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Medical Device Industry HCP Interactions, Transparency and Reporting

Preparedness Assessment

White Paper

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Chapter 1 · Overview

This guidance document will help you assess your Medical Device company's preparedness in the management, oversight and reporting of your company's interactions with Healthcare Professionals (HCP's), Healthcare Organization (HCO's) and other external vendors, throughout the lifecycle of their interaction. Included is a checklist and resource guide that will help with the evaluation of your company's policies, processes, systems and tools used to monitor, collect, aggregate, allocate and report these interactions and the company's compliance with the applicable internal corporate policies and external government, country, and state laws and regulations.

HCP - Rules & Regulations

There continues to be a demand from the public, patients and other groups for the scrutiny and transparency of healthcare manufacturers and dispensers of drugs, devices, biologicals or medical supplies and whether their interactions were for a legitimate business need and if there were any inappropriate transfer of gifts, money or other items of value given to prescribe, purchase, supply, recommend or administer a company's medical product.

Additionally, over the past years more international government, country and state laws and regulations have required Life Sciences Manufacturers, including medical device suppliers and distributors to accurately track, monitor and report the payments and transfer of value made to HCP's and HCO's for various activities performed on behalf of a company. Companies who do not comply with these various reporting requirements may be subject to substantial monetary fines and other legal sanctions by the country and/or state where the violation occurred. Moreover, there could be global reputational damage to the company that may impact the public's trust and confidence in the company and the products they provide.

The Medical Device Industry is governed by various region-based Medical Technology Manufacturers, who joined to form a body of members who provide oversight and guidance for the interactions with healthcare professionals and organizations. Although their specific reporting requirements may vary, they all use the same baseline for their respective" Code of Business Practices and/or Guidelines on Interactions with Healthcare Professionals". Please see each governing body on the "Medical Device Industry – HCP Regulations Checklist" below.

HCP/HCO Interaction Lifecycle

The HCP/HCO Interaction Lifecycle is a five- stage process that an organization uses to manage the various stages of the interaction between the company and the HCP's/HCO's and other external vendors. Please see the HCP/HCO Lifecycle Stages definitions and checklist below to perform a health check of your HCP/HCO Transparency and Reporting program.

- **Planning: Stage I** - Internal and external discussions are held and decisions are made considering answers to the following questions.
    - What activity is being performed? Who are the HCP's/HCO's needed to perform the service?
    - Are any external 3rd party vendors needed to perform the service on behalf of your company?
    - Will Fair Market Value be used to determine the detailed estimated cost of service?
    - Are all internal and external parties involved in the interaction made aware of all the rules and regulations required for that interaction?
    - Are all interactions with the HCP's/HCO's including contracts and payments made in accordance with internal policies and external government, country and state laws and regulations?

- **Initiation: Stage II** - Internal requests and approvals to conduct the HCP activities are taking place. External discussions regarding contracts and fees with all parties are finalized prior to the start of the activity.

- **Engagement: Stage III** - The activity begins including monitoring and tracking of deliverables and service providers.

- **Reconciliation: Stage IV** - The review of all current and future deliverables including the payment and reconciliation of fees and expenses incurred to date.

- **Reporting: Stage V** – The aggregation, allocation and reporting of specific activities and the transfer of values made to HCP's/HCO's and other external vendors for services rendered.

Chapter 2 · HCP/HCO Interaction Lifecycle Checklist

1. PLANNING

- ☐ There is a legitimate business need for the service and the HCP/HCO selected has been vetted and meets the qualification to provide the requested service.
- ☐ The Fair Market Value was used when calculating the HCP/HCO fees for service and reimbursement of expenses.
- ☐ HCP/HCO policies and processes are in place that are compliant with applicable internal policies and external government, country, and state laws and regulations. All internal and external parties involved in the interaction are aware and will adhere to these requirements.

2. INITIATION

- ☐ Internal processes are in place to request and receive approval for the activity and the approval for the selected HCP/HCO and other external vendor(s) to provide the service.
- ☐ Fully executed contracts including payment terms are in place with all HCP's/HCO's and other external vendors for the requested service.
- ☐ Processes are in place to accurately monitor, track and record the services and deliverables of the HCP/HCO and other external vendors.

3. ENGAGEMENT

- ☐ Active monitoring, management and tracking of HCP and HCO activities and deliverables are taking place.
- ☐ Any changes to the activities scope, deliverables or service provider are reviewed, approved, documented, and communicated to all applicable parties.

4. RECONCILIATION

- ☐ All current deliverables have been received and payment obligations have/or will be met in accordance with contract and payment terms.
- ☐ Processes, systems and/or tools are in place to easily and accurately collect and review all data regarding the activity and providers of the activity to ensure compliance with all internal policies and external government, country and state laws and regulations.
- ☐ Unique identifiers are being used to identify and link the payment to the HCP/HCO or other external vendors and the service they performed.

5. REPORTING

- ☐ There is a full understanding of each government, country and state reporting requirements and reporting deadline dates.
- ☐ Adequate processes, systems and tools are in place to accurately and easily collect, aggregate, allocate and report HCP/HCO data based on each reporting requirements

Chapter 3 · Medical Device Industry – Reporting Authority Resource Guide

	Reporting Authority	Description	Website Link
	AdvaMed **(Advanced Medical Technology Association)**	Trade association that leads the US effort to advance medical technology in order to achieve healthier lives and healthier economies around the world. AdvaMed's membership has a global presence in countries including Europe, India, China, Brazil, and Japan	https://www.advamed.org/
	MedTech Europe **(EDMA and Eucomed formed an alliance in 2012)**	Its mission is to make innovative medical technology available to more people, while helping healthcare systems move towards a sustainable path. MedTech Europe encourages policies that help the medical technology industry meet Europe's growing healthcare needs and expectations	https://www.medtecheurope.org/
	Eucomed **(European Confederation of Medical Suppliers Association)**	An organization that advocates for the interests of the designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability.	https://www.medtecheurope.org/
	EDMA **(European Diagnostics Manufacturers Association)**	Represents national associations and major companies engaged in the research, development, manufacturing, or distribution of in vitro diagnostic (IVD) tests in Europe.	https://www.medtecheurope.org/
	MedTech Canada – (formerly MEDEC)	National association representing Canada's innovative medical technology industry	https://medtechcanada.org/
	APACMed (Asia Pacific Medical Technology Association)	Represents manufacturers and suppliers of medical equipment, devices and in-vitro diagnostics, industry associations and other key stakeholders associated with the medical technology industry in Asia Pacific	https://apacmed.org/
	JFMDA (Japan Federation Medical Device Association)	The Japan Federation of Medical Devices Associations (JFMDA) was founded in February 1984 by medical device associations consisting of manufacturers and suppliers of medical and health-care devices, equipment, instruments, and materials.	**https://www.jfmda.gr.jp/en/#:~:text=The%20Japan%20Federation%20of%20Medical,%2C%20equipment%2Cinstruments%20and%20materials** .

	MECOMED (medical devices, imaging, and diagnostics trade association for the Middle East & Africa)	Mecomed is the medical devices, imaging and diagnostics trade association, serving as the voice of international medical technology manufacturers operating in countries across the Middle East & Africa	https://www.mecomed.com/ethical-practices/
	AdvaMed Code of Ethics on Interactions with Health Care Professionals in **China**	The AdvaMed Code of Ethics on Interactions with Health Care Professionals in China ("China Code") clarifies and distinguishes appropriate activity between health care professionals and representatives of AdvaMed member companies in China.	https://www.advamed.org/issues/code-ethics/china-code
	CMS (Center for Medicare and Medicaid Services – Open Payments/PPACA-Sunshine Act)	Open Payments (commonly known as the Sunshine Act) requires applicable manufacturers and applicable group purchasing organizations (GPOs) to report certain payments and other transfers of value given to covered recipients and any ownership or investment interest physicians (excluding medical residents), or their immediate family members, have in their company	https://www.cms.gov/OpenPayments/Program-Participants/Applicable-Manufacturers-and-GPOs/Applicable-Manufacturers-and-GPOs
	Ministry of Solidarity and Health – Health Transparency Base	The Transparency - Health public database makes available all the information declared by companies on their links of interest with health sector actors. Led by the Ministry of Solidarity and Health, this transparency initiative aims to preserve the necessary relationship of trust between citizens, users, and the multiple players in the health system.	**https://www.transparence.sante.gouv.fr/**
	US State Reporting: Connecticut Massachusetts Vermont	Requires applicable manufacturers and applicable group purchasing organizations (GPOs) to report certain payments and other transfers of value given to covered recipients. **Requirements are based on each state's reporting law.**	**Connecticut**: Expenditure Disclosure Form (ct.gov) **Massachusetts**: https://www.mass.gov/pharmaceutical-code-of-conduct **Vermont:** https://ago.vermont.gov/disclosures-manufacturers-prescription-drugs-biological-products-medical-devices/ https://ago.vermont.gov/wp-content/uploads/2019/02/2018-Vermont-Prescribed-Products-Gift-Ban-Guide.pdf

Chapter 4 · Solution

S3 Comply is well-versed in the complexities and brings a wealth of experience working with large global clients as well as "startup" entities. With the latter, we have helped clients establish a framework for compliant information. Our proprietary software can be used by our clients as part of this process, or work can be delegated to S3 Comply analysts to complete the collection, aggregation, and evaluation steps in preparation for annual reporting. And we can also help with reporting.

Each reporting authority requires timely, accurate and complete reporting. To meet the requirements, your company will need to identify appropriate data sources, address data validation & auditing, determine how requisite data will be flagged and aggregated for reporting, assess financial controls as related to target payments, consider employee attestations and potentially provide training if this is new or your employees are inexperienced. This can be a tall order oftentimes distracting your team from their primary mission -- to support and grow your business. The S3 Comply team brings decades of experience. S3 Comply is experienced working with companies to understand the answers to these and other questions regarding your country or state reporting compliance.

Our proven approach, experienced team and purpose-built software ensures you will be up and running quickly and painlessly. You tell us where your data resides and we will collect, aggregate, store, and report. As part of the process, we will evaluate your data for compliance and quality control the effort. *We will let you know up front the cost of managing the service.*

To explore how we can help e-mail us at: info@S3Comply.com