National Drug Rebate Agreement Between The the Secretary of Health and Human Services (hereinafterHereinafter referred to as "the Secretary") and The the Manufacturer

Identified in Section XI of this Agreement (hereinafter referred to as "the Labeler")

The Secretary, on behalf of the U.S. Department of Health and Human Services and all States and the District of Columbia (except to the extent that they have in force an Individual State Agreement)states which have a Medicaid State Plan approved under 42 U.S.C. section 1396a, and the Labelermanufacturer, on its own behalf, for purposes of section 4401 of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, and section 1927 of the Social Security Act (hereinafter referred to as "the Act"), 42 U.S.C. 1396sr-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)" means, with respect to a Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that 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 Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by 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 arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized. 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" means the AMP for the 7/l/90 9/30/90 quarter for purposes of computing the AMP as of 10/l/90. For drugs approved by FDA after October 1, 1990, "Base Date AMP" means the AMP for the first day of the first month in which the drug was marketed. In order to meet this definition, the drug must have been marketed on that first day. If the drug was not marketed on that first day, "Base Date" means the AMP for the first day of the month in which the product was marketed for a full month. 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" means, with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price includes prices to wholesalers, retailers, nonprofit entities, or governmental entities within the States (excluding Depot Prices and Single Award Contract Prices of any agency of the Federal Government). Federal Supply Schedule prices are included in the calculation of the best price.~~

~~The best prices shall be inclusive of cash discounts, free goods, volume discounts, and rebates, (other than rebates under Section 1927 of the Act).~~

~~It shall be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package, and shall not take into account prices that are Nominal in amount. 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 arrangement. The best price for a quarter shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized.~~

(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" ~~refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.~~ will have the meaning set forth in 42 CFR 447.502.

(f) "Centers for Medicare & Medicaid Services (CMS)" ~~(formerly HCFA)~~ 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)" ~~means the index of consumer prices developed and updated by the U.S. Department of Commerce. As referenced in section 1927(c) of the Act, it is the CPI for all urban consumers (U.S. Average) and, except for the base CPI-U, it shall be the index for the month before the beginning of the calendar quarter for which the rebate is made.~~ will have the meaning set forth in 42 CFR 447.502.

(h) "Covered Outpatient Drug" will have the meaning ~~as~~ set forth in ~~Section~~sections 1927(k)(2), (k)(3) and (k)(4) of the Act~~, and with respect to the Manufacturer includes all such drug products meeting this definition. For purposes of coverage under this agreement, all of those Covered Outpatient Drugs are identified by the Manufacturer's labeler code segment of the NDC number. Certain Covered Outpatient Drugs, such as specified by Section 1927 (d) (1) (3) of the Act, may be restricted or excluded from Medicaid payment at State option but shall be included by the Manufacturer for purposes of this agreement.~~ 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) "Individual State Agreement" means an agreement between a State and a Manufacturer authorized or approved by CMS as meeting the requirements specified in Section 1927(a)(1) or (a)(4) of the Act. Amendments or other changes to agreements under 1927(a)(4) shall not be included in this definition unless specifically accepted by CMS.~~

~~An existing agreement that met these requirements as of the date of enactment of P.L. No. 101-508 (November 5, 1990), can be modified to give a greater rebate percentage.~~

(~~k~~i) "Innovator Multiple Source Drug" will have the meaning as set forth in ~~Section~~section 1927(k)(7)(A)(ii) of the Act ~~and shall include all Covered Outpatient Drugs approved under a New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA) or Antibiotic Drug Approval (ADA). A Covered Outpatient Drug marketed by a cross-licensed producer or distributor under the approved NDA shall be included as an innovator multiple source drug when the drug product meets this definition.~~as implemented by 42 CFR 447.502.

(~~l~~j) "Manufacturer" will have the meaning as set forth in ~~Section~~section 1927(k)(5) of the Act ~~except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug.~~as implemented by 42 CFR 447.502.

(~~m~~k) "Marketed" means that a covered outpatient drug ~~was first sold~~is available for sale by a manufacturer in ~~the States after FDA approval.~~ the states.

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

~~(n) "Medicaid Utilization Information" means the information on the total number of units of each dosage form and strength of the Manufacturer's Covered Outpatient Drugs reimbursed during a quarter under a Medicaid State Plan. This information is based on claims paid by the State Medicaid Agency during a calendar quarter and not drugs that were dispensed during a calendar quarter (except it shall not include drugs dispensed prior to January 1, 1991). The Medicaid Utilization Information to be supplied includes: 1) NDC number; 2) Product name; 3) Units paid for during the quarter by NDC number; 4) Total number of prescriptions paid for during the quarter by NDC number; and 5) Total amount paid during the quarter by NDC number. A State may, at its option, compute the total rebate anticipated, based on its own records, but it shall remain the responsibility of the labeler to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.~~

(m) "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.

(~~o~~n) "National Drug Code (NDC)" ~~is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this agreement the complete 11 digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code. For the purposes of making Rebate Payments, Manufacturers must accept the NDC number without package size code from States that do not maintain their records by complete NDC number.~~ will have the meaning as set forth in 42 CFR 447.502.

~~(p) "Net Sales" means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid; and as further defined under the definition of AMP.~~

~~(q) "New Drug" means a Covered Outpatient Drug approved as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act.~~

~~(r) "New Drug Coverage" begins with the date of FDA approval of the NDA, PLA, ELA or ADA, for a period of six months from that date, with the exception of drugs not under the rebate agreement or classes of drugs States elect to exclude.~~

~~(s) "Nominal Price", for purposes of excluding prices from the Best Price calculation, means any price less than 10% of the AMP in the same quarter for which the AMP is computed.~~

(~~t~~o) "Non-innovator Multiple Source Drug" ~~shall~~will have the meaning as set forth in ~~Section~~section 1927(k)(7)(A)(iii) of the Act~~. It also includes Covered Outpatient Drugs approved under an ANDA or AADA~~ as implemented by 42 CFR 447.502.~~.~~

(~~u~~p) "~~Quarter" means calendar quarter unless otherwise specified.~~Quarterly AMP" will have the meaning as set forth in 42 CFR 447.504.

(~~v~~q) ""Rebate ~~Payment" means, with respect to the Manufacturer's Covered Outpatient Drugs, the quarterly payment by the Manufacturer to the State Medicaid Agency, calculated in accordance with section 1927 of the Act and the provisions of this agreement. The terms "Base CPI-U" and "Base Date AMP" will be applicable to the calculations under 1927(c).~~period" will have the meaning as set forth in 42 CFR 447.502.

(~~w~~r) "Secretary" means the Secretary of the ~~United States~~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.

~~(x) "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.~~

~~(y) "Single Award Contract Price" means a price established under a Single Award Contract.~~

(~~z~~s) "Single Source Drug" will have the meaning set forth in ~~Section~~section 1927~~-~~(k)~~-~~(7)~~-~~(A)~~-~~(iv) of the ~~Act. It also includes a Covered Outpatient Drug approved under a PLA, ELA or ABA.~~ Act as implemented by 42 CFR 447.502.

(t) "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 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 (that is, the state rebate invoice).

(aau) "States" means the 50 states and the District of Columbiawill have the meaning as set forth in 42 CFR 447.502.

(bbv) "State Medicaid Agency" means the agency designated by a Statestate under Sectionsections 1902(a)(5) of the Act to administer or supervise the administration of the Medicaid program.

(ccw) "Unit" means 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 Manufacturerdispensable amount. The manufacturer will specify the unit information associated with each Covered Outpatient Drug, as part of the submission of data, in accordance with the Secretary'scovered outpatient drug per the instructions provided pursuant to Appendix Ain CMS-367c.

(ddx) "Unit Rebate Amount (URA)" means the unit amount computed by the Health Care Financing Administration to which the Medicaidcomputed amount to which the state drug utilization information may bedata is applied by Statesstates in invoicing the Manufacturermanufacturer for the rebate payment due.

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

(eez) "Wholesaler" means any entity (including a pharmacy or chain of pharmacies) to which the labeler sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug. 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 Statestate receive payment for the Manufacturer'smanufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the Manufacturermanufacturer agrees to the following: requirements as implemented by 42 CFR 447.510 and the following:

(a) The manufacturer shall identify an individual point of contact 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, 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 (a) To calculate and447.510. Furthermore, except as provided under section V(b) of this agreement, to make a Rebate Payment to each State Medicaid Agency for the Manufacturer's Covered Outpatient Drugs paid for by the State Medicaid Agencymanufacturers are required to 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 quarterrebate period. A separate

~~listing of all Covered Outpatient Drugs and other information, in accordance with CMS's specifications pursuant to Appendix A, must be submitted within 30 calendar days of entering into this agreement and be updated quarterly. The Manufacturer's quarterly report is to include all new NDC numbers and continue to list those NDC numbers for drugs no longer marketed.~~

(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, 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 30 days of the last day of each rebate period beginning with the effective date quarter. Adjustments to all quarterly pricing data shall be reported on at least a quarterly basis.

(e) In accordance with the OMB-approved CMS-367b form, 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 30 days of the end of the month of the effective date, and within 30 days of each month thereafter.

(~~b~~f) Except as provided under V(b), to make ~~such~~ rebate payments ~~for each calendar quarter~~ within 30 days after receiving ~~from~~ the ~~State the Medicaid Utilization Information defined in this agreement. Although a specific amount of information has been defined in I(n) of this agreement, the Manufacturer~~state rebate invoice. The manufacturer is responsible for timely payment of the rebate within 30 days ~~of receiving~~so long as the state invoice contains, at a minimum, ~~information on~~ the number of units paid~~,~~ by NDC ~~number.~~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.

(~~e~~g) To comply with the conditions of 42 U.S.C. section 1396~~s~~r-8, changes thereto ~~and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer.~~, implementing regulations, agency guidance and this Agreement.

(~~d~~ h) In accordance with 1927(a)(1) of the Act, ~~That~~ rebate agreements between the Secretary and the ~~Manufacturer~~ manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall ~~be~~have a mandatory effective date equal to the first day of the ~~calendar quarter~~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.

~~(e) To report to the Secretary, in accordance with specifications pursuant to Appendix A, that information on the Average Manufacturer Price and, in the case of Single Source and Innovator Multiple Source Drugs, the Manufacturer's Best Price for all Covered Outpatient Drugs. The Manufacturer agrees to provide such information within 30 days of the last day of each quarter beginning with (1) the January 1, 1991 March 31, 1991 quarter or (2) the quarter in which any subsequent effective date of this agreement lies. Other information in Appendix A shall also be required within 30 days of the last day of the quarter. Adjustments to AMP or Best Price for prior quarters shall also be reported on this quarterly basis.~~

(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.

~~(f) In the case of Single Source and Innovator Multiple Source drugs, to report to the Secretary, in a manner prescribed by the Secretary, the information in Appendix A on the Base Date AMP. The Manufacturer agrees to provide such information within 30 days of the date of signing this agreement.~~

~~(g) To directly notify the States of a New Drug's Coverage.~~

(~~h~~j) To continue to make a ~~Rebate Payment~~ rebate payment ~~on~~ on all of its ~~Covered Outpatient Drugs~~ covered outpatient drugs ~~for~~ for as long as an agreement with the Secretary is in force and ~~State Medicaid Utilization Information~~state utilization data reports that payment was made for that drug, regardless of whether the ~~Manufacturer~~manufacturer continues to market that drug. If there are no sales by the ~~Manufacturer~~manufacturer during a ~~quarter~~rebate period, the AMP and ~~Best Price last~~best price reported ~~continue to be used in calculating rebates.~~in the prior rebate period should be used in calculating rebates.

(~~i~~k) To keep records (written or electronic) of the data and any other material from which the calculations of AMP and ~~Best Price~~ 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~~federal regulations and the terms of this agreement, the ~~Manufacturer~~manufacturer may make reasonable assumptions in its calculations of AMP and ~~Best Price~~best price, consistent with the ~~intent~~ purpose of section 1927 of the Act, ~~Federal~~federal regulations and the terms of this agreement. A record (written or electronic) ~~outlining~~explaining these assumptions must also be maintained~~.~~ by the manufacturer in accordance with the recordkeeping requirements in 42 CFR 447.534, 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 ~~use his~~employ best efforts to ensure ~~that~~ the State ~~agency will~~Medicaid Agency shall report ~~–~~to the ~~Manufacturer~~manufacturer, within 60 days of the last day of each ~~quarter, and in a manner prescribed by the Secretary, Medicaid Utilization Information paid for during the quarter.~~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 paid for 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 ~~Manufacturers and Wholesalers~~wholesalers and manufacturers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as ~~provided~~set forth in section 1927(b)(3)(B) of the Act and section IV of this agreement.

(c) The Secretary may audit ~~Manufacturer calculations of AMP and Best Price.~~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), ~~up to $100,000 for each item, on a wholesaler, manufacturer, or direct~~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~~covered outpatient drug, if a wholesaler, manufacturer, or direct seller of a ~~Covered Outpatient Drug~~ covered outpatient drug refuses a request by the Secretary, or the Secretary's designee, for information about covered outpatient drug charges or prices ~~by the Secretary 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, ~~in an amount not to exceed $100,000,~~ 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~~best price or base date AMP. The amount of the penalty shall be ~~increased by $10,000 for each day in which such information has not been provided,~~ 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 or the states for a violation of this Agreement or any other provision of law.

V. Dispute Resolution ~~MEDICAID UTILIZATION INFORMATION~~

(a) In the event ~~that in any quarter a discrepancy in Medicaid Utilization Information is discovered by the Manufacturer, which the Manufacturer and the State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy, by NDC number, to the State Medicaid Agency prior to the due date in II(b).~~ 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, 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, to the state.

(b) If the ~~Manufacturer~~ 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 ~~in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II (b). The~~ balance due, if any, plus ~~a reasonable rate of~~ interest as set forth in section 1903(d)(5) of the Act, ~~will be paid or credited~~or be issued a credit by the ~~Manufacturer or the State~~state by the due date of the next quarterly payment in II(~~b~~f) ~~after resolution of the dispute~~.

(c) The ~~State~~state and the ~~Manufacturer~~manufacturer will use their best efforts to resolve ~~the discrepancy within 60 days of receipt of such notification.~~a dispute arising under (a) or (b) above within 60 days of the state's receipt of the manufacturer's ROSI/PQAS. In the event that the ~~State~~state and ~~the Manufacturer~~manufacturer are not able to resolve ~~a discrepancy~~the dispute within 60 days, CMS shall require the ~~State~~state to make available to the ~~Manufacturer the State~~manufacturer the same state hearing ~~mechanism available under the Medicaid Program (42 Code of Federal Regulations section 447.253 (c)).~~ mechanism available to providers for Medicaid payment disputes.

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

~~(e) Adjustments to Rebate Payments shall be made if information indicates that either Medicaid Utilization Information, AMP or Best Price were greater or less than the amount previously specified.~~

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

~~VI DISPUTE RESOLUTION -- PRESCRIPTION DRUGS ACCESS AND STATE SYSTEMS ISSUES~~

~~(a) A State's failure to comply with the drug access requirements of section 1927 of the Act shall be cause for the Manufacturer to notify CMS and for CMS to initiate compliance action against the State under section 1904 of the Act. A request for compliance action may also occur when the Manufacturer shows a pattern or history of inaccuracy in Medicaid Utilization Information.~~
~~(b) Such compliance action by CMS will not relieve the Manufacturer from its obligation of making the Rebate Payment as provided in section 1927 of the Act and this agreement.~~

~~VII~~VI. Confidentiality Provisions

(a) Pursuant to ~~Section~~section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the ~~Manufacturer~~ manufacturer in connection with this ~~Agreement~~ agreement is confidential and, not withstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the ~~Manufacturer~~manufacturer, or prices charged by the ~~Manufacturer~~manufacturer, except as ~~necessary by the Secretary to carry out the provisions of section 1927 of the Act, and to permit review~~ authorized under section ~~1927 of the Act by the Comptroller General.~~ 1927(b)(3)(D).

(b) The ~~Manufacturer~~ manufacturer will hold ~~State Medicaid Utilization Information~~ state drug utilization data confidential. If the ~~Manufacturer~~ 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~~ manufacturer will observe ~~State~~ confidentiality statutes, regulations, and other properly promulgated policy concerning such data.

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

~~VIII~~VII. Nonrenewal And Termination

(a) Unless otherwise terminated by either party pursuant to the terms of this ~~Agreement~~agreement, the ~~Agreement~~ agreement shall be effective ~~for an initial period of one year~~ beginning on the date specified in section II(~~d~~h) of this agreement and shall be automatically renewed for additional successive terms of one year unless the ~~Labeler~~ 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, the manufacturer ~~The Manufacturer~~ may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first ~~calendar quarter~~rebate period beginning 60 days after the ~~Manufacturer~~manufacturer gives written notice ~~requesting termination, or the ending date of the term of the agreement if notice has been given in accordance with VII(a).~~ requesting termination, or CMS initiates termination via written notice to the manufacturer.

~~(c)~~ The Secretary may terminate the agreement ~~Agreement~~ for ~~violations of this agreement or~~ 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 upon 60 days prior written notice to the ~~Manufacturer~~manufacturer of the existence of such violation or other good cause. The Secretary shall provide, upon request, a ~~Manufacturer~~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 ~~nonrenewed or~~ terminated, the ~~Manufacturer~~manufacturer is prohibited from entering into another rebate agreement as ~~provided~~set forth in section 1927(b)(4)(C) of the Act ~~until a period of one calendar quarter has elapsed from the effective date of the termination,~~for at least one rebate period from the effective date of the termination, and the manufacturer addresses 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 good faith efforts to appeal or resolve matters pending with the OIG, 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.

~~IX~~VIII. General Provisions

(a) This agreement is subject to any changes in the Medicaid statute or regulations that affect the rebate program.

(~~a~~b) Any notice required to be given pursuant to the terms and provisions of this ~~Agreement will be sent in writing.~~agreement will be permitted in writing or electronically.

Notice to the Secretary will be sent to:

~~Center~~Centers for Medicaid and ~~State Operations~~CHIP Services
~~Family and Children's~~Disabled & Elderly Health Programs Group
Division of ~~Benefits, Coverage and Payment~~Pharmacy
~~Post Office Box 26686~~
Mail Stop S2-14-26
7500 Security Blvd
Baltimore, MD ~~21207-0486~~21244

~~Notices to CMS concerning data transfer and information systems issues are to be sent to:~~

~~Center for Medicaid and State Operations~~
~~Finance, Systems and Quality Group~~
~~Division of State Systems~~
~~Post Office Box 26686~~
~~Baltimore, MD 21207-0486~~

The CMS address may be updated upon ~~written~~ notice to the ~~Manufacturer~~manufacturer.~~-~~ Notice to the ~~Manufacturer~~manufacturer will be sent to the email and/or physical mailing address as provided ~~with~~under section X of this agreement and updated upon ~~Manufacturer~~manufacturer notification to CMS at the email and/or address in this agreement.

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

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

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

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

(~~f~~g) The terms "State Medicaid Agency" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the agreement unless specifically provided for in the rebate agreement or specifically agreed to by an appropriate CMS official.

(~~g~~h) Except for the conditions specified in II(~~e~~g) and ~~IX~~VIII(a), this ~~Agreement~~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~~manufacturer.~~-~~

(~~h~~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. ~~X~~ CMS-367 ~~APPENDIX~~

~~Appendix A~~CMS-367 attached hereto is part of this agreement.

~~XI~~X. Signatures

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____ Date: _____
_____ (signature)

Title: ~~Deputy~~ Director~~-~~
~~Finance, Systems and Quality~~Disabled and Elderly Health Programs Group~~-~~
Center for Medicaid and ~~State Operations~~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: _____