



**SUNOVION PHARMACEUTICALS INC.**  
**CORPORATE POLICY**

|  |   |   |                     |
|--|---|---|---------------------|
| <b>WORKING TITLE: Public Health Service (PHS) Policy</b> |   | <b>POLICY NO: 3.02</b>  |                     |
| <b>Supersedes:</b>                                       | <b>Approval: Corporate Policy Review Committee (CPRC)</b> | <b>Date Issued:</b><br><b>June 30, 2008 (v1)</b><br><b>Date Amended:</b><br><b>December 14, 2012 (v2)</b> | <b>Page: 1 of 5</b> |

**SECTION 1. PURPOSE:**

- 1.1 This Policy is intended to define the requirements by which Sunovion Inc. ("Sunovion" or the "Company") will determine customer eligibility for prices required for Public Health Service ("PHS" or "340B") covered entities and contract pharmacies in the United States.
- 1.2 This Policy describes the Company's policy for the use and the interpretation of the Health Resources and Services Administration ("HRSA") database to determine customer PHS eligibility.
- 1.3 The 340B Program was established by the Veterans Health Care Act of 1992 ("VHCA"). The VHCA required manufacturers to enter into a pricing agreement for the 340B Program with the Department of Health and Human Services ("HHS"), which requires discounts from manufacturers. The discounted price offered to PHS eligible covered entities directly and through contract pharmacies is exempt from the calculation of Best Price ("BP").
- 1.4 The 340B Program is administered by HRSA. The Office of Pharmacy Affairs ("OPA") within HRSA maintains the list of covered entities and their contract pharmacies eligible for the discounted price on products from manufacturers ("PHS price"). The website is available at <http://opanet.hrsa.gov/opa/>.
- 1.5 A covered entity may contract with a pharmacy to dispense 340B drugs to covered entity patients. These arrangements are known as "Contract Pharmacy" arrangements. Covered entities must follow certain requirements in order to maintain their eligibility for PHS prices from manufacturers. Because covered entities must meet certain requirements for eligibility, the PHS status of a customer can be terminated at any time.
- 1.6 The 340B ceiling price is the maximum price that manufacturers can charge covered entities participating in the 340B Program. The 340B discount is provided through a chargeback mechanism. Manufacturers are free to offer discounts that are lower than the 340B ceiling price.

Such prices are referred to as sub-ceiling prices. Accordingly, covered entities may receive pricing that is significantly lower than the minimum discount that a manufacturer

is required to provide. Sub-ceiling prices offered to PHS covered entities are still BP exempt.

- 1.7 It is Sunovion's policy to comply fully with all applicable requirements in the determination of customer eligibility for the PHS price.

## **SECTION 2. DEFINITIONS:**

- 2.1 Best Price ("BP"): BP refers to the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the average manufacturers price ("AMP") is computed. BP includes all sales and associated rebates, discounts and other price concessions provided by the manufacturer to any entity unless specifically excluded by statute or regulation.
- 2.2 Contract Pharmacy: An outside, sometimes retail, pharmacy that contracts with a covered entity, so that the pharmacy can purchase drugs on behalf of the covered entity under the 340B Program.
- 2.3 Contract System ("CARS/IS"): A system or set of applications used to store contract membership and eligibility determinations.
- 2.4 Covered Entity: The statutory name for facilities and programs eligible to purchase discounted drugs through the 340B Program. Covered entities include: (1) federally qualified health center look-a-like programs; (2) certain disproportionate share hospitals owned by, or under contract with, State or local governments; and (3) several categories of facilities or programs funded by Federal grant dollars, including: (a) federally qualified health centers, (b) AIDS drug assistance programs, (c) hemophilia treatment centers, (d) sexually transmitted disease and tuberculosis grant recipients, and (e) family planning clinics.
- 2.5 HRSA: The Health Resources and Services Administration is an agency of the U.S. Department of Health and Human Services.
- 2.6 Management Data Exchange ("MDX"): A tool which follows a defined process of accepting a list of Customers from CARS/IS and HRSA and performs cleansing and matching algorithms to produce reports and an output file that can be used by membership exchange to assist in determining PHS covered entity eligibility.
- 2.7 Office of Pharmacy Affairs ("OPA"): The Office of Pharmacy Affairs is the division of HRSA that is responsible for administering the 340B Program.
- 2.8 PHS Contract Eligibility List: This term refers to a subset of customers on the current PHS contract that have been manually reviewed by the Company before being placed on the list. Once customers are placed on this list, each chargeback submission for that customer is automatically processed (i.e., paid or denied) and not subject to manual review. Those customers that are inactive and reflect an end date that precedes the date of the chargeback request are denied chargebacks automatically and are not subject to further manual review.

## **SECTION 3. APPLICABILITY AND RESPONSIBILITIES:**

### **3.1 Applicability**

- 3.1.1 This Policy applies to the determination of customer eligibility for prices required to be provided to 340B covered entities directly and through contract pharmacies in the United States. The Policy represents the Company's understanding of the contracting and reporting requirements with the PHS program, as defined by the VHCA and as interpreted by Sunovion.
- 3.1.2 All employees or contractors of Sunovion shall follow this Policy. Any employee or contractor who violates this Policy and any manager who knowingly permits or directs a subordinate to violate this Policy will be disciplined accordingly, up to and including termination of employment.
- 3.1.3 It is Sunovion's policy to comply with all provisions, requirements, terms and conditions of Section 602 of the VHCA, Section 1927 of the Social Security Act ("SSA"), the Pharmaceutical Pricing Agreement ("PPA"), and appropriate sub-regulatory guidance issued by OPA relating to the PHS program.

### **3.2 Responsibilities**

- 3.2.1 The primary responsibility for the implementation and oversight of this Policy is with the Contract Operations Department ("COD") acting in consultation with the Legal Affairs Department ("LAD").
- 3.2.2 The leadership of COD shall be responsible for compliance with this Policy and shall assist management and employees in understanding and implementing this Policy. Monitoring and auditing of this Policy shall be the responsibility of the Compliance Department.
- 3.2.3 The leadership of COD, in consultation with the Compliance Department, shall be responsible for ensuring that all relevant employees receive all necessary training on no less than an annual basis to ensure that they have the means necessary to comply with this Policy. All such training shall be appropriately documented.
- 3.2.4 All employees or contractors who know of and/or suspect a violation of this Policy shall immediately discuss the matter with her or his supervisor (in the case of an employee) or vendor coordinator (if a consultant). If such a discussion is impracticable or if the person prefers, he/she may also report the matter to a member of the Compliance Department, including the Chief Compliance and Ethics Officer (the "Chief Compliance Officer"), a member of the Legal Affairs Department, or the Human Resources Department, or through Sunovion's Compliance Hotline (via telephone at 866-886-1384 or online at: <http://www.ethicspoints.com/>), or such other mechanisms as may be established by the Company. All employees or contractors must raise any perceived or suspected violation of this Policy as specified in this Section 3.

## **SECTION 4. GENERAL:**

- 4.1 In developing this Policy, Sunovion has adopted the definitions and guidance provided in Section 602 of the VHCA, Section 1927 of the SSA, the PPA, and all appropriately issued guidance from OPA.
- 4.2 As of January 21, 2008, the Company has undertaken a manual review of all PHS chargeback customers not previously reviewed on a manual basis. Each customer for whom a PHS chargeback is requested must be compared to the HRSA database to determine the customer's PHS eligibility before a PHS chargeback is paid, if that customer has not been previously been reviewed on a manual basis.
- 4.3 The Company uploaded the 340B roster from the HRSA website of active HRSA 340B eligible entities. The initial PHS membership roster includes each covered entity's HRSA 340B ID, Entity name, Sub-Division name, Entity Primary address (Street, City, State and Zip), HRSA Participating Start and Participating End dates (if applicable). Each eligible customer requesting a PHS Price that was not part of the initial data load will be entered into the System based on the profile in the HRSA databases to evaluate the customer's PHS eligibility. Chargebacks will be denied (rejected) if the determination is that they are not eligible.
- 4.4 The Company has implemented a 340B Term Review process to further verify the PHS eligibility of customers for the PHS Price and to determine if an entity previously reviewed has been terminated from the 340B Program. This process will be executed on a bi-weekly basis and will include customers tied to chargebacks occurring within the time period under review.
- 4.5 It is the responsibility of COD to ensure that any customer that incorrectly received a PHS chargeback is reversed so that the chargeback will not set BP for the applicable quarter. Where applicable, the customer shall also have the relevant end date reflected in the PHS Contract Eligibility List. On a quarterly basis, a sufficiently knowledgeable person in COD shall meet with a sufficiently knowledgeable person from LAD and secure its concurrence with the treatment of all PHS chargeback customers and reversals for the quarter.
- 4.6 At least twice a year, the most senior person in COD or his/her designee and the most senior person from Order Management and Accounts Receivable shall determine since the last semiannual review, if wholesalers have deducted PHS chargebacks despite the fact that Sunovion had reversed those PHS chargebacks. The most senior person from Order Management and Accounts Receivable may provide the most senior person in COD or his/her designee with a list of wholesaler deductions and the customer debit memo numbers for COD to determine if any chargebacks were inappropriately deducted by the wholesaler. To the extent such deductions are identified, Sunovion will initiate a dispute resolution process with the wholesaler, as provided for in the wholesaler contract with the Company or as otherwise set forth in the PHS SOP.
- 4.6.1 The dispute resolution process and the outcome of that process, which must be approved by LAD, shall be fully documented in a form that records the following information:
- Deductions and chargebacks (including date information) at issue;
  - Wholesaler at issue;
  - Wholesaler customer at issue (by name and address);

- Sunovion's demand as part of the dispute resolution process; and
- The outcome of the dispute resolution process (evidenced by a written communication to the wholesaler).

## **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](http://www.ethicspoint.com)

### **5.4 Cross-References to other Corporate Policies**

Sunovion's Best Price Policy 3.01

Sunovion's Standard Operating Procedure regarding Best Price Selection and Calculation

Sunovion's Standard Operating Procedure regarding Public Health Service Customer Eligibility:  
Processes and Procedures for Manual and Automated Review of 304B Eligibility