of the environment, may have upon the capital expenditures, earnings and competitive position of the registrant and its subsidiaries.

- **Legal proceedings**—Item 103 of Regulation S-K requires companies 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 targeting discharge of materials into the environment or primarily for the purpose of protecting the environment.
- **Risk factors**—Item 503(c) of Regulation S-K requires filing companies to provide a discussion of the most significant factors that make an investment in the registrant speculative or risky, clearly stating the risk and specifying how a particular risk affects the particular filing company.
- **Rule 12b-20**—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.”

More detailed guidance on disclosure of material sustainability topics can be found in the **SASB Conceptual Framework**, available for download via <http://www.sasb.org/approach/conceptual-framework/>

Guidance on Accounting of Material Sustainability Topics

For material sustainability topics in the Medical Equipment and Supplies Industry, SASB identified the accounting metrics below in **Table 1. Material Sustainability Topics & Accounting Metrics**.

SASB recommends that each company consider using these sustainability accounting metrics when disclosing their performance with respect to each of the sustainability topics it has identified as material.

As appropriate—and consistent with Rule 12b-20⁴—for each sustainability topic, companies should consider including a narrative description of any material factors necessary to ensure completeness, accuracy and comparability of the data reported. Where not addressed by the specific accounting metrics, but relevant, the registrant should discuss the following related to the topic:

⁴ SEC Rule 12b-20: “In addition to the information expressly required to be included in a statement or report, there shall be added such further material information, if any, as may be necessary to make the required statements, in the light of the circumstances under which they are made not misleading.”

- the registrant's **strategic approach** to managing performance on material sustainability issues;
- the registrant's **competitive positioning**;
- the **degree of control** the registrant has;
- any **measures the registrant has undertaken** or **plans to undertake** to improve performance; and
- data for registrant's **last three completed fiscal years** (when available).

SASB recommends that registrants use SASB Standards specific to their primary industry as identified in the [Sustainability Industry Classification System \(SICS™\)](#). If a registrant generates significant revenue from multiple industries, SASB recommends that it consider the materiality of the sustainability issues that SASB has identified for those industries and disclose the associated SASB accounting metrics.

Users of the SASB Standards

The SASB Standards are intended for companies that engage in public offerings of securities registered under the Securities Act of 1933 (the Securities Act) and those that issue securities registered under the Securities Exchange Act of 1934 (the Exchange Act)⁵, for use in SEC filings, including, without limitation, annual reports on Form 10-K (Form 20-F for foreign issuers), quarterly reports on Form 10-Q, current reports on Form 8-K, and registration statements on Forms S-1 and S-3. Nevertheless, disclosure with respect to the SASB Standards is not required or endorsed by the SEC or other entities governing financial reporting, such as FASB, GASB, or IASB.

Scope of Disclosure

Unless otherwise specified, SASB recommends:

- That a registrant disclose on sustainability issues and metrics for itself and for entities in which the registrant has a controlling interest and therefore are consolidated for financial reporting purposes (controlling interest is generally defined as ownership of 50% or more of voting shares);⁶
- 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. A registrant should disclose, however, information about unconsolidated entities to the extent that such registrant considers the information necessary for investors to understand its performance with respect to sustainability issues (typically this disclosure would be limited to risks and opportunities associated with these entities).

⁵ Registration under the Securities Exchange Act of 1934 is required (1) for securities to be listed on a national securities exchange such as the New York Stock Exchange, the NYSE Amex and the NASDAQ Stock Market or (2) if (A) the securities are equity securities and are held by more than 2,000 persons (or 500 persons who are not accredited investors) and (B) the company has more than \$10 million in assets.

⁶ See US GAAP consolidation rules (Section 810).

Reporting Format

Normalization

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

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

Such data may include high-level operating data such as 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).

Any operational data provided should:

- Convey contextual information that would not otherwise be apparent from SASB accounting metric
- Be deemed generally useful for users of SASB accounting metrics (e.g., investors) in performing their own calculations and creating their own ratios.

Units of Measure

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

Uncertainty

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

Estimates

SASB recognizes that scientifically-based estimates, such as the reliance on certain conversion factors or the exclusion of *de minimis* values, may be necessary for certain quantitative disclosures. Where appropriate, SASB does not discourage the use of such estimates. When using an estimate for a particular disclosure, 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 to address all sustainability impacts or opportunities associated with a sector, industry, or company and, therefore, a company must determine for itself the topics—sustainability-related or otherwise—that warrant discussion in a registrant’s SEC filings.

Disclosure under SASB Standards is voluntary. It is not intended to replace any legal or regulatory requirements that may be applicable to user operations. Where such laws or regulations address legal or regulatory topics, disclosure under SASB Standards is not meant to supersede those requirements. Disclosure according to SASB Standards shall not be construed as demonstration of compliance with any law, regulation, or other requirement.

SASB Standards are intended to be aligned with the principles of materiality enforced by the SEC. However, SASB is not affiliated with or endorsed by the SEC or other entities governing financial reporting, such as FASB, GASB, or IASB.

Forward Looking Statements

Disclosures on sustainability topics can 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 such disclosures 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, including, 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.”

Assurance

In reporting on SASB Standards, it is expected that registrants report with the same level of rigor, accuracy, and responsibility as all other information contained in their SEC filings.

SASB recommends registrants use a higher level of assurance (attestation), such as an Examination Engagement to AT Section 701.

The following sections contain the technical protocols associated with each accounting metric such as guidance on definitions, scope, accounting guidance, compilation, and presentation.

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

Table 1. Material Sustainability Topics & Accounting Metrics

TOPIC	CODE	ACCOUNTING METRIC
Product Safety	HC0201-01	List of products recalled.
	HC0201-02	List of products listed in the FDA's MedWatch Safety Alerts for Human Medical Products (Medical Devices) database.
	HC0201-03	Number of fatalities related to products as reported in the FDA Adverse Event Reporting System.
Ethical Marketing	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.
	HC0201-05	Description of code of ethics governing promotion of off-label use of products, including mechanisms to ensure compliance.
Affordability and Fair Pricing	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.
	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).
Energy, Water, and Waste Efficiency	HC0201-08	Total annual energy consumed (gigajoules) and percentage renewable (e.g., wind, biomass, solar).
	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.
	HC0201-10	Amount of waste (metric tons); percentage that is recycled, incinerated, and landfilled.
Product Design and Lifecycle Management	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.
	HC0201-12	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.
Corruption and Bribery	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.
	HC0201-14	Description of code of ethics governing interactions with health care professionals including mechanisms to ensure employee compliance.

Table 1. Material Sustainability Topics & Accounting Metrics (cont.)

TOPIC	CODE	ACCOUNTING METRIC
Manufacturing and Supply Chain Quality Management	HC0201-15	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.
	HC0201-16	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.).
	HC0201-17	Description of efforts to maintain traceability within the distribution chain, particularly with respect to wholesalers, re-packagers, and/or contract distributors.
	HC0201-18	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.

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. Medical equipment and supply firms that limit the incidence of these claims will 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.

NOTES

HC0201-01

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)

- .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.

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. 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 (“.”).

NOTES

HC0201-03

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 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.
- .20 The registrant shall disclose the amount of any fine or settlement associated with each incident, not including legal fees.
- .21 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.
- .22 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.

NOTES

HC0201-04

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.

- .23 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.”
- .24 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.
- .25 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.

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 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.

- .26 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.
- .27 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).

- .28 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.
- .29 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.
- .30 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.
- .31 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

Description

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.

Accounting Metrics

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

- .32 The registrant shall convert the amount of electricity it purchased from kilowatt hours (kWh) to gigajoules (GJ).
- .33 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).
- .34 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).
- .35 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.

- .36 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).
- .37 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.
- .38 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.

- .39 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).
- .40 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](#).
- .41 Waste shall be limited to that which is produced during the manufacturing process.
- .42 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 will 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.

- .43 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).
- .44 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").
- .45 The registrant shall specify during which lifecycle stage(s) it takes into account the environmental impacts associated with its products.
- .46 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.
- .47 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.
- .48 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.
- .49 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.

.50 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.

.51 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 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.

- .52 The registrant shall briefly describe the nature and context of fines and settlements (e.g., non-prosecution agreement) associated with bribery, corruption, or other unethical business practices (e.g., indirect enticements such as kickbacks). These 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).
- .53 Disclosure shall include violations of the Foreign Corrupt Practices Act related to its anti-bribery or accounting provisions and enforced by the Department of Justice or Securities and Exchange Commission.
- .54 The registrant shall disclose the amount of any fine or settlement associated with each incident, not including legal fees.
- .55 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.

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

- .56 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).

- .57 "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").
- .58 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.
- .59 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).
- .60 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.

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.

- .61 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.
- .62 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.
- .63 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.).

- .64 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).
- .65 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).

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

.67 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.

.68 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 and devices industry, relevant stages include manufacturing, logistics transportation, product wholesale and distribution, and point of delivery at the health care provider.

.69 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.

.70 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.

.71 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).

.72 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.

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SUSTAINABILITY ACCOUNTING STANDARD | HEALTH CARE SECTOR

HEALTH CARE DELIVERY

Sustainability Accounting Standard

Sustainable Industry Classification System™ (SICS™)# HC0301

Prepared by the
Sustainability Accounting Standards Board®

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HEALTH CARE DELIVERY

Sustainability Accounting Standard

About SASB

The Sustainability Accounting Standards Board (SASB) provides sustainability accounting standards for use by publicly-listed corporations in the U.S. in disclosing material sustainability issues for the benefit of investors and the public. SASB standards are designed for disclosure in mandatory filings to the Securities and Exchange Commission (SEC), such as the Form 10-K and 20-F. SASB is an independent 501(c)3 non-profit organization and is accredited to set standards by the American National Standards Institute (ANSI).

SASB is developing standards for more than 80 industries in 10 sectors. SASB's standards-setting process includes evidence-based analysis with in-depth industry research and engagement with a broad range of stakeholders. The end result of this process is the creation of a complete, industry-specific accounting standard which accurately reflects the material issues for each industry.

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INTRODUCTION

Purpose and Structure

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

SASB Standards are comprised of **(1) disclosure guidance and (2) accounting standards on sustainability topics** for use by U.S. and foreign public companies in their annual filings (Form 10-K or 20-F) with the U.S. Securities and Exchange Commission (SEC). To the extent relevant, SASB Standards may also be applicable to other periodic mandatory filings with the SEC, such as the Form 10-Q, Form S-1, and Form 8-K.

SASB's **disclosure guidance** identifies sustainability topics at an industry level and—depending on the specific operating context of a company—may be material to a company within that industry. Each company is ultimately responsible for determining which information is material, and which such company is therefore required to include in its Form 10-K or 20-F and other periodic SEC filings.

SASB's **accounting standards** provide companies with standardized accounting metrics to account for performance on industry-level sustainability topics. When making disclosure on sustainability topics, companies adopting SASB's accounting standards will help to ensure that disclosure is standardized and therefore useful, relevant, comparable and auditable.

Guidance for Disclosure of Material Sustainability Topics in SEC filings

1. Industry-Level Material Sustainability Topics

For the Health Care Delivery Industry, SASB has identified the following material sustainability 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**
- **Fraud and Unnecessary Procedures**
- **Patient Privacy and Electronic Health Records**

NOTE: A description of each topic is provided alongside standard accounting metrics in the rest of this document.

2. Company-Level Determination and Disclosure of Material Sustainability Topics

Sustainability disclosures are governed by the same laws and regulations that govern disclosures by securities issuers generally. 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”.¹

SASB has attempted to identify those sustainability topics (above) that it believes may be material for all companies within the Health Care Delivery Industry. SASB recognizes, however, that each company is ultimately responsible for determining what is material to it.

Regulation S-K, which sets forth certain disclosure requirements associated with Form 10-K and other SEC filings, requires companies, among other things, to 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.”²

Furthermore, 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.”

In determining whether a trend or uncertainty should be disclosed, the SEC has stated that management should use a two-part assessment based on probability and magnitude:

- 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.
- 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.

3. Sustainability Accounting Standard Disclosures in Form 10-K

a. Management’s Discussion and Analysis

Companies should consider making disclosure on sustainability topics as a complete set in the MD&A, in a subsection titled “**Sustainability Accounting Standards Disclosures.**”³

b. Other Relevant Sections of Form 10-K

¹ TSC Industries v. Northway, Inc., 426 U.S. 438 (1976).

² 17 C.F.R. 229.303(Item 3030)(a)(3)(ii).

³ 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.”

In addition to the MD&A section, companies should consider disclosing sustainability information in other sections of Form 10-K, as relevant, including:

- **Description of business**—Item 101 of Regulation S-K requires a company to provide a description of its business and its subsidiaries. Specifically Item 101(c)(1)(xii) expressly requires disclosure regarding certain costs of complying with environmental laws:

Appropriate disclosure also shall be made as to the material effects that compliance with Federal, State and local provisions which have been enacted or adopted regulating the discharge of materials into the environment, or otherwise relating to the protection of the environment, may have upon the capital expenditures, earnings and competitive position of the registrant and its subsidiaries.

- **Legal proceedings**—Item 103 of Regulation S-K requires companies 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 targeting discharge of materials into the environment or primarily for the purpose of protecting the environment.
- **Risk factors**—Item 503(c) of Regulation S-K requires filing companies to provide a discussion of the most significant factors that make an investment in the registrant speculative or risky, clearly stating the risk and specifying how a particular risk affects the particular filing company.
- **Rule 12b-20**—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.”

More detailed guidance on disclosure of material sustainability topics can be found in the **SASB Conceptual Framework**, available for download via <http://www.sasb.org/approach/conceptual-framework/>

Guidance on Accounting of Material Sustainability Topics

For material sustainability topics in the Health Care Delivery Industry, SASB identified the accounting metrics below in **Table 1. Material Sustainability Topics & Accounting Metrics**.

SASB recommends that each company consider using these sustainability accounting metrics when disclosing their performance with respect to each of the sustainability topics it has identified as material.

As appropriate—and consistent with Rule 12b-20⁴—for each sustainability topic, companies should consider including a narrative description of any material factors necessary to ensure completeness, accuracy and comparability of the data reported. Where not addressed by the specific accounting metrics, but relevant, the registrant should discuss the following related to the topic:

⁴ SEC Rule 12b-20: “In addition to the information expressly required to be included in a statement or report, there shall be added such further material information, if any, as may be necessary to make the required statements, in the light of the circumstances under which they are made not misleading.”

- the registrant's **strategic approach** to managing performance on material sustainability issues;
- the registrant's **competitive positioning**;
- the **degree of control** the registrant has;
- any **measures the registrant has undertaken** or **plans to undertake** to improve performance; and
- data for registrant's **last three completed fiscal years** (when available).

SASB recommends that registrants use SASB Standards specific to their primary industry as identified in the [Sustainability Industry Classification System \(SICS™\)](#). If a registrant generates significant revenue from multiple industries, SASB recommends that it consider the materiality of the sustainability issues that SASB has identified for those industries and disclose the associated SASB accounting metrics.

Users of the SASB Standards

The SASB Standards are intended for companies that engage in public offerings of securities registered under the Securities Act of 1933 (the Securities Act) and those that issue securities registered under the Securities Exchange Act of 1934 (the Exchange Act)⁵, for use in SEC filings, including, without limitation, annual reports on Form 10-K (Form 20-F for foreign issuers), quarterly reports on Form 10-Q, current reports on Form 8-K, and registration statements on Forms S-1 and S-3. Nevertheless, disclosure with respect to the SASB Standards is not required or endorsed by the SEC or other entities governing financial reporting, such as FASB, GASB, or IASB.

Scope of Disclosure

Unless otherwise specified, SASB recommends:

- That a registrant disclose on sustainability issues and metrics for itself and for entities in which the registrant has a controlling interest and therefore are consolidated for financial reporting purposes (controlling interest is generally defined as ownership of 50% or more of voting shares);⁶
- 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. A registrant should disclose, however, information about unconsolidated entities to the extent that such registrant considers the information necessary for investors to understand its performance with respect to sustainability issues (typically this disclosure would be limited to risks and opportunities associated with these entities).

⁵ Registration under the Securities Exchange Act of 1934 is required (1) for securities to be listed on a national securities exchange such as the New York Stock Exchange, the NYSE Amex and the NASDAQ Stock Market or (2) if (A) the securities are equity securities and are held by more than 2,000 persons (or 500 persons who are not accredited investors) and (B) the company has more than \$10 million in assets.

⁶ See US GAAP consolidation rules (Section 810).

Reporting Format

Normalization

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

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

Such data may include high-level operating data such as 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).

Any operational data provided should:

- Convey contextual information that would not otherwise be apparent from SASB accounting metric
- Be deemed generally useful for users of SASB accounting metrics (e.g., investors) in performing their own calculations and creating their own ratios.

Units of Measure

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

Uncertainty

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

Estimates

SASB recognizes that scientifically-based estimates, such as the reliance on certain conversion factors or the exclusion of *de minimis* values, may be necessary for certain quantitative disclosures. Where appropriate, SASB does not discourage the use of such estimates. When using an estimate for a particular disclosure, 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 and, therefore, a company must determine for itself the topics—sustainability-related or otherwise—that warrant discussion in a registrant’s SEC filings.

Disclosure under SASB Standards is voluntary. It is not intended to replace any legal or regulatory requirements that may be applicable to user operations. Where such laws or regulations address legal or regulatory topics, disclosure under SASB Standards is not meant to supersede those requirements. Disclosure according to SASB Standards shall not be construed as demonstration of compliance with any law, regulation, or other requirement.

SASB Standards are intended to be aligned with the principles of materiality enforced by the SEC. However, SASB is not affiliated with or endorsed by the SEC or other entities governing financial reporting, such as FASB, GASB, or IASB.

Forward Looking Statements

Disclosures on sustainability topics can 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 such disclosures 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, including, 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.”

Assurance

In reporting on SASB Standards, it is expected that registrants report with the same level of rigor, accuracy, and responsibility as all other information contained in their SEC filings.

SASB recommends registrants use a higher level of assurance (attestation), such as an Examination Engagement to AT Section 701.

The following sections contain the technical protocols associated with each accounting metric such as guidance on definitions, scope, accounting guidance, compilation, and presentation.

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

Table 1. Material Sustainability Topics & Accounting Metrics

TOPIC	CODE	ACCOUNTING METRIC
Quality of Care and Patient Satisfaction	HC0301-01	Hospital Values Based Purchasing Total Performance score, broken down by Clinical Process Domain score, Outcome Domain score, and Patient Experience Domain score.
	HC0301-02	Number of Serious Reportable Events (SREs) as defined by the National Quality Forum.
	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).
	HC0301-04	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.
Access for Low-Income Patients	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.
	HC0301-06	Amount of Medicare Disproportionate Share Hospital (DSH) adjustment payments received.
Employee Recruitment, Development, and Retention	HC0301-07	Employee turnover by voluntary and involuntary for: (1) physicians, (2) non-physician health care practitioners, and (3) all others.
	HC0301-08	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.
Pricing and Billing Transparency	HC0301-09	Description of policies or initiatives to ensure that patients are adequately informed about price before undergoing a procedure.
	HC0301-10	Description 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.
Energy and Waste Efficiency	HC0301-11	Total annual energy consumed (gigajoules) and percentage renewable (e.g., wind, biomass, solar).
	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.).
	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.
Climate Change Impacts on Human Health and Infrastructure	HC0301-14	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 changes in the frequency and intensity of extreme weather events and changes to the morbidity and mortality of illnesses and diseases.

Table 1. Material Sustainability Topics & Accounting Metrics (cont.)

TOPIC	CODE	ACCOUNTING METRIC
Fraud and Unnecessary Procedures	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.
Patient Privacy and Electronic Health Records	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.
	HC0301-17	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.

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

HC0301-01. Hospital Values Based Purchasing Total Performance score, broken down by Clinical Process Domain score, Outcome Domain score, and Patient Experience Domain score.

- .01 The registrant shall disclose the mean Hospital Values Based Purchasing (HVBP) scores for all hospitals it operates, where 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.
- .02 The registrant shall disclose all scores 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.
- .03 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.
- .04 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.
- .05 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.

NOTES

HC0301-01

Additional references:

Centers for Medicare & Medicaid Services, "[National Provider Call: Hospital Values-Based Purchasing](#)" July 11, 2012.

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

- .06 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.”
- .07 The registrant shall disclose the aggregate number of such events that occurred during the fiscal year at the health care facilities it operates.
- .08 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).
- .09 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.
- .10 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.

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).

- .11 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.
- .12 To identify and disclose HAIs, the registrant shall use methodology developed and maintained by the National Healthcare Safety Network (HNSN), the public health surveillance system operated by the Centers for Disease Control and Prevention’s (CDC) Division of Healthcare Quality Promotion (DHQP).
- .13 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 HNSN, insofar as they meet the other requirements of HC0301-3.

NOTES

HC0301-02

Additional references:

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

HC0301-03

Additional references:

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

HC0301-04. 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.

- .14 Readmission shall be defined as an admission to a hospital within 30 days of a discharge from the same or another hospital, where hospital is defined by Section 1886(d)(1)(B) of the Social Security Act.
- .15 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.
- .16 The excess readmission ratio shall be calculated as is defined by the Centers for Medicare & Medicaid Services (CMS), where the excess readmission ratio = risk-adjusted predicted readmissions/risk-adjusted expected readmissions.
- .17 The registrant shall follow all methodology described by CMS, including the use of three years of trailing data to determine excess readmission ratios for the current fiscal year.
- .18 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.
- .19 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.
- .20 The registrant shall consider the CMS’s 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.

Access for Low-Income Patients

Description

Although 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 remain uninsured in 2023. The challenges associated with serving uninsured and low-income patients will be further 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.

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.

- .21 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.
- .22 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.
- .23 The registrant shall describe programs it implements for uninsured individuals including, but not limited to, financial assistance programs or participation in indigent care programs.

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

- .24 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.
- .25 The registrant shall disclose its payment adjustment as an aggregate figure for all eligible hospitals it operates.

NOTES

HC0301-05

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.

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.

- .26 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).
- .27 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
- .28 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.

NOTES

HC0301-07

Additional references:

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

.29 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.

HC0301-08. 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.

.30 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).

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

.32 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 states require that hospitals 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 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.

- .33 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.
- .34 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).
- .35 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.
- .36 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 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.

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

- .40 At minimum, 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).
- .41 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.
- .42 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 information in addition, as separate figures, to the data disclosed for .40 and .41.

Energy and Waste Efficiency

Description

The 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 on energy annually, accounting for 1–3 percent of a hospital's operating budget. Improved energy management and effective waste reduction strategies can lower operating costs and enhance shareholder value.

Accounting Metrics

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

- .43 The registrant shall convert the amount of electricity it purchased from kilowatt hours (kWh) to gigajoules (GJ).
- .44 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).
- .45 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).
- .46 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.).

- .47 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.
- .48 The registrant shall disclose the total weight of the waste generated in kilograms, aggregated for all facilities it owns and operates.
- .49 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.).
- .50 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.

- .51 The registrant shall calculate and disclose the total amount of each type of waste 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.
- .52 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.
- .53 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.
- .54 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.

NOTES

HC0301-13.

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, are likely to present material implications for the health care delivery industry. Companies should subsequently disclose strategies to protect value in light of these challenges.

Accounting Metrics

HC0301-14. 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 changes in the frequency and intensity of extreme weather and changes to the morbidity and mortality of illnesses and diseases.

- .55 The registrant shall discuss its strategic business approach to addressing significant risks presented by the changes in prevalence, geography, and severity of certain diseases that will be caused 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 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).
- .56 The registrant shall discuss its strategic business approach to addressing 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 low-lying and/or hurricane-prone areas.
 - Risks to physical infrastructure based on facility design, such as having key medical equipment in basements or lack of reliable backup power.

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 is likely to 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.

- .57 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).
- .58 The registrant shall disclose the amount of any fine or settlement associated with each incident, not including legal fees.
- .59 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.

- .60 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.
- .61 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.
- .62 The registrant shall indicate which edition of the ONC HIT Certification Criteria its EHR systems are certified to, if not the most currently available.
- .63 Certified EHR systems are those listed on the [Certified Health IT Product List](#) (CHPL).
- .64 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.”

NOTES

HC0301-16

Additional references:

Centers for Medicare and Medicaid Services, “[Introduction to the Medicare EHR Incentive Program for Eligible Professionals](#)”

The New England Journal of Medicine, “[Perspective: The ‘Meaningful Use’ Regulation for Electronic Health Records.](#)” August 5, 2010.

HC0301-17. 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.

- .65 The registrant shall briefly describe the nature and context of fines and settlement 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, 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).
- .66 The registrant shall disclose the amount of any fine or settlement associated with each incident, not including legal fees.
- .67 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.

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SUSTAINABILITY ACCOUNTING STANDARD | HEALTH CARE SECTOR

HEALTH CARE DISTRIBUTORS

Sustainability Accounting Standard

Sustainable Industry Classification System™ (SICS™)# HC0302

Prepared by the
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HEALTH CARE DISTRIBUTORS

Sustainability Accounting Standard

About SASB

The Sustainability Accounting Standards Board (SASB) provides sustainability accounting standards for use by publicly-listed corporations in the U.S. in disclosing material sustainability issues for the benefit of investors and the public. SASB standards are designed for disclosure in mandatory filings to the Securities and Exchange Commission (SEC), such as the Form 10-K and 20-F. SASB is an independent 501(c)3 non-profit organization and is accredited to set standards by the American National Standards Institute (ANSI).

SASB is developing standards for more than 80 industries in 10 sectors. SASB's standards-setting process includes evidence-based analysis with in-depth industry research and engagement with a broad range of stakeholders. The end result of this process is the creation of a complete, industry-specific accounting standard which accurately reflects the material issues for each industry.

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INTRODUCTION

Purpose and Structure

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

SASB Standards are comprised of **(1) disclosure guidance and (2) accounting standards on sustainability topics** for use by U.S. and foreign public companies in their annual filings (Form 10-K or 20-F) with the U.S. Securities and Exchange Commission (SEC). To the extent relevant, SASB Standards may also be applicable to other periodic mandatory filings with the SEC, such as the Form 10-Q, Form S-1, and Form 8-K.

SASB's **disclosure guidance** identifies sustainability topics at an industry level and—depending on the specific operating context of a company—may be material to a company within that industry. Each company is ultimately responsible for determining which information is material, and which such company is therefore required to include in its Form 10-K or 20-F and other periodic SEC filings.

SASB's **accounting standards** provide companies with standardized accounting metrics to account for performance on industry-level sustainability topics. When making disclosure on sustainability topics, companies adopting SASB's accounting standards will help to ensure that disclosure is standardized and therefore useful, relevant, comparable and auditable.

Guidance for Disclosure of Material Sustainability Topics in SEC filings

1. Industry-Level Material Sustainability Topics

For the Health Care Distributors Industry, SASB has identified the following material sustainability topics:

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

NOTE: A description of each topic is provided alongside standard accounting metrics in the rest of this document.

2. Company-Level Determination and Disclosure of Material Sustainability Topics

Sustainability disclosures are governed by the same laws and regulations that govern disclosures by securities issuers generally. 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”.¹

SASB has attempted to identify those sustainability topics (above) that it believes may be material for all companies within the Health Care Distributors Industry. SASB recognizes, however, that each company is ultimately responsible for determining what is material to it.

Regulation S-K, which sets forth certain disclosure requirements associated with Form 10-K and other SEC filings, requires companies, among other things, to 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.”²

Furthermore, 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.”

In determining whether a trend or uncertainty should be disclosed, the SEC has stated that management should use a two-part assessment based on probability and magnitude:

- 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.
- **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.**

3. Sustainability Accounting Standard Disclosures in Form 10-K

a. Management’s Discussion and Analysis

Companies should consider making disclosure on sustainability topics as a complete set in the MD&A, in a sub-section titled **“Sustainability Accounting Standards Disclosures.”**³

¹ TSC Industries v. Northway, Inc., 426 U.S. 438 (1976).

² 17 C.F.R. 229.303(Item 3030)(a)(3)(ii).

³ 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.”

b. Other Relevant Sections of Form 10-K

In addition to the MD&A section, companies should consider disclosing sustainability information in other sections of Form 10-K, as relevant, including:

- **Description of business**—Item 101 of Regulation S-K requires a company to provide a description of its business and its subsidiaries. Specifically Item 101(c)(1)(xii) expressly requires disclosure regarding certain costs of complying with environmental laws:

Appropriate disclosure also shall be made as to the material effects that compliance with Federal, State and local provisions which have been enacted or adopted regulating the discharge of materials into the environment, or otherwise relating to the protection of the environment, may have upon the capital expenditures, earnings and competitive position of the registrant and its subsidiaries.

- **Legal proceedings**—Item 103 of Regulation S-K requires companies 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 targeting discharge of materials into the environment or primarily for the purpose of protecting the environment.
- **Risk factors**—Item 503(c) of Regulation S-K requires filing companies to provide a discussion of the most significant factors that make an investment in the registrant speculative or risky, clearly stating the risk and specifying how a particular risk affects the particular filing company.
- **Rule 12b-20**—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.”

More detailed guidance on disclosure of material sustainability topics can be found in the **SASB Conceptual Framework**, available for download via <http://www.sasb.org/approach/conceptual-framework/>

Guidance on Accounting of Material Sustainability Topics

For material sustainability topics in the Health Care Distributors Industry, SASB identified the accounting metrics below in **Table 1. Material Sustainability Topics & Accounting Metrics**.

SASB recommends that each company consider using these sustainability accounting metrics when disclosing their performance with respect to each of the sustainability topics it has identified as material.

As appropriate—and consistent with Rule 12b-20⁴—for each sustainability topic, companies should consider including a narrative description of any material factors necessary to ensure completeness, accuracy and

⁴ SEC Rule 12b-20: “In addition to the information expressly required to be included in a statement or report, there shall be added such further material information, if any, as may be necessary to make the required statements, in the light of the circumstances under which they are made not misleading.”

comparability of the data reported. Where not addressed by the specific accounting metrics, but relevant, the registrant should discuss the following related to the topic:

- the registrant's **strategic approach** to managing performance on material sustainability issues;
- the registrant's **competitive positioning**;
- the **degree of control** the registrant has;
- any **measures the registrant has undertaken** or **plans to undertake** to improve performance; and
- data for registrant's **last three completed fiscal years** (when available).

SASB recommends that registrants use SASB Standards specific to their primary industry as identified in the [Sustainability Industry Classification System \(SICS™\)](#). If a registrant generates significant revenue from multiple industries, SASB recommends that it consider the materiality of the sustainability issues that SASB has identified for those industries and disclose the associated SASB accounting metrics.

Users of the SASB Standards

The SASB Standards are intended for companies that engage in public offerings of securities registered under the Securities Act of 1933 (the Securities Act) and those that issue securities registered under the Securities Exchange Act of 1934 (the Exchange Act)⁵, for use in SEC filings, including, without limitation, annual reports on Form 10-K (Form 20-F for foreign issuers), quarterly reports on Form 10-Q, current reports on Form 8-K, and registration statements on Forms S-1 and S-3. Nevertheless, disclosure with respect to the SASB Standards is not required or endorsed by the SEC or other entities governing financial reporting, such as FASB, GASB, or IASB.

Scope of Disclosure

Unless otherwise specified, SASB recommends:

- That a registrant disclose on sustainability issues and metrics for itself and for entities in which the registrant has a controlling interest and therefore are consolidated for financial reporting purposes (controlling interest is generally defined as ownership of 50% or more of voting shares);⁶
- 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.

⁵ Registration under the Securities Exchange Act of 1934 is required (1) for securities to be listed on a national securities exchange such as the New York Stock Exchange, the NYSE Amex and the NASDAQ Stock Market or (2) if (A) the securities are equity securities and are held by more than 2,000 persons (or 500 persons who are not accredited investors) and (B) the company has more than \$10 million in assets.

⁶ See US GAAP consolidation rules (Section 810).

A registrant should disclose, however, information about unconsolidated entities to the extent that such registrant considers the information necessary for investors to understand its performance with respect to sustainability issues (typically this disclosure would be limited to risks and opportunities associated with these entities).

Reporting Format

Normalization

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

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

Such data may include high-level operating data such as 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).

Any operational data provided should:

- Convey contextual information that would not otherwise be apparent from SASB accounting metric
- Be deemed generally useful for users of SASB accounting metrics (e.g., investors) in performing their own calculations and creating their own ratios.

Units of Measure

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

Uncertainty

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

Estimates

SASB recognizes that scientifically-based estimates, such as the reliance on certain conversion factors or the exclusion of *de minimis* values, may be necessary for certain quantitative disclosures. Where appropriate, SASB does not discourage the use of such estimates. When using an estimate for a particular disclosure, 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 and, therefore, a company must determine for itself the topics—sustainability-related or otherwise—that warrant discussion in a registrant's SEC filings.

Disclosure under SASB Standards is voluntary. It is not intended to replace any legal or regulatory requirements that may be applicable to user operations. Where such laws or regulations address legal or regulatory topics, disclosure under SASB Standards is not meant to supersede those requirements. Disclosure according to SASB Standards shall not be construed as demonstration of compliance with any law, regulation, or other requirement.

SASB Standards are intended to be aligned with the principles of materiality enforced by the SEC. However, SASB is not affiliated with or endorsed by the SEC or other entities governing financial reporting, such as FASB, GASB, or IASB.

Forward Looking Statements

Disclosures on sustainability topics can 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 such disclosures 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, including, 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."

Assurance

In reporting on SASB Standards, it is expected that registrants report with the same level of rigor, accuracy, and responsibility as all other information contained in their SEC filings.

SASB recommends registrants use a higher level of assurance (attestation), such as an Examination Engagement to AT Section 701.

Table 1. Material Sustainability Topics & Accounting Metrics

TOPIC	CODE	ACCOUNTING METRIC
Product Safety	HC0302-01	Description 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.
	HC0302-02	Description 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.).
Counterfeit Drugs	HC0302-03	Description of methods and technologies used to maintain traceability of products throughout the distribution chain and prevent counterfeiting.
	HC0302-04	Description of due diligence process to qualify suppliers of drug products and medical equipment and devices.
	HC0302-05	Description of process for alerting customers and business partners of potential or known risks associated with counterfeit products.
Fuel Efficiency	HC0302-06	Payload fuel economy = gallons per ton-miles.
	HC0302-07	Description of involvement in efforts to reduce the environmental impact of logistics, including involvement in the EPA SmartWay program.
Product Lifecycle Management	HC0302-08	Description 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.).
	HC0302-09	Describe 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.
Corruption and Bribery	HC0302-10	Description of efforts to minimize conflicts of interest and unethical business practices, including mechanisms to ensure compliance.
	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.

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 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 relate 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 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 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 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 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 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 are likely to 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 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

NOTES

HC0302-07

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 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 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.

NOTES

Additional references:

Guidelines for Sustainable Packaging, Version 1.0 – December 2006, Sustainable Packaging Coalition/Green Blue Institute

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 material implications.

Accounting Metrics

HC0302-10. Description 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.

- .32 The registrant shall briefly describe the nature and context of fines and settlements related to corruption, bribery, or other unethical business practices, 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).
- .33 Disclosure shall include violations of the False Claims Act (such as those related to pricing) and Foreign Corrupt Practices Act related to its anti-bribery or accounting provisions and enforced by the Department of Justice or Securities and Exchange Commission.
- .34 The registrant shall disclose the amount of any fine or settlement associated with each incident, not including legal fees.
- .35 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.

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SUSTAINABILITY ACCOUNTING STANDARD | HEALTH CARE SECTOR

MANAGED CARE

Sustainability Accounting Standard

Sustainable Industry Classification System™ (SICS™)# HC0303

Prepared by the
Sustainability Accounting Standards Board®

August 2013
Version 1.0

MANAGED CARE

Sustainability Accounting Standard

About SASB

The Sustainability Accounting Standards Board (SASB) provides sustainability accounting standards for use by publicly-listed corporations in the U.S. in disclosing material sustainability issues for the benefit of investors and the public. SASB standards are designed for disclosure in mandatory filings to the Securities and Exchange Commission (SEC), such as the Form 10-K and 20-F. SASB is an independent 501(c)3 non-profit organization and is accredited to set standards by the American National Standards Institute (ANSI).

SASB is developing standards for more than 80 industries in 10 sectors. SASB's standards-setting process includes evidence-based analysis with in-depth industry research and engagement with a broad range of stakeholders. The end result of this process is the creation of a complete, industry-specific accounting standard which accurately reflects the material issues for each industry.

SUSTAINABILITY ACCOUNTING STANDARDS BOARD

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INTRODUCTION

Purpose and Structure

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Guidance for Disclosure of Material Sustainability Topics in SEC filings

1. Industry-Level Material Sustainability Topics

For the Managed Care Industry, SASB has identified the following material sustainability topics:

- **Access to Coverage**
- **Improved Outcomes**
- **Plan Performance**
- **Pricing Transparency and Plan Literacy**
- **Customer Privacy and Technology Standards**
- **Climate Change Impacts on Human Health**

NOTE: A description of each topic is provided alongside standard accounting metrics in the rest of this document.

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3. Sustainability Accounting Standard Disclosures in Form 10-K

a. Management’s Discussion and Analysis

Companies should consider making disclosure on sustainability topics as a complete set in the MD&A, in a sub-section titled **“Sustainability Accounting Standards Disclosures.”**³

b. Other Relevant Sections of Form 10-K

¹ TSC Industries v. Northway, Inc., 426 U.S. 438 (1976).

² 17 C.F.R. 229.303(Item 3030)(a)(3)(ii).

³ 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.”

In addition to the MD&A section, companies should consider disclosing sustainability information in other sections of Form 10-K, as relevant, including:

- **Description of business**—Item 101 of Regulation S-K requires a company to provide a description of its business and its subsidiaries. Specifically Item 101(c)(1)(xii) expressly requires disclosure regarding certain costs of complying with environmental laws:

Appropriate disclosure also shall be made as to the material effects that compliance with Federal, State and local provisions which have been enacted or adopted regulating the discharge of materials into the environment, or otherwise relating to the protection of the environment, may have upon the capital expenditures, earnings and competitive position of the registrant and its subsidiaries.

- **Legal proceedings**—Item 103 of Regulation S-K requires companies 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 targeting discharge of materials into the environment or primarily for the purpose of protecting the environment.
- **Risk factors**—Item 503(c) of Regulation S-K requires filing companies to provide a discussion of the most significant factors that make an investment in the registrant speculative or risky, clearly stating the risk and specifying how a particular risk affects the particular filing company.
- **Rule 12b-20**—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.”

More detailed guidance on disclosure of material sustainability topics can be found in the **SASB Conceptual Framework**, available for download via <http://www.sasb.org/approach/conceptual-framework/>

Guidance on Accounting of Material Sustainability Topics

For material sustainability topics in the Managed Care Industry, SASB identified the accounting metrics below in **Table 1. Material Sustainability Topics & Accounting Metrics.**

SASB recommends that each company consider using these sustainability accounting metrics when disclosing their performance with respect to each of the sustainability topics it has identified as material.

As appropriate—and consistent with Rule 12b-20⁴—for each sustainability topic, companies should consider including a narrative description of any material factors necessary to ensure completeness, accuracy and comparability of the data reported. Where not addressed by the specific accounting metrics, but relevant, the registrant should discuss the following related to the topic:

⁴ SEC Rule 12b-20: “In addition to the information expressly required to be included in a statement or report, there shall be added such further material information, if any, as may be necessary to make the required statements, in the light of the circumstances under which they are made not misleading.”

- the registrant's **strategic approach** to managing performance on material sustainability issues;
- the registrant's **competitive positioning**;
- the **degree of control** the registrant has;
- any **measures the registrant has undertaken** or **plans to undertake** to improve performance; and
- data for registrant's **last three completed fiscal years** (when available).

SASB recommends that registrants use SASB Standards specific to their primary industry as identified in the [Sustainability Industry Classification System \(SICS™\)](#). If a registrant generates significant revenue from multiple industries, SASB recommends that it consider the materiality of the sustainability issues that SASB has identified for those industries and disclose the associated SASB accounting metrics.

Users of the SASB Standards

The SASB Standards are intended for companies that engage in public offerings of securities registered under the Securities Act of 1933 (the Securities Act) and those that issue securities registered under the Securities Exchange Act of 1934 (the Exchange Act)⁵, for use in SEC filings, including, without limitation, annual reports on Form 10-K (Form 20-F for foreign issuers), quarterly reports on Form 10-Q, current reports on Form 8-K, and registration statements on Forms S-1 and S-3. Nevertheless, disclosure with respect to the SASB Standards is not required or endorsed by the SEC or other entities governing financial reporting, such as FASB, GASB, or IASB.

Scope of Disclosure

Unless otherwise specified, SASB recommends:

- That a registrant disclose on sustainability issues and metrics for itself and for entities in which the registrant has a controlling interest and therefore are consolidated for financial reporting purposes (controlling interest is generally defined as ownership of 50% or more of voting shares);⁶
- 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. A registrant should disclose, however, information about unconsolidated entities to the extent that such registrant considers the information necessary for investors to understand its performance with respect to sustainability issues (typically this disclosure would be limited to risks and opportunities associated with these entities).

⁵ Registration under the Securities Exchange Act of 1934 is required (1) for securities to be listed on a national securities exchange such as the New York Stock Exchange, the NYSE Amex and the NASDAQ Stock Market or (2) if (A) the securities are equity securities and are held by more than 2,000 persons (or 500 persons who are not accredited investors) and (B) the company has more than \$10 million in assets.

⁶ See US GAAP consolidation rules (Section 810).

Reporting Format

Normalization

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

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

Such data may include high-level operating data such as 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).

Any operational data provided should:

- Convey contextual information that would not otherwise be apparent from SASB accounting metric
- Be deemed generally useful for users of SASB accounting metrics (e.g., investors) in performing their own calculations and creating their own ratios.

Units of Measure

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

Uncertainty

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

Estimates

SASB recognizes that scientifically-based estimates, such as the reliance on certain conversion factors or the exclusion of *de minimis* values, may be necessary for certain quantitative disclosures. Where appropriate, SASB does not discourage the use of such estimates. When using an estimate for a particular disclosure, 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 to address all sustainability impacts or opportunities associated with a sector, industry, or company and, therefore, a company must determine for itself the topics—sustainability-related or otherwise—that warrant discussion in a registrant’s SEC filings.

Disclosure under SASB Standards is voluntary. It is not intended to replace any legal or regulatory requirements that may be applicable to user operations. Where such laws or regulations address legal or regulatory topics, disclosure under SASB Standards is not meant to supersede those requirements. Disclosure according to SASB Standards shall not be construed as demonstration of compliance with any law, regulation, or other requirement.

SASB Standards are intended to be aligned with the principles of materiality enforced by the SEC. However, SASB is not affiliated with or endorsed by the SEC or other entities governing financial reporting, such as FASB, GASB, or IASB.

Forward Looking Statements

Disclosures on sustainability topics can 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 such disclosures 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, including, 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.”

Assurance

In reporting on SASB Standards, it is expected that registrants report with the same level of rigor, accuracy, and responsibility as all other information contained in their SEC filings.

SASB recommends registrants use a higher level of assurance (attestation), such as an Examination Engagement to AT Section 701.

The following sections contain the technical protocols associated with each accounting metric such as guidance on definitions, scope, accounting guidance, compilation, and presentation.

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

Table 1. Material Sustainability Topics & Accounting Metrics

TOPIC	CODE	ACCOUNTING METRIC
Access to Coverage	HC0303-01	Medical Loss Ratio (MLR) = medical costs as percentage of premium revenue.
	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.
	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).
Improved Outcomes	HC0303-04	Percentage of enrollees in wellness programs by type: 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).
	HC0303-06	Number of customers receiving care from Accountable Care Organizations or enrolled in Patient-Centered Medical Home programs.
Plan Performance	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.
	HC0303-08	Enrollee retention rate by plan type, including HMO, local PPO, regional PPO, PFFS, and SNP.
	HC0303-09	Percentage of claims denied that were appealed by customers and ultimately reversed.
	HC0303-10	Grievance rate per 10,000 enrollees.
Pricing Transparency and Plan Literacy	HC0303-11	JD Power & Associates members’ rating on “Information and Communication.”
	HC0303-12	Description of policies and practices related to clarity in pricing and coverage, including health care literacy programs.
Customer Privacy and Technology Standards	HC0303-13	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.
	HC0303-14	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 HIPPA-mandated breach notifications.
Climate Change Impacts on Human Health	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 risks presented by changes in the geographic incidence, morbidity, and mortality of illnesses and diseases.

Access to Coverage

Description

Although 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 remain uninsured in 2023. The PPACA will require that managed care companies 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.

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 to 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.

NOTES

HC0303-01

Additional references:

[“Regulation for Uniform Definitions and Standardized Methodologies for Calculation of the Medical Loss Ratio for Plan Years 2011, 2012, and 2013](#) Per Section 2718 (b) of the Public Health Services Act and the Patient Protection and Affordable Care Act.”

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).

- .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.

NOTES

HC0303-03

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 the health of enrollees. The Patient Protection and Affordable Care Act (PPACA) places increased emphasis on health outcomes through provisions that require health plans to provide coverage for preventive services without cost to members. Further, the Act established the Five Star Quality Rating System for Medicare Advantage Plans. This rating system ties federal reimbursement rates for Medicare Advantage carriers and bonus payments to performance in five domain areas, including specific outcome-based measures. Subsequently, managed care companies that are able to improve the health of enrollees will 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).

- .18 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.
- .19 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.
- .20 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.
- .21 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).
- .22 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).

HC0303-06. Number of customers receiving care from Accountable Care Organizations or enrolled in Patient-Centered Medical Home programs.

- .23 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.
- .24 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).

NOTES

HC0303-05. 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.

Additional references: 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. 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.

- .25 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).
- .26 The registrant shall include in the calculation all plans of each type receiving a Medicare Advantage plan rating. The mean rating shall be disclosed rounded to the nearest tenth (one place after the decimal point).
- .27 Plan ratings are publicly available on Medicare’s “Medicare Plan Finder” [website](#).
- .28 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.

HC0303-08. Enrollee retention rate by plan type, including HMO, local PPO, regional PPO, PFFS, and SNP.

- .29 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.
- .30 The registrant shall disclose retention rates by plan type, which may include HMO, local PPO, regional PPO, PFFS, and SNP.

NOTES

HC0303-07

Definitions: HMO – health maintenance organization; PPO – preferred provider organization; PFFS – private fee for service; SNP – special needs plan.

HC0303-08.

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.

- .31 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.
- .32 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.
- .33 The registrant shall not consider ongoing claims appeals – only those that were resolved during the fiscal year.
- .34 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.
- .35 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).
- .36 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.
- .37 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.
- .38 Multiple appeals to the same claim shall not be counted separately for calculations.

HC0303-10. Grievance rate per 10,000 enrollees.

- .39 The registrant shall calculate the grievance rate as: the number of grievances reported during the fiscal year / (monthly average enrollees / 10,000)
- .40 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.
- .41 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.

NOTES

HC0303-09

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.

Additional references:

US Government Accountability Office report, "[Private Health Insurance – Data on Application and Coverage Denials.](#)"

HC0303-10

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 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.

Accounting Metrics

HC0303-11. JD Power & Associates members' rating on "Information and Communication."

- .42 The registrant shall disclose the Member Health Plan Rating for the fiscal year as a mean rating of plans across all regions (currently 17)
- .43 The Information and Communication Rating shall be disclosed rounded to the nearest tenth (one place after the decimal point).
- .44 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.

- .45 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.
- .46 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.
- .47 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 Act, can lead to significant civil and criminal penalties.

Accounting Metrics

HC0303-13. 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.

- .48 The registrant shall briefly describe the nature and context of proceedings related to HIPAA Act or HITECH Act violations. Proceedings 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).
- .49 The registrant shall disclose the amount of any fine or settlement associated with each incident, not including legal fees.
- .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.

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.

- .51 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.
- .52 Customer data includes, but is not limited to, electronic protected health information (ePHI) and personally identifiable information (PII).

- .53 The registrant should not include in its disclosure any information that compromises the security of its systems, its enrollees' ePHI, or PII.
- .54 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, [Section 164.406 Notification to Media](#)).

NOTES

HC0303-14

Definitions:

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.” (U.S. 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, are likely to 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.

- .55 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.
- .56 The registrant shall discuss any projected impacts on revenue, costs, or plan affordability.
- .57 The registrant should discuss it how it incorporates the effects of climate change into its risk assessment and risk adjustment activities.

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