General Instructions for Completing the Pharmaceutical Pricing Agreement (PPA)

In accordance with the guidance found in the May 7, 1993, *Federal Register*, (link here) Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement (the "Agreement") with the Secretary of Health and Human Services (the "Secretary") in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price ("AMP") decreased by a rebate percentage.

Manufacturer is defined in the guidance listed above, as follows:

The term "Manufacturer" has the meaning as set forth in section 1927(k)(5) of the Social Security Act and includes all entities engaged in –

> (1) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or
>
> (2) the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. A manufacturer must hold legal title to or possession of the NDC number for the covered outpatient drug. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

"Manufacturer" also includes an entity, described in (1) or (2) above, that sells outpatient drugs to covered entities, whether or not the manufacturer participates in the Medicaid rebate program. Furthermore, the Pharmaceutical Pricing Agreement provides that the term also includes any contractor who fulfills the responsibilities pursuant to the PHS drug pricing agreement.

Please print the attached Pharmaceutical Pricing Agreement (PPA) in its entirety and have it signed by a corporate officer, such as the Chief Executive Officer. The form utilizes Adobe Acrobat Reader in an interactive format allowing you to input all applicable information on the computer. However, the form cannot be saved with your information for future use. You must print the form to submit it to the Office of Pharmacy Affairs Branch (OPA).

If your organization would like to receive a signed original, please ensure that you submit TWO signed originals to the OPA. Otherwise, the OPA will send you a copy of the document once it is counter-signed by the Associate Administrator, Healthcare Systems Bureau, Health Resources and Services Administration.

If you have any questions, please contact the 340B Prime Vendor at 1-888-340-2787 or via email at ApexusAnswers@340BPVP.com.

PHARMACEUTICAL PRICING AGREEMENT

(hereinafter referred to as the "Agreement")
Between
THE SECRETARY OF HEALTH AND HUMAN SERVICES
(hereinafter referred to as the "Secretary")
and
THE MANUFACTURER
Identified in Section IX of this Agreement
(hereinafter referred to as the "Manufacturer")

The Secretary, on behalf of the Department of Health and Human Services, and the Manufacturer for purposes of section 602 of the Veterans Health Care Act of 1992, Public Law No. 102-585, which enacted section 340B of the Public Health Service Act (hereinafter referred to as "the Act"), 42 U.S.C. 256b, hereby agree to the following:

I. Definitions

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in the Act and section 1927(k) of the Social Security Act, as interpreted and applied herein:

(a) **"Average Manufacturer Price (hereinafter referred to as the "AMP")"** means the average unit price paid to the Manufacturer for the drug in all States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under the distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Social Security Act), which reduce the actual price paid. It is calculated as a weighted average of each drug of prices for all the Manufacturer's package sizes for each calendar quarter. Specifically, it is calculated as net sales divided by the numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements). For bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangements. The AMP for a calendar quarter must be adjusted by the Manufacturer, if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b) **"Best Price"** has the meaning given it in section 1927(c)(1)(C) of the Social Security Act, and section I(d) of the Medicaid Rebate Agreement.

(c) **"Bundled Sale"** refers to the packaging of drugs of different types where the total price for the package is less than the purchase price of the drugs, if purchased separately.

(d) **"Covered Drug"** means an outpatient drug as set forth in section 1927(k) of the Social Security Act. For purposes of coverage under the Agreement, all covered outpatient drugs are identified by the NDC number.

(e) **"Covered Entity"** means:

(1) certain Public Health Service grantees, "look-alike" Federally Qualified Health Centers and disproportionate share hospitals as described in section 340B(a)(4) of the Act; and

(2) in the case of a covered entity that is a distinct part of a hospital, the hospital itself shall not be considered a covered entity unless it meets the requirements of section 340B(a)(4)(L) of the Act, as determined by the Secretary.

(f) **"Manufacturer"** has the meaning as set forth in section 1927(k)(5) of the Social Security Act except that, for purposes of the Agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the covered outpatient drug. The term includes:

(1) any Manufacturer who sells covered outpatient drugs to covered entities, whether or not the Manufacturer participates in the Medicaid rebate program; and

(2) any contractors which fulfill the responsibilities pursuant to the Agreement, unless excluded by the Secretary.

(g) **"Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration)"** means the agency of the Department of Health and Human Services having the delegated authority to administer the Medicaid and Medicare Programs.

(h) **"Medicaid Rebate Program and Medicaid Rebate Agreement"** mean, respectively, the program, and a signed agreement between the Secretary and the Manufacturer, to implement the provisions of section 1927 of the Social Security Act.

(i) **"National Drug Code (NDC)"** means the identifying drug number maintained by the Food and Drug Administration (FDA). For purposes of the Agreement, the NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specified product or formulation), and package size code when reporting requested information.

(j) **"Over the Counter Drug"** means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drugs under State law).

(k) **"Quarter"** means a calendar quarter unless otherwise specified.

(l) **"Rebate Percentage"** means an amount (expressed in a percentage) equal to the average total rebate required under section 1927(c) of the Social Security Act with respect to each dosage, form, and strength of a single source or innovator multiple source drug during the preceding calendar quarter; divided by the AMP for such a unit of the drug during such quarter.

(m) **"the Secretary"** means the Secretary of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

(n) **"Unit of the Drug"** means a drug unit in the lowest identifiable amount (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each covered outpatient drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Section II of the Agreement.

(o) **"Wholesaler"** means any entity, having a wholesale distributor's license, to which a Manufacturer sells the covered outpatient drug, but which does not relabel or repackage the covered outpatient drug.

II. MANUFACTURER'S RESPONSIBILITIES

Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following:

(a) for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug reported (or which would have been reported had the Manufacturer participated in the Medicaid rebate program) to the Secretary in accordance with the Manufacturer's responsibilities under section 1927(b)(3) of the Social Security Act, reduced by the rebate percentage;

(b) for multiple source, noninnovator multiple source, and over the counter drugs, the AMP is reduced by 11%, as described in 1927(c)(3)(B)(ii) of the Social Security Act;

(c) for those Manufacturers that do not have a reporting requirement under section 1927(b)(3) of the Social Security Act for covered outpatient drugs, to submit to the Secretary upon request, a list of such covered outpatient drugs, and the AMP, baseline AMP, and the Best Price of such covered outpatient drugs;

(d) to retain all records that may be necessary to provide the information described in paragraph (c) of this section for not less than 3 years from the date of their creation;

(e) to afford the Secretary or his designee reasonable access to records of the Manufacturer relevant to the Manufacturer's compliance with the terms of the Agreement;

(f) to permit CMS to share AMP and unit rebate amount submitted under the Medicaid Rebate Agreement on covered outpatient drugs with the Secretary or his designee for purposes of carrying out the Agreement; and

(g) to participate in the HRSA Prime Vendor Program as provided by section 340B(a)(8) of the Act unless otherwise agreed to by the Secretary.

III. SECRETARY'S RESPONSIBILITIES

Pursuant to the requirements under section 340B of the Act, the Secretary agrees to the following:

(a) to make available a list of covered entities on the HRSA, Office of Pharmacy Affairs web site (http://www.bphc.hrsa.gov/opa/), or otherwise, for access by participating Manufacturers, covered entities, State Medicaid agencies, and the general public. This information will be updated, to the extent practicable, on a quarterly basis;

(b) with respect to a covered entity that bills Medicaid using a cost basis for drug purchases, to require the entity to submit its pharmacy Medicaid provider number. The Secretary shall provide respective State Medicaid agencies with the list of such entities and their Medicaid provider numbers. Based on these provider numbers, the State agencies will create an exclusion file which will exclude data from these entities when generating Medicaid rebate requests.

(c) to require each covered entity to retain purchasing and dispensing records of covered outpatient drugs under the Agreement and of any claims for reimbursement submitted for such drugs under Title XIX of the Social Security Act for not less than 3 years.

IV. DISPUTE RESOLUTION

(a) If the Manufacturer believes that a covered entity has violated the prohibition against resale or transfer of covered outpatient drugs, section 340B(a)(5)(B), or the prohibition against duplicate discounts or rebates, section 340B(a)(5)(A), the Manufacturer can access the elective dispute resolution process in the following manner:

(1) The Manufacturer shall attempt in good faith to resolve the matter with the covered entity.

(2) If unable to resolve the dispute, the Manufacturer may provide written notice of the discrepancy to the Secretary.

(3) The Secretary, at his discretion, will initiate an informal dispute resolution process.

(4) If the Secretary finds, after conclusion of the dispute resolution process, that the entity is in violation of such prohibitions, the entity shall be liable to the Manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug as described in section II(a) of the Agreement. Pursuant to section 340B(a) (4) and (5) a covered entity also could be removed from the list of eligible entities.

(b) The Manufacturer may challenge the presence of an entity on the list of eligible entities issued by the Secretary. Upon presentation of appropriate information documenting the entity's ineligibility, the Secretary shall take such steps as necessary to carry out his responsibilities under paragraph III(a) of the Agreement.

(c) If the Secretary believes that the Manufacturer has not complied with the provisions of the Agreement, or has refused to submit reports, or has submitted false information pursuant to the Agreement, the Secretary, at his discretion, may initiate the informal dispute resolution process. If so found, the Secretary may require the Manufacturer to reimburse the entity for discounts withheld and can also terminate the Agreement. A Manufacturer who does not have an agreement with the Secretary pursuant to the Act, will no longer be deemed to meet the requirements of section 1927(a)(5)(A) of the Social Security Act.

(d) A covered entity's failure to comply with the audit requirement pursuant to section 340B(a)(5)(C) of the Act shall be cause for the Manufacturer to notify the Secretary or his designee and for the Secretary to initiate the informal dispute resolution process. Such action will not relieve the Manufacturer from

its obligation to conform to the pricing requirements as provided in section 340B(a) of the Act and the Agreement.

(e) Nothing in this paragraph shall preclude the Manufacturer or the Secretary from exercising such other remedies as may be available by law.

V. CONFIDENTIALITY PROVISIONS

(a) Information disclosed by the Manufacturer in connection with the Agreement, except as otherwise required by law, will not be disclosed by the Secretary or his designee in a form which reveals the Manufacturer, except as necessary to carry out the provisions of section 340B of the Act, and to permit review by the Comptroller General.

(b) The Manufacturer will hold audit information obtained from the covered entities confidential. If the Manufacturer receives further information on such data, that information shall also be held confidential. Nothing in this paragraph shall preclude the Manufacturer from making such information available to the Secretary to enable the Secretary to carry out the provisions of section 340B of the Act.

VI. NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of the Agreement, the Agreement shall be effective for an initial period of 1 year, beginning on the date specified in section IX of the Agreement. It shall be automatically renewed for additional successive terms of 1 year unless the Manufacturer gives written notice of intent not to renew the Agreement at least 90 days before the end of the applicable period.

(b) The Manufacturer may terminate the Agreement for any reason. Such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, and the ending date of the term of the Agreement, if notice has been given 90 days before the end of the term.

(c) The Secretary may terminate the Agreement for a violation of the Agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide the Manufacturer, upon request, the opportunity to participate in an informal dispute resolution process concerning the termination, but such a process shall not delay the effective date of the termination. Disputes arising under a contract between a Manufacturer and a covered entity should be resolved according to the terms of that contract. Actions taken by the parties in such disputes are not grounds for termination of the Agreement with the

Secretary, except to the extent that there is a violation of the provisions of the Agreement.

(d) If the Agreement is not renewed or is terminated, the Manufacturer is prohibited from entering into another Agreement as provided in section 340B of the Act until a period of one complete calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect the ceiling price under paragraph II(a) for any covered outpatient drug purchased before the effective date of termination.

VII. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of the Agreement will be sent in writing.

(1) Notice to the Secretary will be sent to:

Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Mail Stop 8W03A
Rockville, Maryland 20857

(2) Notice concerning data transfer and information systems issues is to be sent to the same address as listed above (section VII(a)(1) of this Agreement).

(3) Notice to the Manufacturer will be sent to the address as provided with the Agreement and updated upon Manufacturer notification to the Secretary at the address in the Agreement.

(b) The Manufacturer will be permitted to audit the records of each covered entity

(1) that directly pertain to the entity's compliance with the prohibition on

(A) the resale or other transfer of covered outpatient drugs to persons not patients of the entity, section 340B(a)(5)(B), and

(B) duplicate discounts pertaining to the rebate under section 1927 of the Social Security Act, section 340B(a)(5)(A);

(2) in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits; and

(3) at the Manufacturer's expense.

(c) No provision in the Agreement shall prohibit the Manufacturer from charging a price for a drug that is lower than the ceiling price as described in section II(a) of the Agreement.

(d) In the event of a transfer in ownership of the Manufacturer, the Agreement is automatically assigned to the new owner.

(e) Nothing in the Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, the Agreement will be construed in all respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.

(f) Nothing in the Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, or Federal laws, or State laws.

(g) The Agreement shall be construed in accordance with Federal common law, and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(h) Except for changes of addresses, the Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.

(i) In the event that a due date falls on a weekend or Federal holiday, items will be due on the first business day following that weekend or Federal holiday.

VIII. EFFECTIVE DATE

The Agreement will be effective upon signing but will in no way alter the effective date upon which drug discounts were to be given to covered entities under any previously signed Pharmaceutical Pricing Agreement between the Secretary and the Manufacturer.

IX. SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____

Title: Associate Administrator
Healthcare Systems Bureau
Health Resources and Services Administration

Date: _____

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments, or other changes to this pricing agreement.

By: _____ Printed Name: _____
(Signature)

Title: _____

Phone Number: _____ Ext. _____ **FAX Number:** _____

e-Mail Address:_____

Date: _____

Manufacturer Labeler Code(s): _____

Name of Manufacturer: _____

Manufacturer Address: _____

_____

_____

_____

Contact Person: _____

Title: _____

Phone Number: _____ Ext. _____ **FAX Number:** _____

e-Mail Address:_____