



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®

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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-20¹—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:

¹ 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
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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