



HEALTH CARE SECTOR

MEDICAL EQUIPMENT & SUPPLIES

Sustainability Accounting Standard

Sustainable Industry Classification System® (SICS®) HC-MS

Prepared by the
Sustainability Accounting Standards Board

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MEDICAL EQUIPMENT & SUPPLIES

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About SASB

The SASB Foundation was founded in 2011 as a not-for-profit, independent standards-setting organization. The SASB Foundation's mission is to establish and maintain industry-specific standards that assist companies in disclosing financially material, decision-useful sustainability information to investors.

The SASB Foundation operates in a governance structure similar to the structure adopted by other internationally recognized bodies that set standards for disclosure to investors, including the Financial Accounting Standards Board (FASB) and the International Accounting Standards Board (IASB). This structure includes a board of directors ("the Foundation Board") and a standards-setting board ("the Standards Board" or "the SASB"). The Standards Board develops, issues, and maintains the SASB standards. The Foundation Board oversees the strategy, finances and operations of the entire organization, and appoints the members of the Standards Board.

The Foundation Board is not involved in setting standards, but is responsible for overseeing the Standards Board's compliance with the organization's due process requirements. As set out in the *SASB Rules of Procedure*, the SASB's standards-setting activities are transparent and follow careful due process, including extensive consultation with companies, investors, and relevant experts.

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INTRODUCTION

Purpose of SASB Standards

The SASB’s use of the term “sustainability” refers to corporate activities that maintain or enhance the ability of the company to create value over the long term. Sustainability accounting reflects the governance and management of a company’s environmental and social impacts arising from production of goods and services, as well as its governance and management of the environmental and social capitals necessary to create long-term value. The SASB also refers to sustainability as “ESG” (environmental, social, and governance), though traditional corporate governance issues such as board composition are not included within the scope of the SASB’s standards-setting activities.

SASB standards are designed to identify a minimum set of sustainability issues most likely to impact the operating performance or financial condition of the typical company in an industry, regardless of location. SASB standards are designed to enable communications on corporate performance on industry-level sustainability issues in a cost-effective and decision-useful manner using existing disclosure and reporting mechanisms.

Businesses can use the SASB standards to better identify, manage, and communicate to investors sustainability information that is financially material. Use of the standards can benefit businesses by improving transparency, risk management, and performance. SASB standards can help investors by encouraging reporting that is comparable, consistent, and financially material, thereby enabling investors to make better investment and voting decisions.

Overview of SASB Standards

The SASB has developed a set of 77 industry-specific sustainability accounting standards (“SASB standards” or “industry standards”), categorized pursuant to SASB’s [Sustainable Industry Classification System® \(SICS®\)](#). Each SASB standard describes the industry that is the subject of the standard, including any assumptions about the predominant business model and industry segments that are included. SASB standards include:

1. **Disclosure topics** – A minimum set of industry-specific disclosure topics reasonably likely to constitute material information, and a brief description of how management or mismanagement of each topic may affect value creation.
2. **Accounting metrics** – A set of quantitative and/or qualitative accounting metrics intended to measure performance on each topic.
3. **Technical protocols** – Each accounting metric is accompanied by a technical protocol that provides guidance on definitions, scope, implementation, compilation, and presentation, all of which are intended to constitute suitable criteria for third-party assurance.
4. **Activity metrics** – A set of metrics that quantify the scale of a company’s business and are intended for use in conjunction with accounting metrics to normalize data and facilitate comparison.

Furthermore, the *SASB Standards Application Guidance* establishes guidance applicable to the use of all industry standards and is considered part of the standards. Unless otherwise specified in the technical protocols contained in the industry standards, the guidance in the SASB Standards Application Guidance applies to the definitions, scope, implementation, compilation, and presentation of the metrics in the industry standards.

The *SASB Conceptual Framework* sets out the basic concepts, principles, definitions, and objectives that guide the Standards Board in its approach to setting standards for sustainability accounting. The *SASB Rules of Procedure* is focused on the governance processes and practices for standards setting.

Use of the Standards

SASB standards are intended for use in communications to investors regarding sustainability issues that are likely to impact corporate ability to create value over the long term. Use of SASB standards is voluntary. A company determines which standard(s) is relevant to the company, which disclosure topics are financially material to its business, and which associated metrics to report, taking relevant legal requirements into account¹. In general, a company would use the SASB standard specific to its primary industry as identified in *SICS*[®]. However, companies with substantial business in multiple *SICS*[®] industries can consider reporting on these additional SASB industry standards.

It is up to a company to determine the means by which it reports SASB information to investors. One benefit of using SASB standards may be achieving regulatory compliance in some markets. Other investor communications using SASB information could be sustainability reports, integrated reports, websites, or annual reports to shareholders. There is no guarantee that SASB standards address all financially material sustainability risks or opportunities unique to a company's business model.

Industry Description

The Medical Equipment & Supplies industry researches, develops, and produces medical, surgical, dental, ophthalmic, and veterinary instruments and devices. Products are used in settings, including hospitals, clinics, and laboratories, and range from disposable items to highly specialized equipment. The increased prevalence of diseases associated with unhealthy lifestyles and an aging population are important factors that may impact growth in this industry. Emerging markets and the expansion of health insurance in the U.S. will contribute to further growth. However, the extension of government insurance programs, provider and payer consolidation, and regulatory emphasis on reduced costs in all markets may result in downward pricing pressure.

¹ **Legal Note:** SASB standards are not intended to, and indeed cannot, replace any legal or regulatory requirements that may be applicable to a reporting entity's operations.

SUSTAINABILITY DISCLOSURE TOPICS & ACCOUNTING METRICS

Table 1. Sustainability Disclosure Topics & Accounting Metrics

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
Affordability & Pricing	Ratio of weighted average rate of net price increases (for all products) to the annual increase in the U.S. Consumer Price Index	Quantitative	Ratio	HC-MS-240a.1
	Description of how price information for each product is disclosed to customers or to their agents	Discussion and Analysis	n/a	HC-MS-240a.2
Product Safety	Number of recalls issued, total units recalled	Quantitative	Number	HC-MS-250a.1
	List of products listed in the FDA's MedWatch Safety Alerts for Human Medical Products database	Discussion and Analysis	n/a	HC-MS-250a.2
	Number of fatalities related to products as reported in the FDA Manufacturer and User Facility Device Experience	Quantitative	Number	HC-MS-250a.3
	Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practices (cGMP), by type ²	Quantitative	Number	HC-MS-250a.4
Ethical Marketing	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims ³	Quantitative	Reporting currency	HC-MS-270a.1
	Description of code of ethics governing promotion of off-label use of products	Discussion and Analysis	n/a	HC-MS-270a.2
Product Design & Lifecycle Management	Discussion of process to assess and manage environmental and human health considerations associated with chemicals in products, and meet demand for sustainable products	Discussion and Analysis	n/a	HC-MS-410a.1
	Total amount of products accepted for take-back and reused, recycled, or donated, broken down by: (1) devices and equipment and (2) supplies	Quantitative	Metric tons (t)	HC-MS-410a.2
Supply Chain Management	Percentage of (1) entity's facilities and (2) Tier I suppliers' facilities participating in third-party audit programs for manufacturing and product quality	Quantitative	Percentage (%)	HC-MS-430a.1
	Description of efforts to maintain traceability within the distribution chain	Discussion and Analysis	n/a	HC-MS-430a.2

² Note to **HC-MS-250a.4** – The entity shall briefly describe the nature, context, and any corrective actions taken as a result of the enforcement actions.

³ Note to **HC-MS-270a.1** – The entity shall briefly describe the nature, context, and any corrective actions taken as a result of the monetary losses.

TOPIC	ACCOUNTING METRIC	CATEGORY	UNIT OF MEASURE	CODE
	Description of the management of risks associated with the use of critical materials	Discussion and Analysis	n/a	HC-MS-430a.3
Business Ethics	Total amount of monetary losses as a result of legal proceedings associated with bribery or corruption ⁴	Quantitative	Reporting currency	HC-MS-510a.1
	Description of code of ethics governing interactions with health care professionals	Discussion and Analysis	n/a	HC-MS-510a.2

Table 2. Activity Metrics

ACTIVITY METRIC	CATEGORY	UNIT OF MEASURE	CODE
Number of units sold by product category	Quantitative	Number	HC-MS-000.A

⁴ Note to **HC-MS-510a.1** – The entity shall briefly describe the nature, context, and any corrective actions taken as a result of the monetary losses.

Affordability & Pricing

Topic Summary

Legislative emphasis on health care cost containment and increased access is likely to continue to place downward pricing pressures on the Medical Equipment & Supplies industry. This pressure may be further articulated by consolidation among health care providers and the role of government-sponsored insurance programs. In the U.S., for example, 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 fair pricing are likely to limit the negative impact of cost containment while recognizing the potential revenue opportunities associated with expanded access.

Accounting Metrics

HC-MS-240a.1. Ratio of weighted average rate of net price increases (for all products) to the annual increase in the U.S. Consumer Price Index

- 1 The entity shall disclose the ratio of weighted average rate of net price increases (for all products) to the annual increase in the U.S. Consumer Price Index.
- 2 The average net price increases should be weighted based on sales volume of all of the entity's medical device products sold in the U.S. during the reporting period.
 - 2.1 The annual average net price increase shall be calculated as percent change versus the prior reporting period and for each product weighted by list price across the entity's U.S. portfolio of medical device products.
 - 2.2 The net price shall represent the average wholesale acquisition cost (WAC) minus rebates, discounts, and returns and shall represent the average WAC minus rebates, discounts, and returns for the reporting period in which it is being calculated.
- 3 The entity should use the annual change (December to December increase) in the [Consumer Price Index](#) for All Urban Consumer (CPI-U) for the reporting period.

HC-MS-240a.2. Description of how price information for each product is disclosed to customers or to their agents

- 1 The entity 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 (e.g., the range, median, or typical price) are provided to customers.
 - 1.1 Customers shall include those purchasing directly from the entity or through intermediaries, such as group purchasing organizations (GPOs) or consultants negotiating on behalf of the customer.

- 2 The entity 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 entity's products.
- 3 The entity may explain the factors that affect price, including, but not limited to:
 - 3.1 Product volume
 - 3.2 Geographic market of customer
 - 3.3 Type of facility the customer is operating

Product Safety

Topic Summary

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. Issues related to product safety, such as equipment failures, manufacturing defects, design flaws, or inadequate disclosure of product-related risks, can lead to significant product liability claims. Firms that limit the incidence of recalls, safety concerns, and enforcement actions for manufacturing concerns may be better positioned to protect shareholder value.

Accounting Metrics

HC-MS-250a.1. Number of recalls issued, total units recalled

- 1 The entity shall disclose the total number of recalls for medical device products that it manufactures.
 - 1.1 Recalls are defined as actions taken by a firm to remove a product from the market, including those conducted on the entity's own initiative, by FDA request, or by FDA order under statutory authority.
 - 1.2 Medical devices are defined by the U.S. Federal Food, Drug, and Cosmetics (FD&C) Act sec. 201(h) as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is recognized in the official National Formulary, or the U.S. Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals, and which is not dependent upon being metabolized for the achievement of its primary intended purposes.
 - 1.3 The scope of disclosure shall include recalls associated with all devices manufactured by the entity or by its subsidiaries.
- 2 The entity shall identify all products manufactured by it or its subsidiaries for which it is listed as the Recalling Firm in the "Devices" product type in the weekly [Enforcement Reports](#) published by the U.S. Food and Drug Administration (FDA), which contain all recalls by Product Type, Product Description, Code Info, Classification, Reason for Recall, and Recalling Firm.
- 3 The entity shall disclose recalls in non-U.S. markets that have been initiated voluntarily, at the request of a non-U.S. national regulatory authority, or by order of a non-U.S. national regulatory authority under statutory authority.
- 4 The entity shall disclose recalls initiated voluntarily that have not been reported to the FDA (or to a national regulatory authority) and/or are not listed in an FDA Enforcement Report.

- 5 The entity shall disclose the total number of device units that were subject to a recall.
- 6 The entity shall disclose, in addition to the total number of drug recalls, the percentage of recalls that were:
 - 6.1 Voluntary
 - 6.2 FDA requested
 - 6.3 FDA mandated
- 7 For FDA-initiated recalls, the entity may disclose the FDA classification of each recall, including:
 - 7.1 Class I
 - 7.2 Class II
 - 7.3 Class III
- 8 For each recalled product, the entity may disclose revenues from 12 months prior to the date of recall. This 12-month period may extend beyond the reporting period for which the entity 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.
- 9 If a recall relates to only a subset of a product (e.g., specific lots or a particular style), then the entity should indicate the scope of the recall; and, if the entity is disclosing revenue associated with the recall, it should be limited to the portion of the product affected by the recall.
- 10 The entity shall discuss notable recalls, such as those that affected a significant number of units of one product or those related to serious injury or fatality. For such recalls the entity may provide:
 - 10.1 Description and cause of the recall issue
 - 10.2 The total number of units recalled
 - 10.3 The cost to remedy the issue
 - 10.4 Whether the recall was initiated voluntarily or at the request of the FDA or non-U.S. national regulatory authority
 - 10.5 Corrective actions
 - 10.6 Any other significant outcomes (e.g., legal proceedings or customer fatalities)

HC-MS-250a.2. List of products listed in the FDA’s MedWatch Safety Alerts for Human Medical Products database

- 1 The entity shall disclose all listings associated with the entity that appear in the “Medical Devices” category of the U.S. Food and Drug Administration (FDA)’s [MedWatch Safety Alerts for Human Medical Products database](#).
 - 1.1 The scope of disclosure includes all listings associated with the entity or its subsidiaries, including trade names for which the entity has patents or classes of products that it manufactures and markets.
- 2 If the entity manufactures a product in a product class listed in the database but has evidence that the listing does not apply to its specific products, it may provide such evidence.

HC-MS-250a.3. Number of fatalities related to products as reported in the FDA Manufacturer and User Facility Device Experience database

- 1 The entity shall disclose the number of fatalities associated with device products it manufactures.
 - 1.1 The scope of the disclosure shall include all fatalities that occurred during the reporting period for which it is disclosing, even if the adverse event began in a prior period.
- 2 The entity may access a list of fatalities through the [FDA Manufacturer and User Facility Device Experience \(MAUDE\)](#) database.

HC-MS-250a.4. Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practices (cGMP), by type

- 1 The entity shall disclose the number and type of U.S. Food and Drug Administration (FDA) enforcement actions taken during the reporting period in response to current Good Manufacturing Practice (or regional equivalent) violations at its facilities, including, but not limited to:
 - 1.1 Form 483s
 - 1.2 Warning letters
 - 1.3 Seizures
 - 1.4 Recalls
 - 1.5 Consent decrees
- 2 The scope of disclosure includes facilities that are owned or operated by the entity.

Note to **HC-MS-250a.4**

- 1 The entity shall describe the nature and context of the enforcement actions.
- 2 The entity 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.

Ethical Marketing

Topic Summary

Medical equipment and supplies companies face challenges associated with marketing of specific products. Direct-to-consumer advertisements for medical devices and outreach to physicians provide opportunities for increasing market share. However, challenges arise from the potential for marketing off-label uses, which can result in significant fines and settlements. Corporate disclosure of legal and regulatory fines and the codes of ethics that govern marketing activities will allow shareholders to better understand performance in this area.

Accounting Metrics

HC-MS-270a.1. Total amount of monetary losses as a result of legal proceedings associated with false marketing claims

- 1 The entity shall disclose the total amount of monetary losses it incurred during the reporting period as a result of legal proceedings associated with false marketing claims.
- 2 The legal proceedings shall include any adjudicative proceeding in which the entity was involved, whether before a court, a regulator, an arbitrator, or otherwise.
- 3 The losses shall include all monetary liabilities to the opposing party or to others (whether as the result of settlement or verdict after trial or otherwise), including fines and other monetary liabilities incurred during the reporting period as a result of civil actions (e.g., civil judgments or settlements), regulatory proceedings (e.g., penalties, disgorgement, or restitution), and criminal actions (e.g., criminal judgment, penalties, or restitution) brought by any entity (e.g., governmental, business, or individual).
- 4 The scope of monetary losses shall exclude legal and other fees and expenses incurred by the entity in its defense.
- 5 The scope of disclosure shall include, but is not limited to, legal proceedings associated with the enforcement of relevant industry regulations, such as the U.S. False Claims Act.

Note to **HC-MS-270a.1**

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

HC-MS-270a.2. Description of code of ethics governing promotion of off-label use of products

- 1 The entity 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."
- 2 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.
- 3 The entity shall describe the mechanisms it has in place to ensure compliance with its code, including, but not limited to:
 - 3.1 Disciplinary actions for violations
 - 3.2 Internal audits
 - 3.3 Regulatory review committees
 - 3.4 Training

Product Design & Lifecycle Management

Topic Summary

Medical equipment and supplies companies face increasing challenges associated with the human and environmental impact of the industry's products. Companies may face consumer and regulatory pressure to limit the use of material inputs that are associated with health concerns, while also addressing issues such as the energy efficiency and end-of-life disposal of specific products. Firms that are able to address these concerns while engaging in efforts to enhance product take-back may be better positioned to meet consumer demand and reduce future liabilities.

Accounting Metrics

HC-MS-410a.1. Discussion of process to assess and manage environmental and human health considerations associated with chemicals in products, and meet demand for sustainable products

- 1 The entity shall describe its strategic approach to addressing specific environmental and human health impacts of its products, including, but not limited to:
 - 1.1 Energy efficiency of products during use
 - 1.2 Disposal of the products
 - 1.3 Material efficiency
 - 1.4 Product packaging
 - 1.5 Toxicity of materials
- 2 The entity shall only describe design considerations that it can determine will deliver a specific, demonstrable environmental benefit.
 - 2.1 Environmental benefits shall be taken to mean those related to:
 - 2.1.1 Energy consumption
 - 2.1.2 Environmental health
 - 2.1.3 Human health
 - 2.1.4 Waste generation
 - 2.1.5 Water use

- 3 The entity shall provide an indication of how central the environmental benefit imparted is to functionality of products.
- 4 The entity shall make its determination in good faith and clarify whether the benefit relates to the product, package, or service, avoiding a general statement of environmental benefits and following guidance from applicable laws and statutes, including, but not limited to:
 - 4.1 U.S. Federal Trade Commission's "Green Guides" (16 C.F.R. Part 260: Guides for the Use of Environmental Marketing Claims)
- 5 The entity shall specify during which lifecycle stage(s) it takes into account the environmental impacts associated with its products.
- 6 The entity shall reference the mechanism through which it implements efforts, including, but not limited to:
 - 6.1 Use of design protocols
 - 6.2 Procurement policies
 - 6.3 Restricted substances lists (RSLs)
 - 6.4 Certifications
 - 6.5 Product take-back programs
 - 6.6 Packaging take-back
- 7 For efforts related to the end-of-life of product management, the entity shall discuss only design-related considerations.
- 8 The entity shall disclose the percentage of products, by revenue, for which it has integrated the aforementioned environmental considerations into the design.

HC-MS-410a.2. Total amount of products accepted for take-back and reused, recycled, or donated, broken down by: (1) devices and equipment and (2) supplies

- 1 The entity shall disclose the amount, in metric tons, of its products that it recovered and reused (refurbished), recycled, or donated.
 - 1.1 This figure shall be broken down into: (1) devices and equipment and (2) supplies.
 - 1.1.1 Devices and equipment include high-value machines and advanced devices.
 - 1.1.2 Supplies include simple supplies and low-cost equipment (e.g., scalpels, gloves, and thermometers).

1.2 This figure shall exclude products that were accepted for take-back but were ultimately discarded as waste.

1.2.1 The entity may indicate if it reclaimed any products it was unable to reuse or recycle because proper, safe disposal was necessary.

2 The entity shall describe programs and initiatives it implements, funds, or participates in that are related to product take-back for end-of-life management of its products.

Supply Chain Management

Topic Summary

Supply chain quality is essential to protecting consumer health and corporate value. Medical equipment and supplies firms that fail to ensure quality and traceability throughout their supply chains are susceptible to fines, lost revenue, and reputational damage. In addition, companies may need to manage the use of material inputs that are considered scarce. Disclosure of supply chain audit programs, strategies to ensure traceability, and the management of critical materials may provide shareholders with an understanding of how companies in this industry are protecting shareholder value.

Accounting Metrics

HC-MS-430a.1. Percentage of (1) entity's facilities and (2) Tier I suppliers' facilities participating in third-party audit programs for manufacturing and product quality

- 1 The entity shall disclose (1) 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.
 - 1.1 A third-party audit program is one conducted by an external auditing agency to a recognized, independent standard.
 - 1.2 The scope of disclosure includes facilities that are owned or operated by the entity.
- 2 The entity shall disclose (2) the percentage of its Tier I suppliers' facilities that participate in third-party audit programs, such as to ISO 13485:2003 Medical devices — Quality management systems — Requirements for regulatory purposes.
 - 2.1 Tier I suppliers are those that transact directly with the entity.
 - 2.2 The entity may limit its disclosure to those suppliers that in aggregate account for greater than or equal to 90 percent of its supplier spending.

HC-MS-430a.2. Description of efforts to maintain traceability within the distribution chain

- 1 The entity shall discuss the type and sophistication of technology it uses to maintain traceability of its products.
 - 1.1 Traceability refers to the ability to track identifying information of a product throughout various stages of manufacturing and distribution.
 - 1.2 Relevant stages of manufacturing and distribution include, but are not limited to:

- 1.2.1 Raw material sourcing
- 1.2.2 Production
- 1.2.3 Point of delivery at the health care provider
- 1.2.4 Product retail and wholesale
- 1.2.5 Transportation logistics

2 Discussion may include, but is not limited to, the use of:

- 2.1 Barcode technology
- 2.2 Chain of custody audits
- 2.3 Radio frequency identification (RFID) tagging

HC-MS-430a.3. Description of the management of risks associated with the use of critical materials

1 The entity shall describe its strategic approach to managing its risks associated with the use of critical materials in its products, including physical limits on availability and access, changes in price, and regulatory and reputational risks, where:

1.1 A critical material is defined as a material that is both essential in use and subject to the risk of supply restriction. This definition is derived from the U.S. National Research Council of the National Academies' [*Minerals, Critical Minerals, and the U.S. Economy*](#) .

1.2 Examples of critical materials include, but are not limited to, the following as defined by the National Research Council:

- 1.2.1 Antimony, cobalt, fluorspar, gallium, germanium, graphite, indium, magnesium, niobium, tantalum, and tungsten;
- 1.2.2 Platinum group metals (platinum, palladium, iridium, rhodium, ruthenium, and osmium); and
- 1.2.3 Rare earth elements, which include yttrium, scandium, lanthanum, and the lanthanides (cerium, praseodymium, neodymium, promethium, samarium, europium, gadolinium, terbium, dysprosium, holmium, erbium, thulium, ytterbium, and lutetium).

2 The entity shall identify the critical materials that present a significant risk to its operations, the type of risk(s) they represent, and the strategies the entity uses to mitigate the risk(s).

- 2.1 Relevant strategies may include diversification of suppliers, stockpiling of materials, development or procurement of alternative and substitute materials, and investments in recycling technology for critical materials.
- 3 All disclosure shall be sufficient such that it is specific to the risks the entity faces but disclosure itself would not compromise the entity's ability to maintain confidential information.
 - 3.1 For example, if an entity determines not to identify a specific critical material that presents a significant risk to its operations due to competitive harm that could result from the disclosure, the entity shall disclose the existence of such risk(s), the type of risk(s), and the strategies used to mitigate the risk(s), but is not required to disclose the relevant critical material.

Business Ethics

Topic Summary

Medical equipment and supplies companies are subject to various international, national, and state laws pertaining to health care fraud and abuse. For example, in the U.S., anti-kickback laws and the 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 throughout their global and domestic operational footprint may have material implications. Corporate disclosure of legal and regulatory fines and the codes of ethics that govern interactions with health professionals may allow shareholders to monitor performance in this area.

Accounting Metrics

HC-MS-510a.1. Total amount of monetary losses as a result of legal proceedings associated with bribery or corruption

- 1 The entity shall disclose the total amount of monetary losses it incurred during the reporting period as a result of legal proceedings associated with bribery or corruption.
- 2 The legal proceedings shall include any adjudicative proceeding in which the entity was involved, whether before a court, a regulator, an arbitrator, or otherwise.
- 3 The losses shall include all monetary liabilities to the opposing party or to others (whether as the result of settlement or verdict after trial or otherwise), including fines and other monetary liabilities incurred during the reporting period as a result of civil actions (e.g., civil judgments or settlements), regulatory proceedings (e.g., penalties, disgorgement, or restitution), and criminal actions (e.g., criminal judgment, penalties, or restitution) brought by any entity (e.g., governmental, business, or individual).
- 4 The scope of monetary losses shall exclude legal and other fees and expenses incurred by the entity in its defense.
- 5 The scope of disclosure shall include, but is not limited to, legal proceedings associated with the enforcement of relevant industry regulations, such as:
 - 5.1 U.S. Federal Anti-Kickback Statute
 - 5.2 U.S. Federal Food, Drug, and Cosmetic Act
 - 5.3 U.S. Foreign Corrupt Practices Act

Note to **HC-MS-510a.1**

- 1 The entity shall briefly describe the nature (e.g., judgment or order issued after trial, settlement, guilty plea, deferred prosecution agreement, or non-prosecution agreement) and context (e.g., kickbacks or fraud), of all monetary losses as a result of legal proceedings.
- 2 The entity shall describe any corrective actions it has implemented as a result of the legal proceedings. This may include, but is not limited to, specific changes in operations, management, processes, products, business partners, training, or technology.

HC-MS-510a.2. Description of code of ethics governing interactions with health care professionals

- 1 The entity shall describe aspects of any code of ethics that relate to its interactions with health care professionals.
 - 1.1 Health care professionals include individuals or entities that 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 entity's products, but do not necessarily provide health care services directly, such as purchasing agents, practice managers, and group purchasing organizations (GPOs).
 - 1.2 The scope of the disclosure shall 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) of the code of ethics.
- 2 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.
- 3 The entity shall discuss mechanisms to ensure compliance with its code of ethics, including, but not limited to:
 - 3.1 Enforcement, including inspection, compliance, and review committees
 - 3.2 Implementation of corrective actions when a code is violated
 - 3.3 Training, including degree and frequency
- 4 If the entity 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.

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