



SUNOVION PHARMACEUTICALS INC.
CORPORATE POLICY

WORKING TITLE: Aggregate Spend Policy		POLICY NO: 1.17	
Supersedes:	Approval: Corporate Policy Review Committee (CPRC)	Date Issued: November 13, 2013	Page: 1 of 4

SECTION 1. PURPOSE:

It is the policy of Sunovion Pharmaceuticals Inc. and its subsidiaries ("Sunovion" or the "Company"), that employees, and others acting on Sunovion's behalf comply with the Aggregate Spend provisions of the Patient Protection and Affordability Care Act ("PPACA," also known as the "Sunshine Act") together with any corresponding state laws or other laws with similar requirements that are not preempted by PPACA. This law contains significant penalties for non-compliance; therefore all employees have an obligation to provide accurate, complete and timely information to enable the Company to comply with the annual Federal filing requirements.

The Sunshine Act has been designed to provide transparency of any Transfers of Value from pharmaceutical and medical device companies to Covered Recipients whether it is related to a clinical trial, research and development or of a commercial/promotional nature.

The Sunshine Act requires pharmaceutical companies to report to the Centers for Medicare & Medicaid Services ("CMS") any Transfer of Value to a Covered Recipient ("Aggregate Spend") including direct compensation, payments to Principal Investigators as well as other Transfers of Value such as reimbursed expenses including travel, lodging and meals.

CMS is obligated under this law to make this data available to the public on a searchable website.

The penalties for erroneous or incomplete transactions range from \$1,000 to \$10,000 **per occurrence** up to \$1,000,000 per reporting entity.

SECTION 2. DEFINITIONS:

- 2.1 **Aggregate Spend Reporting System.** The Company maintains a data warehouse of all spend and transfers of value to all relevant HCPs. This system is fed by the Customer Management System (e.g., Veeva) and by data gathered on Aggregate Spend reporting templates.
- 2.2 **Covered Recipients** are MDs, DOs, Dentists, Chiropractors, Podiatrists and Optometrists who are legally authorized to practice medicine in the United States and hold a current license, regardless of whether they actively treat patients. As an example, medical residents, nurse practitioners and physician assistants are not Covered

Recipients. In addition, CMS has published a list of Teaching Hospitals that it also designates as Covered Recipients.

- 2.3 **Transfers of Value** is broadly defined under the Sunshine Act to include “a transfer of anything of value.” Under CMS regulations, Transfers of Value include both direct and indirect payments on behalf of a Covered Recipient, as well as to a charity or other third party (including another person) or payments made by a vendor or other intermediary on behalf of the Company.
- 2.4 The **Transparency Steering Committee** is comprised of individuals from key functions who have a significant role in providing data for the Sunshine Act filing. The Committee’s purpose is to provide oversight over data collection efforts to ensure all transactions are submitted to the Aggregate Spend Reporting System and to review periodic Aggregate Spend reports for accuracy and completeness. The committee should include members from Compliance and Ethics, information technology, commercial operations, finance, legal, marketing, commercial and research and development functions. The Committee may delegate implementation efforts to three sub-committees: Communications, Commercial and Research and Development matters.

SECTION 3. APPLICABILITY AND RESPONSIBILITIES:

This policy applies to all Sunovion employees, as well as employees of any Sunovion subsidiary and any third party acting on behalf of Sunovion or of one of its subsidiaries. Drug Samples while not part of the Sunshine Act filing are covered under another part of the PPACA statute and will be also disclosed to FDA annually.

SECTION 4. GENERAL:

- 4.1 Any employee who, on behalf of the company, provides a Transfer of Value directly to a Covered Recipient or who is responsible for the indirect Transfer for Value through a vendor or other third-party as part of a Company project or initiative must ensure that:
- All Covered Recipients are clearly identified (including their medical credentials, e.g., MD or DO) in an expense report in the Company’s expense reporting system (e.g., Concur);
 - All contracts and new supplier forms include a Covered Recipient’s National Provider Identifier (“NPI”) number or state medical license number; and
 - Payment amounts and any other Transfers of Value that are not captured in the Company’s expense reporting system are captured by one of the Company’s systems of record that feed the Company’s Aggregate Spend Reporting System (e.g., Veeva or Oracle) or, if engaging a vendor or agent to make these payments or other Transfers of Value, ensuring that the vendors properly report all Transfers of Value to the Compliance and Ethics Department.
- 4.2 The Compliance and Ethics Department shall issue reporting templates to collect the spend data to each affected department for transparency reporting. The Compliance and Ethics Department will periodically provide cost center owners lists of vendors to review with potentially reportable spend to assist in their reporting responsibilities and determine which expenditures must be reported via the Aggregate Spend reporting templates.

- 4.3 The Transparency Steering Committee will review monthly and quarterly reports of Aggregate Spend by Covered Recipient and other analyses of spend to provide oversight to the Aggregate Spend reporting process.
- 4.4 The PPACA regulations require two corporate officers to attest that the filing is complete and accurate. Accordingly, certain employees may be required to sign sub-certifications for the disclosure of spending for activities and the associated Covered Recipients that they are responsible for reporting.
- 4.5 Departmental-level Standard Operating Procedures (“SOPs”) may be necessary to ensure complete, timely and accurate submission. Compliance and Ethics will coordinate the SOP process with each departmental representative.
- 4.6 Documentation of the activity under this policy should be retained pursuant to the timelines set forth in the Company’s Records Retention Schedule.
- 4.7 Employees responsible for activities under this Policy are to be trained periodically on the requirements of the PPACA and other relevant laws.

SECTION 5. OTHER MATTERS:

5.1 Amendment

Management reserves the right to amend this policy as appropriate at any time without prior notice, pursuant to Sunovion Corporate Policy 1.0, **“Corporate Policy Review Committee”**.

5.2 Failure to Comply

EMPLOYEES WHO VIOLATE ANY SUNOVION POLICIES AND PROCEDURES WILL BE SUBJECT TO DISCIPLINARY ACTION, UP TO AND INCLUDING TERMINATION OF EMPLOYMENT.

5.3 Reporting Concerns

Reports concerning wrongful behavior, violations or suspected violations of this or any other policy, the Code of Conduct and Ethics, law or regulation may be submitted on a confidential basis or may be submitted anonymously through Sunovion's Compliance Hotline as set forth below. Reports of violations or suspected violations of alleged misconduct or wrongful behavior will be maintained as confidential as practicable under the circumstances, and as necessary to conduct a full and fair investigation.

Reporting Hotline Options:

- (a) Toll free telephone number. 866-886-1348
- (b) Via the internet at: www.ethicspoint.com

5.4 Audit

The Compliance and Ethics Department shall perform periodic reviews of the implementation of this Policy, under the oversight and guidance of the Chief Compliance and Ethics Officer.

5.5 Cross-References to other Corporate Policies

- Anti Corruption Policy 1.4
- Advisory Boards Policy 3.08
- Business Travel Policy 1.11
- Business Courtesies Policy 3.05
- Business Needs/Fair Market Value Assessment Form
- Conflict of Interests Policy 1.06
- Clinical Studies Policy 9.0
- Educational Grants Policy 1.02
- Guidelines for Interactions with Healthcare Professionals
- Investigator Initiated Studies Policy 1.14
- Records Management and Retention Policy 1.15
- Records Retention Schedule to the RIM Policy