

## **SUNSHINE ACT POLICY**

(Excerpt from EMPLOYEE HANDBOOK)

**APRIL 2022** 

# Sunshine Act Policy (as adopted on April 12, 2022)

## **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 also known as the Healthcare Reform law, was enacted by Congress in 2010. The Sunshine Act is intended to provide more transparency in the relationships between pharmaceutical, biologics, 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 Secretary of Health and Human Services was required to make reported information initially publicly available in a searchable format by September 30, 2014, and by June 30th of each year thereafter. CMS publishes the data submitted by medical device manufacturers on its Open Payments Program website (<a href="http://cms.gov/openpayments">http://cms.gov/openpayments</a>).

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.

Jurisdiction for the Sunshine Act is based upon US Government reimbursement (payment obtained from Medicaid, Medicare or CHIP) for medical covered medical devices, so only transfers of value to physicians involved in reimbursable procedures using covered medical devices are subject to the reporting requirement.

The law also provides that, if a medical device manufacturer can prove that sales to physicians and teaching hospitals in connection with reimbursable procedures are less than 10% of its total gross sales revenue, they are only required to report payments and transfers of value to such physicians and teaching hospitals. The Sunshine Act does not establish jurisdiction over surgical procedures which are non-reimbursable by CMS, such as elective aesthetic surgical procedures, and does not require reporting on transfers of value to surgeons only involved in such elective, non-reimbursable procedures.

## REPORTING RESPONSIBILITIES OF APYX MEDICAL

On an annual basis, the Finance department will prepare an analysis of revenue generated from sales of Apyx Medical's J-Plasma related products to physicians who utilize our products in a reimbursable procedure environment, such as in hospitals or surgical centers, and determine what percentage of total gross sales revenue it represents.

Since sales to such physicians represent less than 10% of total gross sales revenues, such reporting would be limited to payments or transfers of value to such entities.

In order to better streamline the reporting process, the company is taking the position of a "Zero Tolerance" policy, forbidding ANY payments or transfers of values to ANY physicians who utilize our products in a reimbursable procedure environment, such as in a hospital or surgical center. If it is determined that payments or transfers of values have been made by any employee of the company to such individuals, it will result in immediate discipline, up to and including termination.

If an individual is uncertain of the nature of any specific customers they may have business interactions with, they should obtain clarification from their manager, the CFO, or the Executive Vice President immediately.

## **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.