



SUNOVION PHARMACEUTICALS INC.

CORPORATE POLICY

WORKING TITLE: Best Price Selection Policy		POLICY NO: 3.01	
Supersedes:	Approval: Corporate Policy Review Committee (CPRC)	Date Issued: June 30, 2008 (v1) Date Amended: December 14, 2012 (v2)	Page: 1 of 7

SECTION 1. PURPOSE:

- 1.1 This Policy is intended to define the process by which Sunovion Pharmaceuticals Inc. ("Sunovion" or the "Company") selects Best Price and reports this data to the federal government and the states, to the extent required by state law and where the applicable state requirements are consistent with the federal requirements.
- 1.2 The Omnibus Budget Reconciliation Act of 1990 established the Medicaid Rebate Program. That program requires drug manufacturers to enter into a National Medicaid Rebate Agreement ("MRA") with the Secretary of Health & Human Services ("HHS") and to pay rebates to State Medicaid agencies for products dispensed to Medicaid patients. Sunovion has entered into an MRA with HHS. The Veterans' Health Care Act of 1992 and the Deficit Reduction Act of 2005 amended certain provisions of the Medicaid Rebate Statute. The Centers for Medicare and Medicaid Services issued a Final Rule on July 17, 2007, providing additional guidance for the selection and reporting of Best Price. Further guidance is provided in the National Medicaid Rebate Agreement as well as Medicaid Drug Rebate Program Releases published periodically by CMS.
- 1.3 It is Sunovion's policy to comply fully with all applicable federal and state requirements in calculating and reporting Best Price.

SECTION 2. DEFINITIONS:

- 2.1 "Administrative fee" means a payment made to an entity with which Sunovion contracts for services related to the negotiation, development, administration, maintenance, and/or communication of the contract. Administrative fees are a type of service fee.
- 2.2 "Anti-kickback Statute" means the federal statute that prohibits the offer, solicitation, payment, or receipt of remuneration that is intended to reward or induce a prescription, order, or recommendation of a product or service reimbursable under any federally-funded health care program.
- 2.3 "Best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate

period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding (1) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans' Affairs, a State home receiving funds under 38 U.S.C. § 1741, the Department of Defense, the Public Health Service ("PHS"), or a PHS covered entity; (2) prices charged under the Federal Supply Schedule of the General Services Administration; (3) prices used under a designated State Pharmaceutical Assistance Program (SPAP); (4) certain depot prices and single award contract prices; (5) prices negotiated from drug manufacturers for covered discount card drugs under certain endorsed discount card programs; (6) prices negotiated under the Medicare Part D program for Part D covered drugs, including prices to Qualified Retiree Prescription Drug Plans on behalf of covered individuals. Best Price is inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under the Medicaid Rebate Statute). It is determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package. It excludes prices that are merely nominal in amount.

Best Price is reported to CMS on a quarterly basis. The calculation must be performed at the 9-digit National Drug Code ("NDC") level and generally represents a single dosage form and strength for a drug, without regard to the package size. Therefore, a single Best Price value is selected and reported for all package sizes within a product family, after considering the lowest included prices for each 11-digit NDC in each 9-digit NDC family. Best Price is computed at the dispensed unit level, since each package will have a different number of dispensable units.

- 2.4 "Bona fide service fee" means a fee paid by a manufacturer to an entity that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement and that is not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.
- 2.5 "Centers for Medicare and Medicaid Services" ("CMS") means the agency which oversees the Medicaid Drug Rebate Program. CMS is the agency to which Sunovion reports Best Price for each of its products on a quarterly basis.
- 2.6 "Chargeback" means a credit issued to the wholesaler for the difference between what the wholesaler paid for the product and the Sunovion-contracted price to the relevant end customer.
- 2.7 "Contract Oversight Committee" ("COC") means the Sunovion Committee, consisting of designated members of the Government Pricing ("GP"), Managed Markets, Finance, and Legal Affairs Departments ("LAD"), that reviews and approves various contracting strategies and other issues. The members of the COC are designated by the Executive Leadership Team ("ELT") members for the relevant Departments.
- 2.8 "Group Purchasing Organization" ("GPO") means an organization that negotiates purchasing contracts for pharmaceuticals and other health care items, usually at discounted prices, for participating members (e.g., hospitals, long term care facilities, and other health care providers).
- 2.9 "GPO Safe Harbor" means a federal regulation permitting the payment of certain administrative fees without violating the Anti-Kickback Statute.

- 2.10 “Innovator multiple source drug” means a multiple source drug that was originally marketed under an original New Drug Application (“NDA”) approved by the Food and Drug Administration (“FDA”).
- 2.11 “Medicaid Final Rule” means the Final Rule promulgated by CMS on July 17, 2007, under the authority of the Deficit Reduction Act of 2005 (“DRA”).
- 2.12 “Medicaid Rebate Agreement” (“MRA”) means the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his designee and a manufacturer to implement the Medicaid Rebate Statute.
- 2.13 “Nominal price” means a price that is less than 10% of the Average Manufacturer Price (“AMP”) in the same quarter for which the AMP is computed.
- 2.14 “Office of Inspector General” (“OIG”) means the legal, investigative, and compliance arm of the Department of Health and Human Services. OIG is authorized to audit Sunovion’s books, records, and any other documents and undertake certain other activities to verify Sunovion’s compliance with the requirements of the Medicaid Rebate Program.
- 2.15 “Pharmacy Benefit Manager” (“PBM”) means an entity that negotiates pharmaceutical prices for client organizations (for example, unions).
- 2.16 “Pricing Committee” means the Sunovion Committee consisting of designated members of the GP, Managed Markets, Finance and Legal Affairs Departments that have specific responsibility for overseeing Government Pricing issues and functions. The members of the COC are designated by the Executive Leadership Team members for the relevant departments. See Best Price Selection Procedure, Section 5.3.2, for a fuller discussion of the activities of the Pricing Committee.
- 2.17 “Rebate” means a direct payment reflecting a price concession, issued to an end customer consistent with the contractual terms agreed to between the customer and Sunovion.
- 2.18 “Single Source Drug” means a covered outpatient drug produced or distributed under an original NDA approved by the FDA.
- 2.19 “Twelve Quarter Look-back Requirement” means the time frame defined by CMS for allowing prior period adjustments, which are changes in the unit rebate amount resulting from a manufacturer revising its AMP and BP, after AMP and BP information has previously been submitted to CMS.

SECTION 3. APPLICABILITY AND RESPONSIBILITIES:

3.1 Applicability

- 3.1.1 This Policy applies to the selection and reporting of Medicaid Best Price. All Best Prices reported to the government will be accurate, based on all currently available information, and submitted on a timely basis as required by CMS.
- 3.1.2 This Policy applies to all Sunovion employees or contractors responsible for the selection, verification, and certification of Best Price. 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 Any Sunovion employee or contractor who receives a survey or other request for Best Price information from any government entity should forward that request to the Government Price Reporting Department for completion. In addition, a copy of any such government requests for Best Price information must be sent to the Legal Affairs Department. The Legal Affairs Department shall approve any response prior to the submission of that response to the government.

3.2 Responsibilities

- 3.2.1 In consultation with the Pricing Committee, which will meet on a periodic basis, the primary responsibility for implementation and oversight of this Policy is with the GP, Managed Markets, and the Legal Affairs Departments. Meetings involving members of these Departments, in connection with this Policy, shall be chaired by the designated representative of the GP Department.
- 3.2.2 GP, Managed Markets, and LAD shall be responsible for compliance with this Policy and shall assist all employees and contractors in understanding and implementing this Policy. GP, Managed Markets, and LAD shall be responsible for ensuring that all relevant employees and contractors are trained on this Policy, in coordination with the Compliance Department. The GP and Managed Markets Departments shall be responsible for ensuring that employees and contractors understand that they are required to ask any questions that they may have regarding the Policy, discuss any perceived or suspected compliance issues, and report any possible noncompliance to a supervisor and/or others as described in Section 3.2.4. Monitoring and auditing of compliance with this Policy shall be the responsibility of the Compliance Department.
- 3.2.3 Statutory and regulatory interpretations related to this Policy are the responsibility of the Legal Affairs Department. No other Department is permitted to make a statutory or regulatory interpretation related to this Policy or on behalf of Sunovion.
- 3.2.4 Any employees or contractors who know of and/or suspect a violation of this Policy shall immediately discuss the matter with his or her 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.ethicspoint.com/>), or such other mechanisms as may be established by the Company. All employees and contractors must raise any perceived or suspected violation of this Policy as specified in this Section.

SECTION 4. GENERAL:

- 4.1 In developing this Policy, Sunovion has adopted the definitions and guidance contained in the Medicaid Rebate Statute, the 2007 Medicaid Final Rule, and the National Medicaid Rebate Agreement, as well as relevant Drug Manufacturer Releases provided by CMS.

- 4.2 Except as otherwise provided for, in writing, by the Legal Affairs Department, Sunovion shall adhere to the Best Price Selection Procedure then in effect at all times.
- 4.3 The Best Price selection process will be conducted no less frequently than quarterly at the conclusion of each quarter.
- 4.4 Sunovion shall select and calculate Best Price by creating, refining, and reviewing an array of all potentially relevant prices from the relevant period for each product, as set out in the Best Price Selection Procedure.
- 4.5 To facilitate accurate Best Price selection and to ensure compliance with the Anti-Kickback Statute and other applicable legal requirements, all contracts for the sale of drug products, including any modifications to existing contracts, must be fully executed by the end of the quarter to which they first apply. The company shall not enter into any agreements other than fully executed written contracts. Oral agreements are strictly prohibited. A contract or modification fully executed by the end of a quarter may be made effective to the first date in that quarter in which the parties' understanding of the terms of their agreement was reduced to writing. The writing must either be a proposal document, a letter of agreement, or an agreement in a form approved, in writing, by the Legal Affairs Department and reflecting the terms approved by the COC. The writing must reflect an intent of the parties to be bound, subject to the completion of a fully executed contract to be executed by the end of the quarter. In no case shall a contract be recognized for a quarter where a fully executed contract was not completed by the close of that same quarter or where the other requirements set out in this section have not been met. No concession of any kind may be agreed to in a period if that concession is to be applied to purchases made in an earlier quarter.
- 4.6 The Company selects Best Price using a customer-based approach. Best Price is the lowest price to any one customer of the Company that is not excluded from the calculation. The Company's policy is to aggregate price concessions, where the same customer realizes different price concessions. In the case of a chargeback paid through a wholesaler, the chargeback is not a price concession to the wholesaler. It is a price concession to the end customer. The term "same customer" is defined to be any related organizations known to be under common control or ownership.
- 4.7 Sunovion applies the "bona fide service fee" test found in the Medicaid Final Rule to determine if service fees, including administrative fees, should be excluded from the determination of Best Price. In the case of administrative fees paid to GPOs or PBMs, these fees are included in the Best Price selection as price concessions except in instances where the Legal Affairs Department has determined, in writing, that the fees fall within the GPO Safe Harbor as described by the OIG and the requirements of the "bona fide service fee" test are met under the Medicaid Final Rule. Sunovion has determined that the payment of an administrative fee of 3 percent of the purchase price or less is fair market value for the services provided by a GPO or a PBM to Sunovion under the "bona fide service fee" test. Sunovion will, on an annual basis, assess the treatment of these fees.
- 4.8 Before any fee agreement is executed involving a purchaser or an agent of a purchaser (such as a GPO or a PBM), the contract team, including the employees or contractors responsible for its negotiation, will submit to the Legal Affairs Department and to the appropriate representative within the Finance Department such information as these Departments shall require. The Legal Affairs Department must be consulted immediately if a GPO, PBM, or other recipient of a service fee, is suspected or believed

to be passing fees it receives from the Company on to its members, customers, or others.

- 4.9 Prices provided to PBMs are generally excluded from Best Price in accordance with the Medicaid Final Rule. However, prices provided to a PBM that are designed to affect prices at the retail class of trade level are to be included in Best Price, as required by the Medicaid Final Rule. Prices to a PBM are deemed by Sunovion to be included in Best Price where a mail order pharmacy that is owned or controlled by the PBM may receive the benefit of the PBM pricing.
- 4.10 Each quarterly Best Price selection will be identified at a Pricing Committee meeting involving designated members of the GP, Managed Markets, and Legal Affairs Departments, or their designees. The Best Price for a quarter will be the lowest included price, on a unit basis, for each NDC-9. The final Best Price recommendation will be made by a sufficiently knowledgeable person within the GP Department, as designated by the ELT member for that Department, in consultation with the Legal Affairs Department. That recommendation will be provided, along with supporting documentation, to the Chief Financial Officer for final certification and approval prior to reporting to the government.
- 4.11 Recalculations of an initially reported quarterly Best Price will be performed on a timely basis, consistent with the Twelve Quarter Look-back Requirement. The process that applies to the initial determination of Best Price, including all relevant approvals and certifications, will be adapted and followed for any recalculations. Unless a delay is approved by the Legal Affairs Department, in writing, recalculations of Best Price shall be completed within eight quarters of the quarter in which the original report of Best Price was made.
- 4.12 The GP Department will maintain copies of all documents relating to calculation of Best Price for 10 years following the date of submission to the government, or longer as required by law or the Sunovion Records Management and Retention Policy.

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 Cross-References to other Corporate Policies

Records Management and Retention Policy 1.15