S3 Comply
strategy / software / staffing

US "Sunshine Act" Reporting for Medical Device Companies

Don't be caught unaware!

White Paper

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Overview

Medical Device Industry: US Sunshine Act Reporting

For nearly a decade, the US Federal Government under the auspices of the Centers for Medicare and Medicaid (CMS) have collected "open payments" data from manufacturers of medical devices, drugs, biologicals and medical supplies. The intent of the reporting is to provide transparency relative to manufacturer payments and interactions with Healthcare Professionals (HCP's) and Healthcare Organizations including Teaching Hospitals. Failure to address the reporting requirements may result in monetary penalties not to mention the risk to the Company's reputation.

The reporting is multi-faceted and oftentimes challenging – examples below.

- Doctors and other "covered recipients" must be individually identified and verified
- Payment amounts and dates are tracked
- The nature of payments are categorized
- Product category & marketed name of the product are required
- Types of payments are designated (e.g., cash, in-kind)
- Certain expense areas required additional detail – e.g., travel reimbursement includes location information
- Expenditures associated with Clinical Trial research must be separately considered and reported.
- Reported information must be maintained for a 5-year period.

Data is oftentimes collected from a variety of sources and systems. The challenge is aggregating and making sense of the data for reporting and thereafter ensuring secure storage of historical data.

S3 Comply is well-versed in the complexities and brings a wealth of experience working with large global clients as well as "start up" 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.

Chapter 1

Introduction: General Coverage

The "Sunshine Act" -- aka The Patient Protection and Affordable Care Act (PPACA) of 2010 – requires manufacturers *including distributors of medical devices*, drugs, biologicals and medical supplies to track and report to the Federal government payments or transfers of values made to "covered recipients". These recipients include Healthcare Professionals (HCP's) such as doctors and as of 2021, certain nurses with advance degrees, and Teaching Hospitals. The Act also requires manufacturers and Group Purchasing Organizations (GPO's) to report certain ownership and investment interests. The purpose of reporting is to provide enhanced transparency into the relationships between healthcare providers and life science manufacturers -- ***not*** to restrict collaboration or prohibit transfers of value!

To answer whether your company needs to meet reporting requirements associated with medical devices the following should be considered:

1) The medical device requires premarket approval or premarketing notification to the FDA (42 C.F.R. Section 403.902).
2) Your company shares a common ownership with an applicable manufacturer or provides assistance or support to such an entity.
3) The medical device is used to perform a service that is reimbursable under Medicare, Medicaid, or CHIP (e.g., MRI machines, x-rays, ultrasound machines).
4) Payment is available under the Medicare Clinical Trial Policy.

The Sunshine Act 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. We can help.

Chapter 2

What Must Be Reported

Payments or "Transfers of Value" (ToV's) to HCP's and Teaching Hospitals must be reported. These ToV's must be categorized by the Nature of Payment/Spend

Including:

- Consulting fees
- Research
- Compensation for serving as a faculty or speaker at an educational or training event (including accredited & non-credited events)
- Honoraria
- Royalty or License
- Grant
- Gifts
- Entertainment
- Food and beverage
- Travel and Lodging (including specifying the destination)
- Education
- Space Rental or facility fees (to Teaching Hospitals only)
- Excluded from coverage are medical device-related payments less than the annual published thresholds (2021 – equal to or less than $11.05 on a reportable activity; aggregate payments less than $110.40), educational materials benefiting patients or intended for patient use, evaluation/demonstration units of 90 days or less average daily use, or items provided under a contractual warranty, service or maintenance agreement.
- Requisite payment details include the name of the HCP or entity that received the payment, demographics associated with the HCP/HCO (e.g., address, National Provider Identifier Number – NPI #, State License), dollar value of the payment, actual payment date, product category, marketed name of the product, and form of payment (e.g., cash/cash equivalent, In-kind items/services, stock, stock option or any other form of ownership).

Chapter 3

Understanding Your HCP/HCP Interactions

A key aspect of setting up your Sunshine Act reporting framework to meet the requirements is understanding your HCP/HCO Interactions.

Some questions you should be considering are:

- Do you use trained professionals including doctors and nurses to demonstrate your product? Are these individuals employees of your company or are they paid for their services?
- Do you set up sessions with Teaching hospitals or other HCO's to introduce your product?
- Do you work with individual or group practices when you demonstrate or train on your medical device?
- What are the costs associated with these sessions? For example, do trainers travel to the sites and incur expenses? Do you pay for these expenses directly or reimburse the HCO for his/her work? How and in what systems are these expenses and attendant details recorded? Do you pay rent for the use of space at any target facilities?
- Are you currently engaged in Clinical Research? Are you using Contract Research Organizations (CRO's) to manage clinical trials?
- How do you handle Independent Review Board (IRB) interactions? Are HCP's paid directly for their participation? If you use CRO's, do they pay HCO's directly on your behalf?
- Do you pay royalties or license fees and to whom?
- Do you provide grants to Teaching Hospitals? How is that data captured and verified/?
- Do you prepare educational materials with contributions from HCO's?

S3 Comply is experienced working with companies to understand the answers to these and other questions critical to Sunshine Act reporting compliance. Depending upon the circumstances, non-compliance could subject a manufacturer to financial penalties ranging from $1,000 to $10,000 for each payment (not to exceed $150,000) or ToV not reported and $10,000 to $100,000 (not to exceed $1,000,000) for "knowingly" failing to report such a payment. We also understand that the risk is not just monetary. Negative media attention and the potential deleterious impact to a manufacturer's reputation with the medical community is also very important.

Chapter 4

The Reporting Cadence

The deadline for the Medical Device Manufacturer to submit data associated with the prior calendar year to CMS is March 31st. CMS provides specific instructions associated with:

- Formatting the reportable data file (e.g., pipe delimited csv)
- Coding certain aspects of the data
- Uploading the file
- Attesting the data.

Importantly, the Medical Device Manufacturer must identify who will "attest" to the data for the enterprise and re-certify this individual each year. Research payments must be reported in a separate file with certain data element differences from other general payments. Some Manufacturers prefer to ask a 3rd party vendor to prepare and upload the files – S3 Comply performs this service for clients today. We also provide a Client "Review" file that can be easily previewed by Company stakeholders and the attestor prior to finalizing approval on the CMS system.

Once the data has been uploaded and attested, the next step is the review period. HCP's and HCO's are granted 45 days to review the data for the prior calendar year. If they disagree with any information provided, they may "dispute" the data. Their objections are registered with CMS and notification is provided from CMS to the Company. The Company can then provide their rationale to the party associated with the dispute and/or change the data. One challenge worthy of note is that CMS does not facilitate these communications. Instead, the Company is required to communicate with the HCP/HCO to resolve the matter. Thereafter, the data will either be modified or the dispute will be resolved with overt or tacit agreement by the HCO/HCP. Once again, S3 Comply directly supports its clients throughout the dispute process especially with regard to providing documentation, the rationale for classifying the data -- and tracking the dispute status.

Once all disputes have been handled, data concerning the Company's ToV's and Ownership/Investment interests is published on a CMS public website for the given year.

Chapter 5

Three Steps to Success

Step 1: Assessment

- Confirm Covered Medical Device(s)
- Determine HCP/HCO Interactions
- Identify Data Sources: Systems & Documentation
- Identify Stakeholders
- Map Implementation Approach/ Workflow

Step 2: Set Up

- Prepare Input Templates/ Interfaces
- Confirm Output Reports: CMS, Company Operational Reports
- Configure "Dashboard" for Quick View & Downloads
- Implement Business Rules (e.g., CMS Thresholds by Yr, Clinical Studies & Principal Investigator References)
- Prepare Test Data/ Test

Step 3: Implementation

- Collect Data
- Import Data
- Analyze/ Evaluate for Reporting
- Conduct Quality Control
- Prepare & Review Reports
- Report

Our proven approach, experienced team and purpose-built software --- HCPHUB™ --- 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