



**SUNSHINE ACT POLICY**

**(excerpt from EMPLOYEE HANDBOOK)**

**DECEMBER 2020**

## Sunshine Act Policy (as adopted on December 20, 2019)

### **RELEVANT PURPOSE**

The National Physician Payment Transparency Program (also known as, the "Sunshine Act" or the "Open Payments Program"), a provision of the Patient Protection and Affordable Care Act, was enacted by Congress in 2010 as part of the Healthcare Reform law. The Sunshine Act is intended to provide more transparency in the relationships between pharmaceutical and medical device manufacturers and healthcare providers, by requiring manufacturers to report payments and other "transfers of value" to U.S. physicians and teaching hospitals to the Centers for Medicare and Medicaid Services ("CMS") on an ongoing basis.

### **SUMMARY OF THE LAW AND ITS REQUIREMENTS**

The Sunshine Act implementing regulations require Apyx Medical and other medical device manufacturers, to track payments and other transfers of value to physicians and teaching hospitals that occurred on or after August 1, 2013. The 2013 data collection period was from August 1, 2013 to December 31, 2014. In subsequent years, Apyx Medical will be required to record and report data regarding these payments and transfers of value to the CMS on an annual basis. Reports will need to be filed by December 31st of each reporting year reflecting all reportable payments and transfers of value to physicians and teaching hospitals for the previous calendar year. The Secretary of Health and Human Services was required to make reported information publicly available in a searchable format by September 30, 2014 and June 30th of each year thereafter. CMS will publish the data submitted by Apyx Medical and other manufacturers on its Open Payments Program website (<http://cms.gov/openpayments>).

Examples of the types of payments and transfers of value to physicians and teaching hospitals that Apyx Medical is required to report include, but are not limited to: gifts, food and beverages, travel expenses, honoraria, research studies, including the value of supplies and equipment, grants, education, charitable contributions, direct compensation for serving as a faculty or speaker at medical education programs, consulting fees, ownership or investment interest, royalties, license fees and other speaking fees.

Covered recipients (i.e., physicians and teaching hospitals) will have the opportunity to review the data submitted by manufacturers prior to the data being made publicly available. For this reason, it is extremely important that Apyx Medical employees (and certain contractors) responsible for making payments or transfers of value to covered recipients accurately report such transfers. To the extent a covered recipient disputes reported data, the employee/contractor who incurred the expense or provided the transfer of value will be required to validate the data submitted. The Finance Department will serve as data stewards, aggregating data submitted by employees and reporting it consistent with the Sunshine Act, but the completeness and accuracy of data are the responsibility of the employees/contractors involved in the payments/transfers of value.

### **FOR WHOM WILL EMPLOYEES BE REQUIRED TO RECORD DATA?**

"Physicians" for which Reporting is Required.

The term "physician" includes only the following types of healthcare professionals:

- Medical Doctors (MD)
- Doctors of Optometry (OD)
- Doctors of Osteopathy (DO)
- Doctors of Dental Surgery and Doctors of Dental Medicine (DDS, DMD)

- Doctors of Podiatry (DPM)
- Doctors of Chiropractic Medicine (DC)

Payments and transfers of value need to be reported only for those physicians who are currently licensed to practice in the United States. Nurses, physician's assistants, and office staff are not included.

### **QUALIFYING "TEACHING HOSPITALS" FOR REPORTING PURPOSES**

CMS maintains a list of teaching hospitals, available on its website: <http://www.cms.gov>

Institutions are included on the CMS list if they received a payment in the prior calendar year under one of the defined Medicare Direct Graduate Medical Education or Independent Medical Education programs. Employees interacting with hospitals should check the most up-to-date teaching hospital list to determine whether reporting is required for a particular hospital.

### **WHAT INFORMATION MUST EMPLOYEES REPORT?**

Employees interacting with Covered Recipients are responsible to record all necessary data for each payment or transfer of value. Each individual payment or transfer of value must be recorded and reported with the following information:

- Name of the Physician or Teaching Hospital
  - ✓ The name must be listed on the report at it appears in the National Plan and Provider Enumeration System ("NPES"). The registry can be found at the web address: <https://npiregistry.cms.hhs.gov/>. If the physician is not listed on PPESR registry, the report must list first, middle and last name.
- Business Address of Physician or Teaching Hospital
- Physician Identifiers
- Physician Specialty
- National Provider Identifier ("NPI") (if applicable and as listed in NPES). If an NPI number is not available, it need not be included.
  - ✓ NPI Numbers can be found at the following web address: <https://npiregistry.cms.hhs.gov/>.
- State professional license number
- Amount of Payment or Other Transfer of Value
  - ✓ The dollar amount of a payment or value of a transfer must be recorded.
  - ✓ A payment made to a group of physicians should be divided among those benefitting from the transfer. For example, if a device or a meal is given to a practice, the value of the device or meal should be divided among the physicians in the practice who will be using the device or participated in the meal.
- Date of Payment or Transfer of Value
  - ✓ Transfers made over multiple dates, rather than as a lump sum, may be reported as individual transfers, or as a single line item for the total payment, using the first payment date.
- Form of Payment or Transfer of Value
- Cash, in-kind items or services, stock or other ownership interest, dividends or other returns on investment

- Nature of Payment or Transfer of Value
  - ✓ Payments and transfers must be described as falling into one of the following categories, whichever fits most accurately. To the extent a payment may be divided among multiple categories, such as if a \$1000 stipend is given \$700 of which is for travel expenses and \$200 of which is for food and beverage, those payments should be categorized accordingly.
- Consulting Fee
- Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than at a continuing education program
- Honoraria
- Gift
- Entertainment
- Food and Beverage
  - ✓ Office Calls: In a group setting, such as an office call, food cost is calculated by taking the total cost of the meal and dividing by the number of people participating, including office staff, nurses etc. Then, only the per capita cost is attributable to each participating physician for reporting purposes.
  - ✓ Large Conferences: Buffet meals, snack, drinks etc. provided generally at large scale conferences and events need not be reported.
- Travel and lodging (including the destination)
- Education
  - ✓ This category includes payments and transfers for classes, activities, programs or events that involve the imparting or acquiring of particular knowledge or skills, such as those used for a profession. Attendees at accredited or certified continuing education programs are not intended to be captured. However, even at accredited or certified education programs, any travel or meals provided must be reported.
  - ✓ There are certain exceptions to reporting for certified education programs. See "Exceptions to Reporting" below.
- Research
  - ✓ Research-related payments and transfers have special rules and may qualify for delayed publication of payments. See "Special Rules for Research Payments" below.
- Charitable Contributions
- Royalty or License
- Current or prospective ownership or investment interest
- Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program
- Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program
- Grant
- Space rental or facility fees (teaching hospitals only)
- Related, device, biological or medical supply
  - ✓ The name(s) of the related device or product, if applicable. Reports can include up to five (5) products for each line item. The report must include the name under which a device was marketed and the therapeutic area or product category for the device.
- Payments to Third Parties
  - ✓ The report must indicate whether the payment or transfer was provided to a third party at the request of the physician or teaching hospital. These payments are reported in the name of the requesting physician along with the name of the third party.

- Payments or transfers to physician owners or investors
  - ✓ The report must indicate whether payment was provided to a physician or immediate family member of a physician who holds an ownership interest in the Company. Ownership interests held by physicians or their immediate family members must be reported with the:
    - ✓ invested dollar amount and
    - ✓ the value and terms of the ownership or investment interest (excluding interest in publicly traded securities or mutual funds).

### EXCEPTIONS TO REPORTING

- Continuing Education
  - ✓ Attendees: Transfers related to the education of attendees at certified continuing education programs are not intended to be reported at all. This includes, educational materials used during continuing education lectures, etc.
  - ✓ Speakers: Payments to faculty and speakers at certified continuing education programs are not reportable if the speaker meets the following criteria, otherwise such payments must be reported. The event meets the certification requirements for one of the following:
    - The Accreditation Council for Continuing Medical Education
    - The American Academy of Family Physicians
    - The American Dental Association
    - The American Osteopathic Association
    - The manufacturer does not pay the speaker directly
    - The manufacturer for not select the speaker or provide the third party vendor with a specific list of names for speakers
- Indirect payments where the manufacturer is unaware of the identity of the physician
  - ✓ This exception may apply where, for example, where a device is donated to an organization, but the manufacturer does not know which, if any, physicians would be using the device.
- Nominal Payments
  - ✓ Individual transfers under \$10 (nominal individual transfers still must be recorded and reported in the event they meet the aggregate reporting threshold)
  - ✓ Aggregate transfers under \$100
- Product Samples to be used by a Patient
  - ✓ Includes coupon and vouchers to be used by a patient to get samples
- Educational materials and items that directly benefit Patients or are intended to be used by or with Patients
  - ✓ Includes, for example, an anatomical model given to a physician to educate a patient about a condition or procedure
- Short term loans for product evaluation
  - ✓ Providing a device or product to a physician for a short-term trial period, not to exceed 90 days, for the purpose of evaluating the device or product is not reportable.
- Items or services provided under a contractual warranty
  - ✓ Such as replacement parts or products
- Transfers to physicians in their capacity as a patient, rather than a physician
- Transfers to physicians in an alternate non-medical professional capacity
- Discount and rebates

- ✓ Discounts and rebates offered to physicians who purchase devices or products are not reportable.
- In-kind items used/or the provision of charity care to patients who cannot pay
- Dividends from publicly traded securities and mutual funds
- Transfers related to an administrative proceeding, legal defense, prosecution or legal settlement
- Transfers made solely in the context of a pre-existing personal, non-business relationship
  - ✓ Such as when a device or product is given to a family member in their capacity as a family member and not as a physician.

### **SPECIAL RULES FOR RESERARCH PAYMENTS**

*General Rule:* Certain research related payments qualify for *delayed publication* by CMS, if they meet the following criteria:

- Research on or development of a new product or a new application of an existing product; or clinical investigations regarding a new product
- There must be a research and development agreement in writing, with a research protocol between the manufacturer and physician

*Date of Publication:* Qualifying research payments must be reported the year after they occur but will not be published until the earliest of:

- FDA approval
- 4 years after the transfer occurred

*Reportable Information:* Research payment reports must include the following information instead of the generally reportable information:

- Name of research institution, individual or entity receiving payment
  - ✓ If a physician, must include:
    - Name as listed in NPPES
    - NPI number
    - State professional license number
    - Specialty
    - Business Address
  - ✓ If a teaching hospital, must include:
    - name
    - business address
- Total amount of payment
- Name of study
- Names of related devices or products
- Names of principal investigators, if any

### **PENALTIES FOR FAILURE TO COMPLY WITH THE SUNSHINE ACT**

Records, in the event of a compliance audit by CMS, must be kept for five (5) years. Manufacturers that fail to maintain records and to report in a timely and accurate manner may be subject to significant civil monetary penalties, including:

- A penalty of between \$1,000 and \$10,000 for each payment or transfer not reported timely and accurately, total penalties for one year not to exceed \$150,000.

- Penalties between \$10,000 and \$100,000 for each payment or transfer not timely and accurately reported, total penalties for one year not to exceed \$1,000,000, for knowing failure to report.
- Knowing and other failures to report are aggregated separately for a total annual penalty maximum of \$1,150,000.

The Sunshine Act defines "knowing" as (1) when a person (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (2) requires no proof of a specific intent to defraud.

Questions about this law, proper recording and categorization of payments and transfers, and Apyx Medical efforts to comply can be directed to the Chief Financial Officer.

### **INTERACTIONS WITH PHYSICIANS AND TEACHING HOSPITALS**

#### *Informing Physicians and Teaching Hospitals About Sunshine Act Reporting*

The Sunshine Act requires that Apyx Medical and all other companies report qualifying payments, transfers and interactions. The only way a physician may avoid appearing on Apyx Medical disclosures to CMS is to decline meals, educational materials, grants and all other reportable payments and transfers of value.

As such, employees are responsible to inform physicians or teaching hospitals, either verbally or in writing, which payments, transfers and interactions will be reportable under the Sunshine Act, such that physicians or teaching hospitals may choose not to accept such payments transfers and interactions.

At Apyx Medical-sponsored events and in-office interactions, employees must provide a sign-in sheet for participants. Physicians or teaching hospitals will have the option to opt out of receiving Apyx Medical's in-kind benefits (meals, parking validation, travel and hotel accommodations, devices, etc.). If a physician or teaching hospital opts out of receiving these benefits, no payments will be reported for that event or interaction for that physician or teaching hospital.

#### *Gifts, Meals, and Entertainment*

All gifts and entertainment, other than those below the \$10.00 nominal threshold or the \$100.00 aggregate threshold are reportable under the Sunshine Act.

Meals are generally reportable with the exception of large conferences or events where food and beverage is offered to all attendees at a buffet or snack table that is not monitored. At office calls, food cost is calculated by taking the total cost of the meal and dividing by the number of people participating, including office staff, nurses etc. Then, only the per capita cost is attributable to each participating physician for reporting purposes.

#### *When may a gifts or entertainment be provided?*

Apyx Medical employees should not give gifts to physicians unless they have been approved by either their supervisor, or the Chief Financial Officer or another member of the Management Team.

In general, gifts should:

- Be offered only occasionally
- Not be of substantial value

- Designed primarily for the education of patients or physicians

Gifts should not be provided:

- For the personal benefit of a customer (such as floral arrangements, artwork, music CDs, or tickets to a sporting event)
- As cash or a cash equivalent (such as a loan, gift certificate, savings bond, or lottery ticket); or
- As a price term or in place of a price concession

*When may a meal be provided?*

Meals may be provided if they are:

- In connection with informational presentations or discussions that provide scientific or educational value
- Occasional
- Modest as judged by local standards taking into account the meal provided (e.g., lunch, breakfast), and the economics of the area, and
- In a venue and manner conducive to informational communication

Additionally:

- Meals may be reimbursed to Apyx Medical consultants or independent sales representatives or provided in connection with Apyx Medical-sponsored consulting or advisory meetings if the consulting services and activities related to the services are the primary focus of the meeting, and any meals are clearly subordinate in terms of time and emphasis
- Financial support for meals or receptions may be provided to third-party sponsors of scientific and educational conferences or professional meetings

*Speakers, Consultants, Advisory Committees, Clinical Research and Other Fee-for-Service Arrangements*

Apyx Medical may pay reasonable fees for the performance of bona fide services by physicians or teaching hospitals, provided certain criteria are met. These "fee-for-service" arrangements may include, for example, speakers, consultants, participation on advisory committees, and research services.

Apyx Medical may reimburse physicians for expenses associated with fee-for-service arrangements, such as reasonable travel and meals. However, all such expenses, including both fee for service and ancillary expenses must be reported under the Sunshine Act.

*Fee-for-service arrangements should be entered only if:*

- Apyx Medical needs the services, and that need has been appropriately documented
- Participants are chosen based on their qualifications and expertise
- Participation is limited to the number of people needed to do the work
- Payment is based on the fair market value of the work or services, and
- Apyx Medical and the physician sign a written contract in a form approved by management that includes:
  - ✓ the legitimate business need for the services
  - ✓ the participant's qualifications
  - ✓ a description of the services, and
  - ✓ fair market value compensation

### **SUBMITTING SUNSHINE ACT REPORTS**

Employees are responsible to submit reports of all data collected with respect to this Sunshine Act Policy to their supervisors. A sample Sunshine Act Reporting Form for individual payments, transfers or interactions is attached to this Policy.

Employees are required to submit data reports within seven (7) days of the reportable payment, transfer or interaction. If an employee fails to submit a report within thirty (30) days of the reportable payment, transfer or interaction, that employee will receive a warning letter. Employees who continually fail to submit or submit late reports will be subject to further discipline, as described in the "Penalties for Violating the Sunshine Act Policy" section below, including termination of employment.

### **SUMMARY OF EMPLOYEE RESPONSIBILITIES**

- Employees are responsible to review and understand this policy and the requirements of the Sunshine Act.
- Employees must inform physicians and teaching hospitals of any reportable payments, transfers or interactions prior to such payment, transfer or interaction, such that the physician or teaching hospital may choose not to accept such payment, transfer or interaction to avoid Sunshine Act reporting.
- Employees are responsible for providing a sign-in sheet for participants at Apyx Medical events and interactions.
- Employees must record all Sunshine Act required information for each reportable
- payment, transfer or interaction with physicians or teaching hospitals.
- Employees are responsible to submit reports regarding Sunshine Act payments, transfers or interactions on a routine basis, as soon as possible within 7 days of the payment, transfer or interaction. Employees may use the attached Sunshine Act Reporting Form as a guideline for Sunshine Act reports.
- Although nominal payments, transfers or interactions (those under \$10 or \$100 in aggregate) to individual physicians or teaching hospitals are not reportable, these payments, transfers or interactions should still be recorded to determine whether they meet the aggregate reporting threshold.
- If an employee is unsure whether a particular payment, transfer or interaction is reportable, it is the employee's responsibility to find out by asking his or her supervisor and/or contacting the Chief Financial Officer or a member of the Finance Department for a determination. In the event a determination is not made prior to the payment, transfer or interaction, the employee should record the data as if it were reportable and submit the report for a determination.

### **CONFIDENTIAL DISCLOSURE**

Apyx Medical encourages employees to report any issues or concerns related to compliance or ethical obligations under the Sunshine Act and other laws and regulations. Reports may be made confidentially to a supervisor, the Chief Financial Officer or another member of the Management Team. If you are more comfortable reporting to the head of your department, any officer of the Company, or anyone else in a position of responsibility, you should feel free to do so. What is important is that you make the report.

All reports will be followed up by the Finance Department and, where applicable, by additional appropriate individuals. It is Apyx Medical's policy not to retaliate against any employee for raising issues or reporting concerns in good faith.

The Company encourages reports to be made in person, to ensure that we understand your concerns accurately and avoid misunderstandings. To the extent possible and appropriate under the circumstances, the Company will endeavor to maintain the confidentiality of the identity of anyone who reports a suspected violation of law or policy or who participates in the investigation. However, the need to conduct an adequate investigation and to take corrective action may require disclosure of certain information. In some circumstances, the Company may be required by law to identify a person who makes a report or who is a witness. Employees also should be aware that members of the Management Team and Company Counsel, as well as others, are legally obligated to act in the best interests of the Company.

#### **PENALTIES FOR VIOLATING THE SUNSHINE ACT POLICY**

Apyx Medical takes compliance with these policies, and the laws and regulations underlying these policies, very seriously. Employees who fail to comply with these policies, or who negligently or willfully fail to detect and report violations of these policies, will be subject to disciplinary action at the discretion of management, including but not limited to:

- additional training
- coaching
- written warning letter probation
- suspension
- termination of employment

Discipline for such acts or omissions need not be progressive in nature. Apyx Medical may, where appropriate, terminate employment without having imposed any less severe disciplinary measures. Nothing in the Sunshine Act Policy is intended to alter an employee's employment-at-will status, to create legal rights, or to create a contract between the Company and any of its employees.