ADDENDUM –Updated Agreement: National Drug Rebate Agreement Between the Secretary of Health and Human Services (Hereinafter referred to as "the Secretary") and the Manufacturer

The Secretary, on behalf of the U.S. Department of Health and Human Services and all states which have a Medicaid State Plan approved under 42 U.S.C. 1396a, and the manufacturer, on its own behalf, for purposes of section 1927 of the Social Security Act ("the Act"), 42 U.S.C. 1396r-8, 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 section 1927 of the Act and implementing Federal regulations, as interpreted and applied herein:

(a) "Average Manufacturer Price (AMP)" will have the meaning set forth in section 1927(k)(1) of the Act as implemented by 42 CFR 447.504.

(b) "Base Consumer Price Index-Urban (CPI-U)" is the CPI-U for September, 1990. For drugs approved by the Food and Drug Administration (FDA) after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

(c) "Base Date AMP" will have the meaning set forth in sections 1927(c)(2)(A)(ii)(II) and 1927(c)(2)(B) of the Act.

(d) "Best Price" will have the meaning set forth in section 1927(c)(1)(C) of the Act as implemented by 42 CFR 447.505.

(e) "Bundled Sale" will have the meaning set forth in 42 CFR 447.502.

(f) "Centers for Medicare & Medicaid Services (CMS)" means the agency of the U.S. Department of Health and Human Services having the delegated authority to operate the Medicaid Program.

(g) "Consumer Price Index-Urban (CPI-U)" will have the meaning set forth in 42 CFR 447.502.

(h) "Covered Outpatient Drug" will have the meaning set forth in sections 1927(k)(2), (k)(3) and (k)(4) of the Act as implemented by 42 CFR 447.502.

(i) "Depot Price" means the price(s) available to any depot of the federal government, for purchase of drugs from the Manufacturer through the depot system of procurement.

(j) "Innovator Multiple Source Drug" will have the meaning as set forth in section 1927(k)(7)(A)(ii) of the Act as implemented by 42 CFR 447.502.

(~~j~~k) "Manufacturer" will have the meaning as set forth in section 1927(k)(5) of the Act as implemented by 42 CFR 447.502.

(~~k~~l) "Marketed" means that a covered outpatient drug is available for sale by a manufacturer in the states.

(~~l~~m) "Monthly AMP" will have the meaning as set forth in 42 CFR 447.510.

(~~m~~n) ~~"~~"Multiple Source Drug~~"~~" will have the meaning as set forth in section 1927(k)(7)(A)(i) of the Act as implemented by 42 CFR 447.502.

(~~n~~o) "National Drug Code (NDC)" will have the meaning as set forth in 42 CFR 447.502.

(~~o~~p) "Non-innovator Multiple Source Drug" will have the meaning as set forth in section 1927(k)(7)(A)(iii) of the Act as implemented by 42 CFR 447.502.

(~~p~~q) "Quarterly AMP" will have the meaning as set forth in 42 CFR 447.504.

(~~q~~r) "Rebate period" will have the meaning as set forth in section 1927(k)(8) of the Act as implemented by 42 CFR 447.502.

(~~r~~s) "Secretary" means the Secretary of the U.S. Department of Health and Human Services, or any successor thereto, or any officer or employee of the U.S. Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated. In this agreement, references to CMS indicate such successor authority.

(~~s) "~~t) "Single-Award Contract" means a contract between the federal government and a Manufacturer resulting in a single supplier for a Covered Outpatient Drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single award contract.

(u) "Single-Award Contract Price" means a price established under a Single-Award Contract.

(v) "Single Source Drug" will have the meaning set forth in section 1927(k)(7)(A)(iv) of the Act as implemented by 42 CFR 447.502.

(~~t~~w) "State Drug Utilization Data" means the total number of both fee-for-service (FFS) and managed care organization (MCO) units of each dosage form and strength of the manufacturer's covered outpatient drugs ~~reimbursed~~ dispensed and/or paid for, as applicable during a rebate period under a Medicaid State Plan, other than units dispensed to Medicaid beneficiaries that were purchased by covered entities through the drug discount program under section 340B of the Public Health Service Act; state utilization data is supplied on the CMS-R-144 form (OMB control number: 0938-0582) (that is, the state rebate invoice).

(~~u~~x) "States" will have the meaning as set forth in 42 CFR 447.502.

(~~v~~y) "State Medicaid Agency" means the agency designated by a state under sections 1902(a)(5) and 1927(k)(9) of the Act to administer or supervise the administration of the Medicaid program.

(~~w~~z) "Unit" means drug unit in the lowest dispensable amount. The manufacturer will specify the unit information associated with each covered outpatient drug per the instructions provided in CMS-367c (OMB control number 0938-0578).

(~~x~~aa) "Unit Rebate Amount (URA)" means the computed amount to which the state drug utilization data is applied by states in invoicing the ~~manufacturer for the rebate payment due.~~

(~~y~~bb) "United States" will have the meaning as set forth in 42 CFR 447.502.

(~~z~~cc) "Wholesaler" will have the meaning as set forth in section 1927(k)(11) of the Act as implemented by 42 CFR 447.502.

II. Manufacturer's Responsibilities

In order for the Secretary to authorize that a state receive payment for the manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the manufacturer agrees to the requirements as implemented by 42 CFR 447.510 and the following:

(a) The manufacturer shall identify an individual point of contact for the Legal, Invoice, and Technical contacts at a United States address to facilitate the necessary communications with states with respect to rebate invoice issues.

(b) Beginning with the quarter in which the National Drug Rebate Agreement (rebate agreement) is signed for all covered outpatient drugs of all labeler codes of a manufacturer, calculate, and report all required pricing data on every covered outpatient drug by NDC in accordance with section 1927 of the Act and as implemented by 42 CFR 447.510. Furthermore, except as provided under section V.(b). of this agreement, manufacturers are required to calculate a URA and make a rebate payment in accordance with each calculated URA to each State Medicaid Agency for the manufacturer's covered outpatient drug(s) by NDC paid for by the state during a rebate period. CMS may calculate a URA based on manufacturer-submitted product and pricing data and provide the URA to states in order to facilitate rebate billing. However, CMS's URA calculation does not relieve the manufacturer of its responsibility to calculate the URA.

(c) In accordance with the specifications pursuant to Office of Management and Budget (OMB)-approved CMS-367c form, report all covered outpatient drugs and corresponding drug product, pricing, and related data to the Secretary, upon entering into this agreement. This information is to be updated as necessary to include new NDCs and updates to existing NDCs. CMS uses drug information listed with FDA, such as Marketing Category and Drug Type, to be able to verify ~~in some cases~~ that an NDC meets the definition of a covered outpatient drug, therefore, manufacturers should ensure that their NDCs are electronically listed with FDA. Reports to CMS should include all applicable NDCs identifying the drug product which may be dispensed to a beneficiary, including package NDCs (outer package NDCs and inner package NDCs).

(d) Beginning with the effective date quarter and in accordance with the specifications pursuant to OMB-approved CMS-367a form (OMB control number 0938-0578), report quarterly pricing data to the Secretary for all covered outpatient drugs in accordance with 42 CFR 447.510. This includes reporting for any package size which may be dispensed to the beneficiary. The manufacturer agrees to provide such information ~~within~~ not later than 30 days ~~of~~ after the ~~last day~~ end of each rebate period beginning with the effective date quarter. Adjustments to all prior quarterly pricing data ~~shall~~ must be reported ~~on at least a quarterly basis.~~ for a period not to exceed 12 quarters from when the pricing data were originally due as required under 42 CFR 447.510(b).

(e) In accordance with the OMB-approved CMS-367b form (OMB control number 0938- 0578), report information including monthly AMPs and monthly AMP units for all covered outpatient drugs in accordance with 42 CFR 447.510. The manufacturer agrees to provide such information ~~within~~ not later than 30 days ~~of~~ after the end of the month of the effective date, and ~~within~~ not later than 30 days after the end of each month thereafter.

(f) Except as provided under V.(b)., to make rebate payments ~~within~~ not later than 30 days after receiving the state rebate invoice. The manufacturer is responsible for timely payment of the rebate within 30 days so long as the state invoice contains, at a minimum, the number of units paid by NDC in accordance with 1927(b)(1) of the Act. To the extent that changes in product, pricing, or related data cause increases to previously-submitted total rebate amounts, the manufacturer will be responsible for timely payment of those increases in the same 30-day time frame as the current rebate invoice. To the extent that changes in product, pricing, or related data cause decreases to previously-submitted total rebate amounts, the manufacturer should communicate with the states regarding where to apply the line-item (NDC-level) credit.

(g) To comply with the conditions of 42 U.S.C. section 1396r-8, changes thereto, implementing regulations, agency guidance and this Agreement.

(h) In accordance with 1927(a)(1) of the Act, rebate agreements between the Secretary and the manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall have a mandatory effective date equal to the first day of the rebate period that begins more than 60 days after the date the agreement is entered into. Rebate agreements entered into on or after November 29, 1999 will also have an effective date equal to the date the rebate agreement is entered into that will permit optional state coverage of the manufacturer's NDCs as of that date.

(i) To obtain and maintain access to the system used by the Medicaid Drug Rebate program, use that system to report required data to CMS, and ensure that their contact information is kept updated as required in the OMB-approved CMS-367d form (OMB control number 0938-0578).

(j) To continue to make a rebate payment on all of its covered outpatient drugs for as long as an agreement with the Secretary is in force and state utilization data reports that payment was made for that drug, regardless of whether the manufacturer continues to market that drug. If there are no sales by the manufacturer during a rebate period, the AMP and best price reported in the prior rebate period should be used in calculating rebates.

(k) To keep records (written or electronic) of the data and any other material from which the calculations of AMP and best price were derived in accordance with 42 CFR 447.510, and make such records available to the Secretary upon request. In the absence of specific guidance in section 1927 of the Act, federal regulations and the terms of this agreement, the manufacturer may make reasonable assumptions in its calculations of AMP and best price, consistent with the purpose of section 1927 of the Act, federal regulations and the terms of this agreement. A record (written or electronic) explaining these assumptions must also be maintained by the manufacturer in accordance with the recordkeeping requirements in 42 CFR ~~447.534~~447.510, and such records must be made available to the Secretary upon request.

(l) To notify CMS of any filing of bankruptcy, and to transmit such filing to CMS within seven days of the date of filing.

III. Secretary's Responsibilities

(a) The Secretary will employ best efforts to ensure the State Medicaid Agency shall report to the manufacturer, ~~within~~ not later than 60 days ~~of~~ after the last day of each rebate period, the rebate invoice (CMS-R-144) or the minimum utilization information as described in section II.(f). of this agreement, that is, information about Medicaid utilization of covered outpatient drugs that were dispensed and/or paid for, as applicable, during the rebate period. Additionally, the Secretary will expect any changes to prior quarterly state drug utilization data to be reported at the same time.

(b) The Secretary may survey those wholesalers and manufacturers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as set forth in section 1927(b)(3)(B) of the Act and section IV of this agreement.

(c) The Secretary may audit manufacturer information reported under section 1927(b)(3)(A) of the Act.

IV. Penalty Provisions

(a) The Secretary may impose a civil monetary penalty under section III.(b)~~,~~. as set forth in 1927(b)(3)(B) of the Act and applicable regulations, on a wholesaler, manufacturer, or direct seller of a covered outpatient drug, if a wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request by the Secretary, or the Secretary's designee, for information about covered outpatient drug charges or prices in connection with a survey or knowingly provides false information, including in any of its quarterly reports to the Secretary. The provisions of section 1128A of the Act (other than subsection (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B) of the Act and applicable regulations.

(b) The Secretary may impose a civil monetary penalty, for each item of false information as set forth in 1927(b)(3)(C)(ii) of the Act and applicable regulations.

(c) The Secretary may impose a civil monetary penalty for failure to provide timely information on AMP, best price or base date AMP. The amount of the penalty shall be determined as set forth in 1927(b)(3)(C)(i) of the Act and applicable regulations.

(d) Nothing in this Agreement shall be construed to limit the remedies available to the United States government or the states for a violation of this Agreement or any other provision of law.

V. Dispute Resolution

(a) In the event a manufacturer discovers a potential discrepancy with state drug utilization data on the rebate invoice, which the manufacturer and state in good faith are unable to resolve prior to the payment due date, the manufacturer will submit a Reconciliation of State Invoice (ROSI) form, the CMS-304 (OMB control number: 0938-0676), to the state. If such a discrepancy is discovered for a prior rebate period's invoice, the manufacturer will submit a Prior Quarter Adjustment Statement (PQAS) form, CMS-304a (OMB control number: 0938- 0676), to the state.

(b) If the manufacturer disputes in good faith any part of the state drug utilization data on the rebate invoice, the manufacturer shall pay the state for the rebate units not in dispute within the required due date in II.(f). Upon resolution of the dispute, the manufacturer will either pay the balance due, if any, plus interest as set forth in section 1903(d)(5) of the Act, or be issued a credit by the state by the due date of the next quarterly payment in II(f).

(c) The state and the manufacturer will use their best efforts to resolve a dispute arising under (a) or (b) above within ~~60 days of~~ a reasonable time frame after the state's receipt of the manufacturer's ROSI/PQAS. In the event that the state and manufacturer are not able to resolve the dispute within ~~60 days, CMS shall require~~ a reasonable time frame, CMS will employ best efforts to ensure the state ~~to make~~ makes available to the manufacturer the same state hearing mechanism available to providers for Medicaid payment disputes (42 CFR 447.253(e)).

(d) Nothing in this section shall preclude the right of the manufacturer to audit the state drug utilization data reported (or required to be reported) by the state. The Secretary encourages the manufacturer and the state to develop mutually beneficial audit procedures.

(e) The state hearing mechanism is not binding on the Secretary for purposes of the Secretary's authority to implement the civil money penalty provisions of the statute or this agreement.

VI. Confidentiality Provisions

(a) Pursuant to section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the manufacturer in connection with this agreement is confidential and, notwithstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the manufacturer, or prices charged by the manufacturer, except as authorized under section 1927(b)(3)(D).

(b) The manufacturer will hold state drug utilization data confidential. If the manufacturer audits this information or receives further information on such data, that information shall also be held

confidential. Except where otherwise specified in the Act or agreement, the manufacturer will observe confidentiality statutes, regulations, and other properly promulgated policy concerning such data.

(c) Notwithstanding the nonrenewal or termination of this agreement for any reason, these confidentiality provisions will remain in full force and effect.

VII. Nonrenewal and Termination

(a) Unless otherwise terminated by either party pursuant to the terms of this agreement, the agreement shall be effective beginning on the date specified in section II.(h). of this agreement and shall be automatically renewed for additional successive terms of one year from the date specified in section II.(h)., unless the manufacturer gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.

(b) In accordance with section VII.(a). of this agreement and section 1927(b)(4)(B)(ii) of the Act, the manufacturer may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first rebate period beginning 60 days after the manufacturer gives written notice requesting termination, or CMS initiates termination via written notice to the manufacturer. The Secretary may terminate the agreement for failure of a manufacturer to make rebate payments to the state(s), failure to report required data, for other violations of this agreement, or other good ~~cause~~ causes upon 60 days prior written notice to the manufacturer of the existence of such violation or other good ~~cause~~ causes. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(c) Manufacturers on the Office of Inspector General's (OIG's) List of Excluded Individuals/Entities (Exclusion List) will be subject to immediate termination from the Medicaid drug rebate program unless and until the manufacturer is reinstated by the OIG. Appeals of exclusion and any reinstatement will be handled in accordance with section 1128 of the Act and applicable regulations. Manufacturers that are on the OIG Exclusion List and are reinstated by the OIG under certain circumstances may be evaluated for reinstatement to the Medicaid drug rebate program by CMS. Reinstatement to the Medicaid drug rebate program would be for the next rebate period that begins more than 60 days from the date of the OIG's reinstatement of the manufacturer after exclusion.

(d) If this rebate agreement is terminated, the manufacturer is prohibited from entering into another rebate agreement as set forth in section 1927(b)(4)(C) of the Act for at least one rebate period from the effective date of the termination~~, and the~~. The manufacturer ~~addresses~~ must also address to the satisfaction of CMS any outstanding violations from any previous rebate agreement(s), including, but not limited to, payment of any outstanding rebates and also make good faith efforts to appeal or resolve matters pending with the OIG relating to the MDRP or exclusion as referenced in subsection (c) of this section, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

VIII. General Provisions

(a) This agreement is authorized by the applicable provisions of sections 1902, 1903, 1905, and 1927 of the Act, and the implementing regulations at 42 CFR Part 447. This agreement is subject to any changes in the Medicaid statute or regulations that affect the rebate program.

(b) Any notice required to be given pursuant to the terms and provisions of this agreement will be permitted in writing or electronically. Notice to the Secretary will be sent to: Centers for Medicaid and CHIP Services~~,~~ Disabled & Elderly Health Programs Group~~,~~ Division of Pharmacy, Mail Stop S 2-14-26, 7500 Security Blvd~~.,~~ Baltimore, MD 21244~~.~~ The CMS address may be updated upon notice to the manufacturer. Notice to the manufacturer will be sent to the email and/or physical mailing address as provided under section X of this agreement and updated upon manufacturer notification to CMS at the email and/or address in this agreement.

(c) In the event of a transfer in ownership of the manufacturer, this agreement and any outstanding rebate liability are automatically assigned to the new owner subject to the conditions as set forth in section 1927 of the Act.

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

(e) Nothing in this agreement shall be construed as a waiver or relinquishment of any legal rights of the manufacturer or the Secretary under the Constitution, the Act, other federal laws, or state laws.

(f) The rebate agreement shall be construed in accordance with Federal law and ambiguities shall be interpreted in the manner which best effectuates the statutory ~~scheme~~ construct.

(g) The terms “State Medicaid Agency” and “Manufacturer” incorporate any contractors which fulfill responsibilities pursuant to the agreement unless such contractors are specifically ~~provided for~~ excluded in the rebate agreement or such exclusion is specifically agreed to by an appropriate CMS official.

(h) Except for the conditions specified in II.(g). and VIII.(a)., as well as applicable OMB-approved forms, this 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, the report or other item will be due on the first business day following that weekend or Federal holiday.

IX. CMS-367

CMS-367 attached hereto is part of this agreement.

X. Signatures

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____ Date: _____
(signature)

Title: Director Disabled and Elderly Health Programs Group
Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

ACCEPTED FOR THE MANUFACTURER

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

By: _____ _____
(signature) (please print name)

Title: _____
Name of Manufacturer: _____
Manufacturer Address _____
_____
Manufacturer Labeler Code(s): _____
Date: _____