NEW YORK
state department of
HEALTH

Howard A. Zucker, M.D., J.D.
Acting Commissioner of Health

Sue Kelly
Executive Deputy Commissioner

DEC 31 2014

Mr. Michael Melendez
Associate Regional Administrator
Department of Health & Human Services
Centers for Medicare & Medicaid Services
New York Regional Office
Division of Medicaid and Children's Health Operations
26 Federal Plaza - Room 37-100 North
New York, New York 10278

RE: SPA #14-038
Non-Institutional Services

Dear Mr. Melendez:

The State requests approval of the enclosed amendment #14-038 to the Title XIX (Medicaid) State Plan for non-institutional services to be effective October 1, 2014 (Appendix I). This amendment is being submitted based on State legislation. A summary of the plan amendment is provided in Appendix II.

The State of New York reimburses these services through the use of rates that are consistent with and promote efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area as required by §1902(a)(30) of the Social Security Act and 42 CFR §447.204.

Copies of pertinent sections of State legislation are enclosed for your information (Appendix III).

If you have any questions regarding this State Plan Amendment submission, please do not hesitate to contact John E. Ulberg, Jr., Medicaid Chief Financial Officer, Division of Finance and Rate Setting at (518) 474-6350.

Sincerely,

Jason A. Helgerson
Medicaid Director
Office of Health Insurance Programs

Enclosures

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL **FOR: HEALTH CARE FINANCING ADMINISTRATION**	1. TRANSMITTAL NUMBER: **14-038**	2. STATE **New York**
	3. PROGRAM IDENTIFICATION: **TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)**	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE **October 1, 2014**	

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION: **§1902 of the Social Security Act, and 42 CFR 447**	7. FEDERAL BUDGET IMPACT: **a. FFY 10/01/14-09/30/15 $ (468,893)** **b. FFY 10/01/15-09/30/16 $ (30,967,293)**
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: **Attachment 3.1-A Supplement: Page 2(b)** **Attachment 3.1-B Supplement: Page 2(b)**	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: **Attachment 3.1-A Supplement: Page 2(b)** **Attachment 3.1-B Supplement: Page 2(b)**

10. SUBJECT OF AMENDMENT:
State Specific Supplemental Rebate Agreement
(FMAP = 50%)

11. GOVERNOR'S REVIEW *(Check One)*:
☒ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☐ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL:	16. RETURN TO: **New York State Department of Health** **Bureau of Federal Relations & Provider Assessments** **99 Washington Ave – One Commerce Plaza** **Suite 1460** **Albany, NY 12210**
13. TYPED NAME: **Jason A. Helgerson**	
14. TITLE: **Medicaid Director** **Department of Health**	
15. DATE SUBMITTED: DEC 31 2014	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:	18. DATE APPROVED:
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL:	20. SIGNATURE OF REGIONAL OFFICIAL:
21. TYPED NAME:	22. TITLE:

23. REMARKS:

Appendix I
2014 Title XIX State Plan
Fourth Quarter Amendment
Amended SPA Pages

New York
2(b)

10. Prior approval is required for all dental care except preventive prophylactic and other routine dental care services and supplies.

12a. Prior authorization or dispensing validation is required for some prescription drugs. The State has established a preferred drug program with prior authorization for drugs not included on the preferred drug list. The prior authorization complies with the requirements of Section 1927(d)(5) of the Social Security Act and provides for a 24-hour turnaround by either telephone or other telecommunications device from receipt of request and provides for a 72-hour supply of drugs in emergency circumstances. In addition, brand-name drugs that have a FDA approved, A-rated generic equivalent must be prior authorized unless exempted by the Commissioner of Health. Prior authorization is required for a generic equivalent of a brand name drug, including a generic equivalent that is on the preferred drug list or the clinical drug review program, when the net cost of the brand name drug, after consideration of all rebates, is less than the cost of the generic equivalent.

Drugs for which Medical Assistance reimbursement is available are limited to the following:

1. Outpatient drugs of any manufacturer which has entered into and complies with a rebate agreement under Sections 1902(a)(54) and 1927(a) of the Act with the Centers for Medicare and Medicaid Services (CMS) which are prescribed for a medically accepted indication. All drugs covered by the National Drug Rebate Agreements remain available to Medicaid beneficiaries, although some may require prior authorization. Drugs for the treatment of erectile dysfunction, as set forth in 42 U.S.C. §1396r-8(d)(2)(K), are not a covered service, on and after April 1, 2006, unless such drugs are used to treat conditions other than sexual or erectile dysfunction and these uses have been approved by the Food and Drug Administration.

2. Supplemental Rebate Programs

   The State is in compliance with Section 1927 of the Social Security Act. The State has the following policies for the Supplemental Rebate Programs for the Medicaid population.

   a) CMS has authorized the State of New York to enter into the National Medicaid Pooling Initiative (NMPI) for drugs provided to Medicaid beneficiaries. The NMPI Supplemental Rebate Agreement (SRA) and the Amendment to the SRA submitted to CMS on March 30, 2006 have been authorized for pharmaceutical manufacturers' existing agreements through their current expiration dates. The updated NMPI SRA submitted to CMS on June 30, 2013 has been authorized for renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid beneficiaries.

   b) CMS has authorized the State of New York to enter into Medicaid State-specific Supplemental Rebate Agreement directly with manufacturers to receive supplemental rebates of covered outpatient drugs for Medicaid beneficiaries. The State-specific Supplemental Rebate Agreement was submitted to CMS on March 31, 2010 and has been authorized by CMS. The updated State-specific Supplemental Rebate Agreement submitted to CMS on March 31, 2010 has been authorized for renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid beneficiaries.

New York
2(b)

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Appendix II
2014 Title XIX State Plan
Fourth Quarter Amendment
Summary

SUMMARY
SPA #14-038

This State Plan Amendment proposes to revise the State Rebate Agreement previously approved by CMS to include definitions and structural changes that would provide the option of including Medicaid managed care utilization for accrual of supplemental rebates.

Appendix III
2014 Title XIX State Plan
Fourth Quarter Amendment
Authorizing Provisions

Public Health

§ 272. Preferred drug program. 1. There is hereby established a preferred drug program to promote access to the most effective prescription drugs while reducing the cost of prescription drugs for persons in state public health plans.

2. When a prescriber prescribes a non-preferred drug, state public health plan reimbursement shall be denied unless prior authorization is obtained, unless no prior authorization is required under this article.

3. The commissioner shall establish performance standards for the program that, at a minimum, ensure that the preferred drug program and the clinical drug review program provide sufficient technical support and timely responses to consumers, prescribers and pharmacists.

4. Notwithstanding any other provision of law to the contrary, no preferred drug program or prior authorization requirement for prescription drugs, except as created by this article, paragraph (a-1) or (a-2) of subdivision four of section three hundred sixty-five-a of the social services law, paragraph (g) of subdivision two of section three hundred sixty-five-a of the social services law, subdivision one of section two hundred forty-one of the elder law and shall apply to the state public health plans.

5. The drug utilization review board shall consider and make recommendations to the commissioner for the adoption of a preferred drug program. (a) In developing the preferred drug program, the board shall, without limitation: (i) identify therapeutic classes or drugs to be included in the preferred drug program; (ii) identify preferred drugs in each of the chosen therapeutic classes; (iii) evaluate the clinical effectiveness and safety of drugs considering the latest peer-reviewed research and may consider studies submitted to the federal food and drug administration in connection with its drug approval system; (iv) consider the potential impact on patient care and the potential fiscal impact that may result from making such a therapeutic class subject to prior authorization; and (v) consider the potential impact of the preferred drug program on the health of special populations such as children, the elderly, the chronically ill, persons with HIV/AIDS and persons with mental health conditions.

(b) In developing the preferred drug program, the board may consider preferred drug programs or evidence based research operated or conducted by or for other state governments, the federal government, or multi-state coalitions. Notwithstanding any inconsistent provision of section one hundred twelve or article eleven of the state finance law or section one hundred forty-two of the economic development law or any other law, the department may enter into contractual agreements with the Oregon Health and Science University Drug Effectiveness Review Project to provide technical and clinical support to the board and the department in researching and recommending drugs to be placed on the preferred drug list.

(c) The board shall from time to time review all therapeutic classes included in the preferred drug program, and may recommend that the commissioner add or delete drugs or classes of drugs to or from the preferred drug program, subject to this subdivision.

(d) The board shall establish procedures to promptly review prescription drugs newly approved by the federal food and drug administration.

6. The board shall recommend a procedure and criteria for the approval of non-preferred drugs as part of the prior authorization process. In developing these criteria, the board shall include consideration of the

following:

(a) the preferred drug has been tried by the patient and has failed to produce the desired health outcomes;

(b) the patient has tried the preferred drug and has experienced unacceptable side effects;

(c) the patient has been stabilized on a non-preferred drug and transition to the preferred drug would be medically contraindicated; and

(d) other clinical indications for the use of the non-preferred drug, which shall include consideration of the medical needs of special populations, including children, the elderly, the chronically ill, persons with mental health conditions, and persons affected by HIV/AIDS.

7. The commissioner shall provide thirty days public notice on the department's website prior to any meeting of the board to develop recommendations concerning the preferred drug program. Such notice regarding meetings of the board shall include a description of the proposed therapeutic class to be reviewed, a listing of drug products in the therapeutic class, and the proposals to be considered by the board. The board shall allow interested parties a reasonable opportunity to make an oral presentation to the board related to the prior authorization of the therapeutic class to be reviewed. The board shall consider any information provided by any interested party, including, but not limited to, prescribers, dispensers, patients, consumers and manufacturers of the drug in developing their recommendations.

8. The commissioner shall provide notice of any recommendations developed by the board regarding the preferred drug program, at least five days before any final determination by the commissioner, by making such information available on the department's website. Such public notice may include: a summary of the deliberations of the board; a summary of the positions of those making public comments at meetings of the board; the response of the board to those comments, if any; and the findings and recommendations of the board.

9. Within ten days of a final determination regarding the preferred drug program, the commissioner shall provide public notice on the department's website of such determinations, including: the nature of the determination; and analysis of the impact of the commissioner's determination on state public health plan populations and providers; and the projected fiscal impact to the state public health plan programs of the commissioner's determination.

10. The commissioner shall adopt a preferred drug program and amendments after considering the recommendations from the board and any comments received from prescribers, dispensers, patients, consumers and manufacturers of the drug.

(a) The preferred drug list in any therapeutic class included in the preferred drug program shall be developed based initially on an evaluation of the clinical effectiveness, safety and patient outcomes, followed by consideration of the cost-effectiveness of the drugs.

(b) In each therapeutic class included in the preferred drug program, the board shall determine whether there is one drug which is significantly more clinically effective and safe, and that drug shall be included on the preferred drug list without consideration of cost. If, among two or more drugs in a therapeutic class, the difference in clinical effectiveness and safety is not clinically significant, then cost effectiveness (including price and supplemental rebates) may also be considered in determining which drug or drugs shall be included on the preferred drug list.

(c) In addition to drugs selected under paragraph (b) of this subdivision, any prescription drug in the therapeutic class, whose cost to the state public health plans (including net price and supplemental rebates) is equal to or less than the cost of another drug in the therapeutic class that is on the preferred drug list under paragraph (b)

of this subdivision, may be selected to be on the preferred drug list, based on clinical effectiveness, safety and cost-effectiveness.

(d) Notwithstanding any provision of this section to the contrary, the commissioner may designate therapeutic classes of drugs, including classes with only one drug, as all preferred prior to any review that may be conducted by the board pursuant to this section.

11. (a) The commissioner shall provide an opportunity for pharmaceutical manufacturers to provide supplemental rebates to the state public health plans for drugs within a therapeutic class; such supplemental rebates shall be taken into consideration by the board and the commissioner in determining the cost-effectiveness of drugs within a therapeutic class under the state public health plans.

(b) The commissioner may designate a pharmaceutical manufacturer as one with whom the commissioner is negotiating or has negotiated a manufacturer agreement, and all of the drugs it manufactures or markets shall be included in the preferred drug program. The commissioner may negotiate directly with a pharmaceutical manufacturer for rebates relating to any or all of the drugs it manufactures or markets. A manufacturer agreement shall designate any or all of the drugs manufactured or marketed by the pharmaceutical manufacturer as being preferred or non preferred drugs. When a pharmaceutical manufacturer has been designated by the commissioner under this paragraph but the commissioner has not reached a manufacturer agreement with the pharmaceutical manufacturer, then the commissioner may designate some or all of the drugs manufactured or marketed by the pharmaceutical manufacturer as non preferred drugs. However, notwithstanding this paragraph, any drug that is selected to be on the preferred drug list under paragraph (b) of subdivision ten of this section on grounds that it is significantly more clinically effective and safer than other drugs in its therapeutic class shall be a preferred drug.

(c) Supplemental rebates under this subdivision shall be in addition to those required by applicable federal law and subdivision seven of section three hundred sixty-seven-a of the social services law. In order to be considered in connection with the preferred drug program, such supplemental rebates shall apply to the drug products dispensed under the Medicaid program and the EPIC program. The commissioner is prohibited from approving alternative rebate demonstrations, value added programs or guaranteed savings from other program benefits as a substitution for supplemental rebates.

12. The commissioner may implement all or a portion of the preferred drug program through contracts with administrators with expertise in management of pharmacy services, subject to applicable laws.

13. For a period of eighteen months, commencing with the date of enactment of this article, and without regard to the preferred drug program or the clinical drug review program requirements of this article, the commissioner is authorized to implement, or continue, a prior authorization requirement for a drug which may not be dispensed without a prescription as required by section sixty-eight hundred ten of the education law, for which there is a non-prescription version within the same drug class, or for which there is a comparable non-prescription version of the same drug. Any such prior authorization requirement shall be implemented in a manner that is consistent with the process employed by the commissioner for such authorizations as of one day prior to the date of enactment of this article. At the conclusion of the eighteen month period, any such drug or drug class shall be subject to the preferred drug program requirements of this article; provided, however, that the commissioner is authorized to immediately subject any such drug

no prior authorization without regard to the provisions of subdivisions five through eleven of this section.

APPENDIX A

STANDARD CLAUSES FOR NEW YORK STATE CONTRACTS

PLEASE RETAIN THIS DOCUMENT
FOR FUTURE REFERENCE.

January 2014

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STANDARD CLAUSES FOR NYS CONTRACTS

The parties to the attached contract, license, lease, amendment or other agreement of any kind (hereinafter, "the contract" or "this contract") agree to be bound by the following clauses which are hereby made a part of the contract (the word "Contractor" herein refers to any party other than the State, whether a contractor, licenser, licensee, lessor, lessee or any other party):

1. EXECUTORY CLAUSE. In accordance with Section 41 of the State Finance Law, the State shall have no liability under this contract to the Contractor or to anyone else beyond funds appropriated and available for this contract.

2. NON-ASSIGNMENT CLAUSE. In accordance with Section 138 of the State Finance Law, this contract may not be assigned by the Contractor or its right, title or interest therein assigned, transferred, conveyed, sublet or otherwise disposed of without the State's previous written consent, and attempts to do so are null and void. Notwithstanding the foregoing, such prior written consent of an assignment of a contract let pursuant to Article XI of the State Finance Law may be waived at the discretion of the contracting agency and with the concurrence of the State Comptroller where the original contract was subject to the State Comptroller's approval, where the assignment is due to a reorganization, merger or consolidation of the Contractor's business entity or enterprise. The State retains its right to approve an assignment and to require that any Contractor demonstrate its responsibility to do business with the State. The Contractor may, however, assign its right to receive payments without the State's prior written consent unless this contract concerns Certificates of Participation pursuant to Article 5-A of the State Finance Law.

3. COMPTROLLER'S APPROVAL. In accordance with Section 112 of the State Finance Law (or, if this contract is with the State University or City University of New York, Section 355 or Section 6218 of the Education Law), if this contract exceeds $50,000 (or the minimum thresholds agreed to by the Office of the State Comptroller for certain S.U.N.Y. and C.U.N.Y. contracts), or if this is an amendment for any amount to a contract which, as so amended, exceeds said statutory amount, or if, by this contract, the State agrees to give something other than money when the value or reasonably estimated value of such consideration exceeds $10,000, it shall not be valid, effective or binding upon the State until it has been approved by the State Comptroller and filed in his office. Comptroller's approval of contracts let by the Office of General Services is required when such contracts exceed $85,000 (State Finance Law Section 163.6-a). However, such pre-approval shall not be required for any contract established as a centralized contract through the Office of General Services or for a purchase order or other transaction issued under such centralized contract.

4. WORKERS' COMPENSATION BENEFITS. In accordance with Section 142 of the State Finance Law, this contract shall be void and of no force and effect unless the Contractor shall provide and maintain coverage during the life of this contract for the benefit of such employees as are required to be covered by the provisions of the Workers' Compensation Law.

5. NON-DISCRIMINATION REQUIREMENTS. To the extent required by Article 15 of the Executive Law (also known as the Human Rights Law) and all other State and Federal statutory and constitutional non-discrimination provisions, the Contractor will not discriminate against any employee or applicant for employment because of race, creed, color, sex (including gender identity or expression), national origin, sexual orientation, military status, age, disability, predisposing genetic characteristics, marital status or domestic violence victim status. Furthermore, in accordance with Section 220-e of the Labor Law, if this is a contract for the construction, alteration or repair of any public building or public work or for the manufacture, sale or distribution of materials, equipment or supplies, and to the extent that this contract shall be performed within the State of New York, Contractor agrees that neither it nor its subcontractors shall, by reason of race, creed, color, disability, sex, or national origin: (a) discriminate in hiring against any New York State citizen who is qualified and available to perform the work; or (b) discriminate against or intimidate any employee hired for the performance of work under this contract. If this is a building service contract as defined in Section 230 of the Labor Law, then, in accordance with Section 239 thereof, Contractor agrees that neither it nor its subcontractors shall by reason of race, creed, color, national origin, age, sex or disability: (a) discriminate in hiring against any New York State citizen who is qualified and available to perform the work; or (b) discriminate against or intimidate any employee hired for the performance of work under this contract. Contractor is subject to fines of $50.00 per person per day for any violation of Section 220-e or Section 239 as well as possible termination of this contract and forfeiture of all moneys due hereunder for a second or subsequent violation.

6. WAGE AND HOURS PROVISIONS. If this is a public work contract covered by Article 8 of the Labor Law or a building service contract covered by Article 9 thereof, neither Contractor's employees nor the employees of its subcontractors may be required or permitted to work more than the number of hours or days stated in said statutes, except as otherwise provided in the Labor Law and as set forth in prevailing wage and supplement schedules issued by the State Labor Department. Furthermore, Contractor and its subcontractors must pay at least the prevailing wage rate and pay or provide the prevailing supplements, including the premium rates for overtime pay, as determined by the State Labor Department in accordance with the Labor Law. Additionally, effective April 28, 2008, if this is a public work contract covered by Article 8 of the Labor Law, the Contractor understands and agrees that the filing of payrolls in a manner consistent with Subdivision 3-a of Section 220 of the Labor Law shall be a condition precedent to payment by the State of

any State approved sums due and owing for work done upon the project.

7. NON-COLLUSIVE BIDDING CERTIFICATION. In accordance with Section 139-d of the State Finance Law, if this contract was awarded based upon the submission of bids, Contractor affirms, under penalty of perjury, that its bid was arrived at independently and without collusion aimed at restricting competition. Contractor further affirms that, at the time Contractor submitted its bid, an authorized and responsible person executed and delivered to the State a non-collusive bidding certification on Contractor's behalf.

8. INTERNATIONAL BOYCOTT PROHIBITION. In accordance with Section 220-f of the Labor Law and Section 139-h of the State Finance Law, if this contract exceeds $5,000, the Contractor agrees, as a material condition of the contract, that neither the Contractor nor any substantially owned or affiliated person, firm, partnership or corporation has participated, is participating, or shall participate in an international boycott in violation of the federal Export Administration Act of 1979 (50 USC App. Sections 2401 et seq.) or regulations thereunder. If such Contractor, or any of the aforesaid affiliates of Contractor, is convicted or is otherwise found to have violated said laws or regulations upon the final determination of the United States Commerce Department or any other appropriate agency of the United States subsequent to the contract's execution, such contract, amendment or modification thereto shall be rendered forfeit and void. The Contractor shall so notify the State Comptroller within five (5) business days of such conviction, determination or disposition of appeal (2NYCRR 105.4).

9. SET-OFF RIGHTS. The State shall have all of its common law, equitable and statutory rights of set-off. These rights shall include, but not be limited to, the State's option to withhold for the purposes of set-off any moneys due to the Contractor under this contract up to any amounts due and owing to the State with regard to this contract, any other contract with any State department or agency, including any contract for a term commencing prior to the term of this contract, plus any amounts due and owing to the State for any other reason including, without limitation, tax delinquencies, fee delinquencies or monetary penalties relative thereto. The State shall exercise its set-off rights in accordance with normal State practices including, in cases of set-off pursuant to an audit, the finalization of such audit by the State agency, its representatives, or the State Comptroller.

10. RECORDS. The Contractor shall establish and maintain complete and accurate books, records, documents, accounts and other evidence directly pertinent to performance under this contract (hereinafter, collectively, "the Records"). The Records must be kept for the balance of the calendar year in which they were made and for six (6) additional years thereafter. The State Comptroller, the Attorney General and any other person or entity authorized to conduct an examination, as well as the agency or agencies involved in this contract, shall have access to the Records during normal business hours at an office of the Contractor within the State of New York or, if no such office is available, at a mutually agreeable and reasonable venue within the State, for the term specified above for the purposes of inspection, auditing and copying. The State shall take reasonable steps to protect from public disclosure any of the Records which are exempt from disclosure under Section 87 of the Public Officers Law (the "Statute") provided that: (i) the Contractor shall timely inform an appropriate State official, in writing, that said records should not be disclosed; and (ii) said records shall be sufficiently identified; and (iii) designation of said records as exempt under the Statute is reasonable. Nothing contained herein shall diminish, or in any way adversely affect, the State's right to discovery in any pending or future litigation.

11. IDENTIFYING INFORMATION AND PRIVACY NOTIFICATION. (a) Identification Number(s). Every invoice or New York State Claim for Payment submitted to a New York State agency by a payee, for payment for the sale of goods or services or for transactions (e.g., leases, easements, licenses, etc.) related to real or personal property must include the payee's identification number. The number is any or all of the following: (i) the payee's Federal employer identification number, (ii) the payee's Federal social security number, and/or (iii) the payee's Vendor Identification Number assigned by the Statewide Financial System. Failure to include such number or numbers may delay payment. Where the payee does not have such number or numbers, the payee, on its invoice or Claim for Payment, must give the reason or reasons why the payee does not have such number or numbers.

(b) Privacy Notification. (1) The authority to request the above personal information from a seller of goods or services or a lessor of real or personal property, and the authority to maintain such information, is found in Section 5 of the State Tax Law. Disclosure of this information by the seller or lessor to the State is mandatory. The principal purpose for which the information is collected is to enable the State to identify individuals, businesses and others who have been delinquent in filing tax returns or may have understated their tax liabilities and to generally identify persons affected by the taxes administered by the Commissioner of Taxation and Finance. The information will be used for tax administration purposes and for any other purpose authorized by law. (2) The personal information is requested by the purchasing unit of the agency contracting to purchase the goods or services or lease the real or personal property covered by this contract or lease. The information is maintained in the Statewide Financial System by the Vendor Management Unit within the Bureau of State Expenditures, Office of the State Comptroller, 110 State Street, Albany, New York 12236.

12. EQUAL EMPLOYMENT OPPORTUNITIES FOR MINORITIES AND WOMEN. In accordance with Section 312 of the Executive Law and 5 NYCRR 143, if this contract is: (i) a written agreement or purchase order instrument, providing for a total expenditure in excess of $25,000.00,

whereby a contracting agency is committed to expend or does expend funds in return for labor, services, supplies, equipment, materials or any combination of the foregoing, to be performed for, or rendered or furnished to the contracting agency; or (ii) a written agreement in excess of $100,000.00 whereby a contracting agency is committed to expend or does expend funds for the acquisition, construction, demolition, replacement, major repair or renovation of real property and improvements thereon; or (iii) a written agreement in excess of $100,000.00 whereby the owner of a State assisted housing project is committed to expend or does expend funds for the acquisition, construction, demolition, replacement, major repair or renovation of real property and improvements thereon for such project, then the following shall apply and by signing this agreement the Contractor certifies and affirms that it is Contractor's equal employment opportunity policy that:

(a) The Contractor will not discriminate against employees or applicants for employment because of race, creed, color, national origin, sex, age, disability or marital status, shall make and document its conscientious and active efforts to employ and utilize minority group members and women in its work force on State contracts and will undertake or continue existing programs of affirmative action to ensure that minority group members and women are afforded equal employment opportunities without discrimination. Affirmative action shall mean recruitment, employment, job assignment, promotion, upgradings, demotion, transfer, layoff, or termination and rates of pay or other forms of compensation;

(b) at the request of the contracting agency, the Contractor shall request each employment agency, labor union, or authorized representative of workers with which it has a collective bargaining or other agreement or understanding, to furnish a written statement that such employment agency, labor union or representative will not discriminate on the basis of race, creed, color, national origin, sex, age, disability or marital status and that such union or representative will affirmatively cooperate in the implementation of the Contractor's obligations herein; and

(c) the Contractor shall state, in all solicitations or advertisements for employees, that, in the performance of the State contract, all qualified applicants will be afforded equal employment opportunities without discrimination because of race, creed, color, national origin, sex, age, disability or marital status.

Contractor will include the provisions of "a", "b", and "c" above, in every subcontract over $25,000.00 for the construction, demolition, replacement, major repair, renovation, planning or design of real property and improvements thereon (the "Work") except where the Work is for the beneficial use of the Contractor. Section 312 does not apply to: (i) work, goods or services unrelated to this contract; or (ii) employment outside New York State. The State shall consider compliance by a contractor or subcontractor with the requirements of any federal law concerning equal employment opportunity which effectuates the purpose of this section. The contracting agency shall determine whether the imposition of the requirements of the provisions hereof duplicate or conflict with any such federal law and if such duplication or conflict exists, the contracting agency shall waive the applicability of Section 312 to the extent of such duplication or conflict. Contractor will comply with all duly promulgated and lawful rules and regulations of the Department of Economic Development's Division of Minority and Women's Business Development pertaining hereto.

13. CONFLICTING TERMS. In the event of a conflict between the terms of the contract (including any and all attachments thereto and amendments thereof) and the terms of this Appendix A, the terms of this Appendix A shall control.

14. GOVERNING LAW. This contract shall be governed by the laws of the State of New York except where the Federal supremacy clause requires otherwise.

15. LATE PAYMENT. Timeliness of payment and any interest to be paid to Contractor for late payment shall be governed by Article 11-A of the State Finance Law to the extent required by law.

16. NO ARBITRATION. Disputes involving this contract, including the breach or alleged breach thereof, may not be submitted to binding arbitration (except where statutorily authorized), but must, instead, be heard in a court of competent jurisdiction of the State of New York.

17. SERVICE OF PROCESS. In addition to the methods of service allowed by the State Civil Practice Law & Rules ("CPLR"), Contractor hereby consents to service of process upon it by registered or certified mail, return receipt requested. Service hereunder shall be complete upon Contractor's actual receipt of process or upon the State's receipt of the return thereof by the United States Postal Service as refused or undeliverable. Contractor must promptly notify the State, in writing, of each and every change of address to which service of process can be made. Service by the State to the last known address shall be sufficient. Contractor will have thirty (30) calendar days after service hereunder is complete in which to respond.

18. PROHIBITION ON PURCHASE OF TROPICAL HARDWOODS. The Contractor certifies and warrants that all wood products to be used under this contract award will be in accordance with, but not limited to, the specifications and provisions of Section 165 of the State Finance Law, (Use of Tropical Hardwoods) which prohibits purchase and use of tropical hardwoods, unless specifically exempted, by the State or any governmental agency or political subdivision or public benefit corporation. Qualification for an exemption under this law will be the responsibility of the contractor to establish to meet with the approval of the State.

In addition, when any portion of this contract involving the use of woods, whether supply or installation, is to be performed by any subcontractor, the prime Contractor will indicate and certify in the submitted bid proposal that the subcontractor has been informed and is in compliance with specifications and provisions regarding use of tropical hardwoods as detailed in §165 State Finance Law. Any such use must meet with the approval of the State; otherwise, the bid may not be considered responsive. Under bidder certifications, proof of qualification for exemption will be the responsibility of the Contractor to meet with the approval of the State.

19. MACBRIDE FAIR EMPLOYMENT PRINCIPLES. In accordance with the MacBride Fair Employment Principles (Chapter 807 of the Laws of 1992), the Contractor hereby stipulates that the Contractor either (a) has no business operations in Northern Ireland, or (b) shall take lawful steps in good faith to conduct any business operations in Northern Ireland in accordance with the MacBride Fair Employment Principles (as described in Section 165 of the New York State Finance Law), and shall permit independent monitoring of compliance with such principles.

20. OMNIBUS PROCUREMENT ACT OF 1992. It is the policy of New York State to maximize opportunities for the participation of New York State business enterprises, including minority and women-owned business enterprises as bidders, subcontractors and suppliers on its procurement contracts.

Information on the availability of New York State subcontractors and suppliers is available from:

NYS Department of Economic Development
Division for Small Business
Albany, New York 12245
Telephone: 518-292-5100
Fax: 518-292-5884
email: opa@esd.ny.gov

A directory of certified minority and women-owned business enterprises is available from:

NYS Department of Economic Development
Division of Minority and Women's Business Development
633 Third Avenue
New York, NY 10017
212-803-2414
email: mwbecertification@esd.ny.gov
https://ny.newnycontracts.com/FrontEnd/VendorSearchPublic.asp

The Omnibus Procurement Act of 1992 requires that by signing this bid proposal or contract, as applicable, Contractors certify that whenever the total bid amount is greater than $1 million:

(a) The Contractor has made reasonable efforts to encourage the participation of New York State Business Enterprises as suppliers and subcontractors, including certified minority and women-owned business enterprises, on this project, and has retained the documentation of these efforts to be provided upon request to the State;

(b) The Contractor has complied with the Federal Equal Opportunity Act of 1972 (P.L. 92-261), as amended;

(c) The Contractor agrees to make reasonable efforts to provide notification to New York State residents of employment opportunities on this project through listing any such positions with the Job Service Division of the New York State Department of Labor, or providing such notification in such manner as is consistent with existing collective bargaining contracts or agreements. The Contractor agrees to document these efforts and to provide said documentation to the State upon request; and

(d) The Contractor acknowledges notice that the State may seek to obtain offset credits from foreign countries as a result of this contract and agrees to cooperate with the State in these efforts.

21. RECIPROCITY AND SANCTIONS PROVISIONS. Bidders are hereby notified that if their principal place of business is located in a country, nation, province, state or political subdivision that penalizes New York State vendors, and if the goods or services they offer will be substantially produced or performed outside New York State, the Omnibus Procurement Act 1994 and 2000 amendments (Chapter 684 and Chapter 383, respectively) require that they be denied contracts which they would otherwise obtain. NOTE: As of May 15, 2002, the list of discriminatory jurisdictions subject to this provision includes the states of South Carolina, Alaska, West Virginia, Wyoming, Louisiana and Hawaii. Contact NYS Department of Economic Development for a current list of jurisdictions subject to this provision.

22. COMPLIANCE WITH NEW YORK STATE INFORMATION SECURITY BREACH AND NOTIFICATION ACT. Contractor shall comply with the provisions of the New York State Information Security Breach and Notification Act (General Business Law Section 899-aa; State Technology Law Section 208).

23. COMPLIANCE WITH CONSULTANT DISCLOSURE LAW. If this is a contract for consulting services, defined for purposes of this requirement to include analysis, evaluation, research, training, data processing, computer programming, engineering, environmental, health, and mental health services, accounting, auditing, paralegal, legal or similar services, then, in accordance with Section 163 (4-g) of the State Finance Law (as amended by Chapter 10 of the Laws of 2006), the Contractor shall timely, accurately and properly comply with the requirement to submit an annual employment report for the contract to the agency that awarded

the contract, the Department of Civil Service and the State Comptroller.

24. PROCUREMENT LOBBYING. To the extent this agreement is a "procurement contract" as defined by State Finance Law Sections 139-j and 139-k, by signing this agreement the contractor certifies and affirms that all disclosures made in accordance with State Finance Law Sections 139-j and 139-k are complete, true and accurate. In the event such certification is found to be intentionally false or intentionally incomplete, the State may terminate the agreement by providing written notification to the Contractor in accordance with the terms of the agreement.

25. CERTIFICATION OF REGISTRATION TO COLLECT SALES AND COMPENSATING USE TAX BY CERTAIN STATE CONTRACTORS, AFFILIATES AND SUBCONTRACTORS.
To the extent this agreement is a contract as defined by Tax Law Section 5-a, if the contractor fails to make the certification required by Tax Law Section 5-a or if during the term of the contract, the Department of Taxation and Finance or the covered agency, as defined by Tax Law 5-a, discovers that the certification, made under penalty of perjury, is false, then such failure to file or false certification shall be a material breach of this contract and this contract may be terminated, by providing written notification to the Contractor in accordance with the terms of the agreement, if the covered agency determines that such action is in the best interest of the State.

26. **IRAN DIVESTMENT ACT**. By entering into this Agreement, Contractor certifies in accordance with State Finance Law §165-a that it is not on the "Entities Determined to be Non-Responsive Bidders/Offerers pursuant to the New York State Iran Divestment Act of 2012" ("Prohibited Entities List") posted at:
http://www.ogs.ny.gov/about/regs/docs/ListofEntities.pdf

Contractor further certifies that it will not utilize on this Contract any subcontractor that is identified on the Prohibited Entities List. Contractor agrees that should it seek to renew or extend this Contract, it must provide the same certification at the time the Contract is renewed or extended. Contractor also agrees that any proposed Assignee of this Contract will be required to certify that it is not on the Prohibited Entities List before the contract assignment will be approved by the State.

During the term of the Contract, should the state agency receive information that a person (as defined in State Finance Law §165-a) is in violation of the above-referenced certifications, the state agency will review such information and offer the person an opportunity to respond. If the person fails to demonstrate that it has ceased its engagement in the investment activity which is in violation of the Act within 90 days after the determination of such violation, then the state agency shall take such action as may be appropriate and provided for by law, rule, or contract, including, but not limited to, imposing sanctions, seeking compliance, recovering damages, or declaring the Contractor in default.

The state agency reserves the right to reject any bid, request for assignment, renewal or extension for an entity that appears on the Prohibited Entities List prior to the award, assignment, renewal or extension of a contract, and to pursue a responsibility review with respect to any entity that is awarded a contract and appears on the Prohibited Entities list after contract award.

APPENDIX B
New York State Medicaid Pharmacy Supplemental Drug Rebate Program
Manufacturer Bid Sheet

MANUFACTURER RECEIPT AND SUBMISSION INFORMATION (For Manufacturer Use Only)	DEPARTMENT TRANSMISSION AND RECEIPT INFORMATION (For Medicaid Department Use Only)
Manufacturer Name:	Date Manufacturer Bid Sheet Sent to Manufacturer:
Labeler Number(s)	Sender's Name:
Street Address:	Sender's Title:
Street Address:	Sender's Bureau:
City, State, Zip:	Sender's Division:
	Sender's Office:
Date Manufacturer Bid Sheet Received from Department:	Sender's Telephone:
Recipient's Name:	Sender's Email:
Recipient's Title:	
Recipient's Email:	Date Department Received Completed Manufacturer's Bid Sheet:
Recipient's Telephone	Recipient's Name:
	Recipient's Title:
Date Completed Manufacturer's Bid Sheet Sent to Department:	Recipient's Bureau:
Pricing Submitter's Name:	Recipient's Division:
Pricing Submitter's Title:	Recipient's Office:
Pricing Submitter's Email:	Recipient's Telephone:
Pricing Submitter's Telephone:	Recipient's Email:

General Information				Pricing for Preferred Position within the Fee-For-Service Program				Pricing not Related to Preferred/Formulary Position		NCU Contingencies	
State	NDC Number	Product Description	Price Effective Date	NCU One-of-One	NCU One-of-Two	NCU One-of-Three	NCU One-of-Many	NCU FFS Only	NCU FFS & MC	Is NCU Condition Limited Y/N?	Additional Information including Condition Limited Offer Details
NY											Attach additional information as needed
NY											
NY											
NY											
NY											
NY											
NY											
NY											
NY											
NY											
NY											
NY											
NY											
NY											
NY											
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NY											
NY											
NY											
NY											

OHIP: Include the 11-digit NDC without hyphens.

OHIP: Include drug label name and strength.

OHIP: Use this column to identify the first date on which the listed net cost can be used to calculate supplemental rebates for the NDC. This can be a specific date after the Contract Date or the first date on which the drug is identified as a Prefered Drug on the NY PDL published on the Department's Web site.

OHIP: Identify pricing for one of one preferred product.

OHIP: Identify pricing for one of two preferred products.

OHIP: Identify pricing for one of three preferred products.

OHIP:Identify pricing for more than three preferred products.

OHIP: Identify pricing for the fee-for-service (FFS) program utilization not associated with preferred position/preferred drug list. Note: condition limited contingencies may be applied.

OHIP: Identify pricing for fee-for-service (FFS) & managed care program (MC) program utilization not associated with preferred /formulary position. Note: condition limited contingencies may be applied.

OHIP: Select [Y]es or [N]o from the drop down box to indicate whether the NCU is a Condition-Limited Net Cost and provide detailed information about the condition in the Additional Information Column. It is not necessary to indicate in this column or the Additional Information column that the NCU condition is based on competitive proicing for preferred position (i.e. one- of-one, one-of- two or one-of- three).

APPENDIX C
New York State Medicaid Pharmacy Supplemental Drug Rebate Program
Supplemental Rebate Final Net Cost Schedule

MANUFACTURER RECEIPT OF NET COST SCHEDULE
(For Manufacturer Use Only)

Date Net Cost Schedule Received:

Manufacturer Name:
Labeler Number:
Street Address:
Street Address:
City, State, Zip:

Recipient's Name:
Recipient's Title:
Recipient's Telephone:
Recipient's Email:

DEPARTMENT'S TRANSMISSION OF NET COST SCHEDULE
(For Medicaid Department Use Only)

Date Net Cost Schedule Sent to Manufacturer:

Sender's Name:
Sender's Title:
Sender's Bureau:
Sender's Division:
Sender's Office:
Sender's Telephone:
Sender's Email:

General Information				Pricing for Preferred Position within the Fee-For-Service Program				Pricing Not Related to Preferred/Formulary Position		NCU Contingencies	
State	NDC Number	Product Description	Price Effective Date	NCU One-of-One	NCU One-of-Two	NCU One-of-Three	NCU One-of-Many	NCU FFS Only	NCU FFS & MC	Is NCU Condition Limited? (Y/N)	Additional Information including Condition Limited Offer Details
NY											Attach additional information as needed
NY											
NY											
NY											
NY											
NY											
NY											
NY											
NY											
NY											
NY											
NY											
NY											

APPENDIX D

CERTIFICATE OF AUTHENTICITY
PAPER NET COST SCHEDULE

I, _____(Name and Title), duly authorized representative of _____(Manufacturer), hereby certify:

1. that the attached Net Cost Schedule is a true and correct copy of the Net Cost Schedule the Department provided in PDF format to Manufacturer on _____(date);

2. that no changes have been made to the Net Cost Schedule, except to include accurate information concerning each of, and only, the following items: Date Net Cost Schedule Received, Recipient's Name, Recipient's Title, Recipient's Telephone, Recipient's Email;

3. that the Net Cost(s) per Unit Manufacturer submitted, which are contained on the attached Net Cost Schedule, represents firm offer(s) that Manufacturer made to the State and will not retract, unless authorized to do so by the Agreement;

4. that Manufacturer understands and agrees that receipt of the attached Net Cost Schedule does not require the Department to include Manufacturer's Supplemental Covered Product(s) on its Preferred Drug List; and

5. that the signature below is that of a duly authorized representative of Manufacturer with the authority to execute agreements binding Manufacturer.

Signature:_____ Date:_____

Printed Name:_____ Title:_____

APPENDIX E

CERTIFICATE OF AUTHENTICITY
NET COST SCHEDULE ELECTRONIC FORMAT

I, _____(Name and Title), duly authorized representative of _____(Manufacturer), hereby certify:

1. that the information contained in the following columns on the attached Net Cost Schedule Electronic Format consists only of the information contained in identically named columns on the Net Cost Schedule provided in PDF format by the Department on _____(date): State, NDC Number, Product Description, Price Effective Date, NCU One-of-One, NCU One-of-Two, NCU One-of-Three, NCU One-of-Many, Is NCU Condition Limited Y/N, Additional Information;

2. that for each row of the attached Net Cost Schedule Electronic Format in which the column "NDC Number" is populated, the information in each column described in paragraph one above is the same as the information for the corresponding row/column cell on the Net Cost Schedule provided in PDF format by the Department on _____(date);

3. that the Net Cost(s) per Unit Manufacturer submitted, which are contained on the attached Net Cost Schedule, represents firm offer(s) that Manufacturer made to the State and will not retract, unless authorized to do so by the Agreement;

4. that Manufacturer understands and agrees that receipt of the attached Net Cost Schedule does not require the Department to include Manufacturer's Supplemental Covered Product(s) on its Preferred Drug List; and

5. that the signature below is that of a duly authorized representative of Manufacturer with the authority to execute agreements binding Manufacturer.

Signature:_____ Date:_____

Printed Name:_____ Title:_____

APPENDIX F

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Appendix G

NOTICES

All notices permitted or required hereunder shall be in writing and shall be transmitted either:

(a) via certified or registered United States mail, return receipt requested;
(b) by facsimile transmission;
(c) by personal delivery;
(d) by expedited delivery service; or
(e) by e-mail.

Such notices shall be addressed as follows or to such different addresses as the parties may from time to time designate:

State of New York Department of Health
Name:
Title:
Address:
Telephone Number:
Facsimile Number:
E-Mail Address:

[*Insert Manufacturer's Name*]
Name:
Title:
Address:
Telephone Number:
Facsimile Number:
E-Mail Address:

Any such notice shall be deemed to have been given either at the time of personal delivery or, in the case of expedited delivery service or certified or registered United States mail, as of the date of first attempted delivery at the address and in the manner provided herein, or in the case of facsimile transmission or email, upon receipt.

The parties may, from time to time, specify any new or different address in the United States as their address for purpose of receiving notice under this AGREEMENT by giving fifteen (15) days written notice to the other party sent in accordance herewith. The parties agree to mutually designate individuals as their respective representative for the purposes of receiving notices under this AGREEMENT. Additional individuals may be designated in writing by the parties for purposes of implementation and administration/billing, resolving issues and problems, and/or for dispute resolution.

Appendix H

For CONTRACTOR that creates, receives, maintains or transmits individually identifiable health information on behalf of a New York State Department of Health HIPAA-Covered Program

I. Definitions. For purposes of this Appendix H of this AGREEMENT:
   A. "Business Associate" shall mean CONTRACTOR.
   B. "Covered Program" shall mean the STATE.
   C. Other terms used, but not otherwise defined, in this AGREEMENT shall have the same meaning as those terms in the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act ("HITECH") and implementing regulations, including those at 45 CFR Parts 160 and 164.

II. Obligations and Activities of Business Associate:
   A. Business Associate agrees to not use or disclose Protected Health Information other than as permitted or required by this AGREEMENT or as Required By Law.
   B. Business Associate agrees to use the appropriate administrative, physical and technical safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this AGREEMENT and to comply with the security standards for the protection of electronic protected health information in 45 CFR Part 164, Subpart C. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this AGREEMENT.
   C. Business Associate agrees to report to Covered Program as soon as reasonably practicable any use or disclosure of the Protected Health Information not provided for by this AGREEMENT of which it becomes aware. Business Associate also agrees to report to Covered Program any Breach of Unsecured Protected Health Information of which it becomes aware. Such report shall include, to the extent possible:
      1. A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach, if known;
      2. A description of the types of Unsecured Protected Health Information that were involved in the Breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);
      3. Any steps individuals should take to protect themselves from potential harm resulting from the breach;
      4. A description of what Business Associate is doing to investigate the Breach, to mitigate harm to individuals, and to protect against any further Breaches; and
      5. Contact procedures for Covered Program to ask questions or learn additional information.
   D. Business Associate agrees, in accordance with 45 CFR § 164.502(e)(1)(ii), to ensure that any Subcontractors that create, receive, maintain, or transmit Protected Health Information on behalf of the Business Associate agree to the same

restrictions and conditions that apply to Business Associate with respect to such information.

E. Business Associate agrees to provide access, at the request of Covered Program, and in the time and manner designated by Covered Program, to Protected Health Information in a Designated Record Set, to Covered Program in order for Covered Program to comply with 45 CFR § 164.524.

F. Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that Covered Program directs in order for Covered Program to comply with 45 CFR § 164.526.

G. Business Associate agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Program to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR § 164.528; and Business Associate agrees to provide to Covered Program, in time and manner designated by Covered Program, information collected in accordance with this AGREEMENT, to permit Covered Program to comply with 45 CFR § 164.528.

H. Business Associate agrees, to the extent the Business Associate is to carry out Covered Program's obligation under 45 CFR Part 164, Subpart E, to comply with the requirements of 45 CFR Part 164, Subpart E that apply to Covered Program in the performance of such obligation.

I. Business Associate agrees to make internal practices, books, and records, including policies and procedures and Protected Health Information, relating to the use and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of, Covered Program available to Covered Program, or to the Secretary of the federal Department of Health and Human Services, in a time and manner designated by Covered Program or the Secretary, for purposes of the Secretary determining Covered Program's compliance with HIPAA, HITECH and 45 CFR Parts 160 and 164.

III. Permitted Uses and Disclosures by Business Associate

A. Except as otherwise limited in this AGREEMENT, Business Associate may only use or disclose Protected Health Information as necessary to perform functions, activities, or services for, or on behalf of, Covered Program as specified in this AGREEMENT.

B. Business Associate may use Protected Health Information for the proper management and administration of Business Associate.

C. Business Associate may disclose Protected Health Information as Required By Law.

IV. Term and Termination

A. This AGREEMENT shall be effective for the term as specified on the cover page of this AGREEMENT, after which time all of the Protected Health Information provided by Covered Program to Business Associate, or created or received by Business Associate on behalf of Covered Program, shall be destroyed or returned to Covered Program; provided that, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in this Appendix H of this AGREEMENT.

B. Termination for Cause. Upon Covered Program's knowledge of a material breach by Business Associate, Covered Program may provide an opportunity for Business Associate to cure the breach and end the violation or may terminate this AGREEMENT if Business Associate does not cure the breach and end the violation within the time specified by Covered Program, or Covered Program may immediately terminate this AGREEMENT if Business Associate has breached a material term of this AGREEMENT and cure is not possible.

C. Effect of Termination.

1. Except as provided in paragraph (c)(2) below, upon termination of this AGREEMENT, for any reason, Business Associate shall return or destroy all Protected Health Information received from Covered Program, or created or received by Business Associate on behalf of Covered Program. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.
2. In the event that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered Program notification of the conditions that make return or destruction infeasible. Upon mutual agreement of Business Associate and Covered Program that return or destruction of Protected Health Information is infeasible, Business Associate shall extend the protections of this AGREEMENT to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

V. Violations

A. Any violation of this AGREEMENT may cause irreparable harm to the STATE. Therefore, the STATE may seek any legal remedy, including an injunction or specific performance for such harm, without bond, security or necessity of demonstrating actual damages.

B. Business Associate shall indemnify and hold the STATE harmless against all claims and costs resulting from acts/omissions of Business Associate in connection with Business Associate's obligations under this AGREEMENT. Business Associate shall be fully liable for the actions of its agents, employees, partners or subcontractors and shall fully indemnify and save harmless the STATE from suits, actions, damages and costs, of every name and description relating to breach notification required by 45 CFR Part 164 Subpart D, or State Technology Law § 208, caused by any intentional act or negligence of Business Associate, its agents, employees, partners or subcontractors, without limitation; provided, however, that Business Associate shall not indemnify for that portion of any claim, loss or damage arising hereunder due to the negligent act or failure to act of the STATE.

VI. Miscellaneous

A. Regulatory References. A reference in this AGREEMENT to a section in the Code of Federal Regulations means the section as in effect or as amended, and for which compliance is required.

B. Amendment. Business Associate and Covered Program agree to take such action as is necessary to amend this AGREEMENT from time to time as is necessary for Covered Program to comply with the requirements of HIPAA, HITECH and 45 CFR Parts 160 and 164.

C. Survival. The respective rights and obligations of Business Associate under (IV)(C) of this Appendix H of this AGREEMENT shall survive the termination of this AGREEMENT.

D. Interpretation. Any ambiguity in this AGREEMENT shall be resolved in favor of a meaning that permits Covered Program to comply with HIPAA, HITECH and 45 CFR Parts 160 and 164.

E. HIV/AIDS. If HIV/AIDS information is to be disclosed under this AGREEMENT, Business Associate acknowledges that it has been informed of the confidentiality requirements of Public Health Law Article 27-F.

APPENDIX I

New York State-specific Supplemental Rebate Agreement

Participating State's Medicaid Programs Approved by CMS in the Medicaid State Plan(s)

Participating State: New York

Non-Medicaid programs approved by CMS in the Medicaid State Plan:

1. None

MEDICAID SUPPLEMENTAL REBATE AGREEMENT
Between
The New York State Department of Health
and

_____
Enter Manufacturer Name, Labeler Code/s

This Agreement commencing on _____ by and between THE STATE OF NEW YORK, acting by and through the New York State Department of Health, having its principal office at Corning Tower, Empire Plaza, Albany, New York 12237, (hereinafter referred to as the STATE), and_____(hereinafter referred to as the MANUFACTURER, having its principal place of business at _____, and shall be interpreted pursuant to the laws of the State of New York. The 21-page "Letter of Agreement" attached hereto, containing substantive terms and conditions of this MEDICAID SUPPLEMENTAL REBATE AGREEMENT, is hereby incorporated into this AGREEMENT and made a part hereof.

IN WITNESS WHEREOF, the parties hereto have executed this AGREEMENT as of the dates appearing under their signatures.

MANUFACTURER SIGNATURE	.	STATE AGENCY SIGNATURE
By: _____	.	By: _____
_____ Printed Name	.	_____ Printed Name
Title: _____	.	Title: _____
Date: _____	.	Date: _____

. State Agency Certification:
"In addition to the acceptance of this contract, I also certify that original copies of this signature page will be attached to all other exact copies of this contract."

Federal ID No.: _____

NYS Comptroller's No._____

Agency Code: 12000

CORPORATION ACKNOWLEDGMENT

STATE OF _____)
) ss:
COUNTY OF _____)

On the_____day of_____in the year 20___, before me, the undersigned, personally appeared_____, personally known to me or proved to me on the basis of satisfactory evidence to be the individual(s) whose name(s) is(are) subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their/ capacity(ies), and that by his/her/their signature(s) on the instrument, the individual(s), or the person upon behalf of which the individual(s) acted, executed the instrument.

_____
(Signature and office of the individual taking acknowledgment)

ATTORNEY GENERAL'S SIGNATURE	.	STATE COMPTROLLER'S SIGNATURE
_____	.	_____
Title:_____	.	Title:_____
Date:_____	.	Date: _____

LETTER OF AGREEMENT
concerning
Medicaid Supplemental Rebate Agreement

LABELER CODE: _____

MANUFACTURER NAME: _____

WHEREAS, Article 2-A, Section 270 through and including Section 273, of the New York Public Health Law authorizes the Commissioner and Department to create and implement the New York Preferred Drug Program, including the receipt of Supplemental Rebates; and

WHEREAS, the Department desires to expand its Supplemental Rebate Agreement intended to include Medicaid Managed Care Organization drug utilization; and

WHEREAS, the Department desires to expand its Supplemental Rebate Agreement intended to decrease the cost of Drugs reimbursed by the New York Medical Assistance Program ("Medicaid"); and

WHEREAS, the Department agrees to make payments for Manufacturer's Drugs utilized by Medicaid enrollees; and

WHEREAS, Manufacturer agrees to provide to the Department a Supplemental Rebate for such utilized Drugs when the conditions set forth below are met;

NOW, THEREFORE, for and in consideration of mutual promises and covenants herein set forth, the parties agree as follows:

1 DEFINITIONS

1.1 As used in this Supplemental Drug Rebate Agreement of covered outpatient drugs for Medicaid beneficiaries, the following terms have the meanings set forth in this Part (Part 1):

1.1.1 "Act" means the Social Security Act of 1935, as amended.

1.1.2 "Agreement" means this Supplemental Drug Rebate Agreement.

1.1.3 "Brand Drug" is a Drug that is either a single source drug or an innovator multiple source drug, as those terms are defined in Section 1927(k)(7)(A)(ii) and (iv) of the Act, 42 U.S.C. § 1396r-8(k)(7)(A)(ii) and (iv).

1.1.4 "CMS" means the Centers for Medicare & Medicaid Services of the United States Department of Health and Human Services.

1.1.5 "CMS Rebate" means, with respect to a Covered Product NDC, either the sum of the rebate amounts calculated in accordance with Paragraphs (c)(1) and (c)(2) of Section

1927 of the Act, 42 U.S.C. § 1396r-8(c)(1) and (c)(2), or the rebate amount calculated in accordance with Paragraph (c)(3) of Section 1927 of the Act, 42 U.S.C. § 1396r-8(c)(3), as applicable to the Covered Product NDC.

1.1.6 "CMS Unit Rebate Amount" means, as applicable to a Covered Product, the unit amount for a Covered Product NDC that CMS computes and transmits to the State to be used in calculating the amount of CMS Rebate Manufacturer owes the State for its Covered Products in accordance with Paragraphs (c)(1) and (c)(2) or Paragraph (c)(3) of Section 1927 of the Act, 42 U.S.C. § 1396r-8(c)(1), (2) and (3).

1.1.7 "Commissioner" means the New York State Commissioner of Health. If permitted by law, and in the Commissioner's sole discretion, the Department may fulfill obligations that this Agreement imposes on the Commissioner.

1.1.8 "Condition-Limited Net Cost" means a Net Cost that the State may use to calculate Supplemental Rebates for a ~~Preferred Supplemental~~ Covered Product NDC only under a specific set of conditions that are described on the Net Cost Schedule.

1.1.9 "Contract Date" means the date this Agreement commences as specified in the first paragraph of page one of this Agreement.

1.1.10 "Covered Product" means a Drug which is the subject of a HHS Agreement to which the Manufacturer is a party. "Covered Products" include, but are not limited to, Supplemental Covered Products, ~~and~~ Preferred Supplemental Covered Products and Medicaid MCO Covered Products.

1.1.11 "Department" means the New York State Department of Health.

1.1.12 "Drug" means a "covered outpatient drug" as defined in Paragraph (k)(2) of section 1927 of the Act, 42 U.S.C. § 1396r-8(k)(2).

1.1.13 "Formulary" means a list consisting of the prescription and non-prescription drugs for which a Medicaid MCO provides pharmacy coverage.

1.1.14 "Drug Utilization Review Board" or "DUR Board" means the entity created by New York Social Services Law § 369-bb.

1.1.15 "HHS Agreement" means the Manufacturer's National Medicaid drug rebate agreement with the Secretary of the United States Department of Health and Human Services, entered into pursuant to Section 1927 of the Social Security Act, 42 U.S.C. § 1396r-8.

1.1.16 "Manufacturer" means the non-State party to this Agreement.

1.1.17 "Manufacturer Bid Sheet" means a document the Department sends to Manufacturer pursuant to Section 4.~~3~~ 4 or 4.~~5~~ 6, or as an attachment to the notice described in Subsection A of Section 4.~~4~~ 5, to solicit Net Costs for Covered Products and that Manufacturer returns to the Department with the Net Costs Manufacturer offers to the Department. A Manufacturer Bid Sheet shall contain at least the same categories of

information that Section 4.7 requires for a Net Cost Schedule.

1.1.18 "Medicaid Managed Care Organization" or "Medicaid MCO" means a Medicaid managed care organization that is responsible for coverage of drugs for Medicaid recipients who are enrolled with the managed care entity, as further described in 42 U.S.C. § 1396b(m)(2)(viii) and NY Social Services Law § 364-j, as may be amended from time to time, and in the Medicaid MCO's contract with the Department.

1.1.19 "Medicaid MCO Covered Product" means a Covered Product that is included in a Medicaid MCO's formulary and for which the Manufacturer will pay Supplemental Rebates to the Department pursuant to this Agreement.

1.1.20 National Drug Code (NDC) is the 10- or 11-digit product identifier assigned by the United States Food and Drug Administration to a specific combination of labeler, drug, trade package size and type, as described in 21 C.F.R. § 207.35(b).

1.1.21 "Net Cost Per Unit" or "Net Cost" means the amount, by NDC, agreed upon by the parties to this Agreement as the ~~Supplemental~~ Covered ~~Drug~~ Product NDC's Net Cost, including any Condition-Limited Net Cost(s), set forth as such in the Net Cost Schedule.

1.1.22 "Net Cost Schedule" means the document the Department creates, updates and maintains that lists, by NDC number, the amount of the Net Cost(s) Per Unit that Manufacturer offered and the Department will use to calculate Supplemental Rebates ~~for Preferred Supplemental Covered Products~~ pursuant to this Agreement.

1.1.23 "New York Preferred Drug List" or "NY PDL" means the preferred drug list created by the Commissioner in accordance with the NY Preferred Drug Program.

1.1.24 "New York Preferred Drug Program" or "NY PDP" means the preferred drug program created by NY Public Health Law § 272.

1.1.25 "New York Preferred Drug Program Prior Authorization" or "NY PDP Prior Authorization" means prior authorization, within the meaning of NY Public Health Law §§ 272 and 273, which the Commissioner requires for Non-preferred Drugs ~~that are not exempt from NY PDP Prior Authorization by NY Public Health Law § 272(12)~~.

1.1.26 "Non-preferred Drug" has the meaning this term has in NY Public Health Law § 270(5).

1.1.27 ~~"Pharmacy and Therapeutics Committee" or "P&T Committee" is the entity created by NY Public Health Law § 271.~~

1.1.27 "Pharmacy Benefit Manager" or "PBM" means an organization contracted with a Medicaid MCO to administer its prescription drug coverage program, and that is primarily responsible for developing and maintaining the MCO formulary and processing and paying prescription drug claims.

1.1.28 "Pharmacy Provider" means an entity ~~or person~~ reimbursed pursuant to NY Social Services Law § 367-a, for the drugs ~~they are~~ it is licensed or permitted by law to dispense or administer, and ~~who are~~ that is enrolled as a State Medicaid Provider and, with respect to a Medicaid MCO, means an entity that is reimbursed pursuant to the entity's contract with the Medicaid MCO or PBM for the drugs that such entity is licensed or permitted by law to dispense or administer to Medicaid recipients enrolled with the MCO.

1.1.29 "Postmark Date" means the date on which written material is sent by the State or Manufacturer to the other party, which date is marked on the transmitted material's wrapper or, if the transmitted material does not have a wrapper, is electronically marked on such material. If more than one date appears on the wrapper or the transmitted material, as relevant, the latest such date shall be the Postmark Date. Transmission methods that can produce a Postmark Date include, but are not limited to, the USPS, courier service, carrier, facsimile, electronic mail and electronic wire transfer.

1.1.30 "Preferred Drug" has the meaning this term has in NY Public Health Law § 270(7). Covered Products that are "Preferred Drugs" include, but are not limited to, Preferred Supplemental Covered Products.

1.1.31 "Preferred Supplemental Covered Product" means a Covered Product that meets the requirements of Paragraph A, B or C of this Subsection, so that the Covered Product:

A. is both on the Net Cost Schedule and identified as a Preferred Drug on the NY PDL;

B. (i) previously met the requirements of Paragraph (A) of this Subsection, but is no longer identified as a Preferred Drug on the NY PDL and (ii) NY PDP Prior Authorization is required for all Brand Drugs in its Therapeutic Class; or

C. is expressly identified as a Preferred Supplemental Covered Product through an amendment to this Agreement entered into in accordance with Section ~~9~~ 8.9.

1.1.32 "Price Effective Date" is the date shown on a Net Cost Schedule which establishes when a listed Net Cost will first be used to calculate Supplemental Rebates for the relevant ~~Preferred Supplemental~~ Covered Product NDC. The Price Effective Date on a Net Cost Schedule shall be the date the Manufacturer specifies for a ~~Supplemental~~ Covered Product NDC on the Manufacturer Bid Sheet that contains its final Net Cost offer for such NDC. Manufacturer may either provide a specific date for the Price Effective Date or, with respect to a Covered Product that is a Preferred Supplemental Covered Product, state on the Manufacturer Bid Sheet that the Price Effective Date ~~for a Supplemental Covered Product NDC~~ is the date on which such Supplemental Covered Product first appears as a Preferred Drug on the NY PDL that is posted on the Department's Web site, provided that such posting-date is after the Contract Date.

1.1.33 "Prospective Drug Utilization Review" or "Prospective DUR" has the meaning it has in NY Social Services Law § 369-aa(6).

1.1.34 "Rebate Summary" means the report, which complies with the requirements for Medicaid Utilization Information in the HHS Agreement that the Department sends to Manufacturer itemizing the State Utilization Data supporting the Supplemental Rebate Invoice.

1.1.35 "Section," "Subsection," "Paragraph" and "Part" when not clearly referring to a federal or state statute or regulation, refers to a portion of this Agreement.

1.1.36 "Standard Clinical Criteria" means the standardization of formularies and/or prior authorization criteria applicable to MCO and FFS utilization for a Medicaid MCO Covered Product.

1.1.37 "State" means the State of New York.

1.1.38 "State Utilization" means the units of Covered Products that are included in State Utilization Data.

1.1.39 "State Utilization Data" means the data used by the Department that summarizes reimbursement of Pharmacy Providers under the New York Medicaid Program and all other state programs included in this Agreement pursuant to Section 4.2~~0~~ 1. State Utilization Data excludes data from covered entities identified in 42 U.S.C. § 256b(a)(4) in accordance with 42 U.S.C. §§ 256b(a)(5)(A) and 1396r-8(a)(5)(C).

1.1.40 "Step Therapy" has the meaning it has in NY Social Services Law § 369-aa(16).

1.1.41 "Supplemental Covered Product" means a Covered Product listed on Manufacturer's Net Cost Schedule. "Supplemental Covered Products" may include~~, but are not limited to,~~ Preferred Supplemental Covered Products.

1.1.42 "Supplemental Rebate" means, with respect to ~~the Preferred Supplemental~~ a Covered Product~~(s)~~, the quarterly amount payable by Manufacturer to the State pursuant to Sections 3.~~5~~ 7.

1.1.43 "Supplemental Rebate Amount Per Unit" means, for each unit of each ~~Preferred Supplemental~~ Covered Product NDC dispensed or administered by a Pharmacy Provider, an amount equal to WAC unit cost minus CMS Unit Rebate Amount minus Net Cost Per Unit, as long as such difference is greater than zero dollars ($0.00) US.

1.1.44 "Supplemental Rebate Invoice" is the bill the Department sends to Manufacturer demanding payment of the Supplemental Rebates Manufacturer owes the State in accordance with this Agreement.

1.1.45 "Therapeutic Class" has the meaning it has in NY Public Health Law § ~~272(5)(a)~~ 270(13).

1.1.46 "Wholesale Acquisition Cost" or "WAC" has the same meaning this term has in Subparagraph (c)(6)(B) of Section 1847A of the Act, 42 U.S.C. § 1395w-3a(c)(6)(B), which is reported, as of the last day of the invoiced quarter, in the wholesale price guides or other publications of drug or biological pricing data which the Department, in its sole discretion, selects, provided that unless the publication the Department selects is no longer available to the general public with or without a fee, the Department shall not change the wholesale price guide or other publication of drug or biological data from which it derives WACs for purposes of this Agreement except after giving notice of such intent to Manufacturer when it solicits Net Costs pursuant to Section 4.~~3~~ 4 or Section 4.~~5~~ 6.

2 TERM AND SCOPE OF THE AGREEMENT

2.1 This Agreement shall be effective for an initial period of three years from the Contract Date and shall be automatically renewed for additional three-year terms, unless it is not renewed in accordance with Section ~~8~~ 7.~~2~~ or it is terminated in accordance with: Section 3.~~7~~ 9, 3.~~8~~ 10, 5.4, ~~8~~ 7.1, ~~8~~ 7.2 or ~~8~~ 7.3; the Standard Clauses for all New York State Contracts, annexed to this Agreement as Appendix A; or the Federal Health Insurance Portability and Accountability Act ("HIPAA") Business Associate Agreement Governing Privacy and Security, annexed to this Agreement as Appendix H.

2.2 The scope of this Agreement consists of matters pertaining to Manufacturer's payment of Medicaid Supplemental Rebates for State and Medicaid MCO Utilization of ~~Preferred Supplemental~~ Covered Products and, if applicable, the State's designation of Covered Products as Preferred or Non-preferred Drugs in the NY PDP and its requirement of NY PDP Prior Authorization for any Supplemental Covered Products.

3 MANUFACTURER 'S RESPONSIBILITIES

3.1 The Manufacturer shall include any applicable Standard Clinical Criteria for Medicaid MCO Covered Products in the Condition-Limited Net Cost section of the Manufacturer Bid Sheet.

3.2 The Manufacturer shall not pay supplemental rebates to a Medicaid MCO on a Medicaid MCO Covered Product when standard clinical criteria apply and the State is collecting supplemental rebates for the Medicaid MCO Covered Product pursuant to this Agreement.

3.3 Manufacturer's obligation to pay Supplemental Rebates for State Utilization of a ~~Preferred Supplemental~~ Covered Product NDC shall begin on the later of the Contract Date or the earliest Price Effective Date for the ~~Preferred Supplemental~~ Covered Product NDC that appears on any Net Cost Schedule. (Section 4.1~~3~~ 4

describes the method of calculating such Supplemental Rebates.)

3.4 The Manufacturer may discontinue paying Supplemental Rebates for State Utilization of a ~~Preferred Supplemental~~ Covered Product NDC with respect to utilization that occurs after the earliest of the events described in Subsections A, B, and C ~~and D~~ of this Section following the Contract Date.

A. The Agreement is not renewed or otherwise terminates;

B. The Drug is no longer a Covered Product and, as permitted by Section ~~9~~ 8.6, Manufacturer assigns its obligation to pay CMS Rebates for such Drug;

C. With respect to a Preferred Supplemental Covered Product, the Department requires NY PDP Prior Authorization for such previously designated Preferred Supplemental Covered Product, provided, however, that Manufacturer's obligation to pay Supplemental Rebates for State Utilization of a Preferred Supplemental Covered Product NDC does not terminate under this Subsection where the Department requires prior authorization under any program other than the NY PDP.

~~D. The Covered Product is exempt from NY PDP Prior Authorization under NY Public Health Law § 272(12) and the Commissioner designates it as a Nonpreferred Drug in the NY PDP.~~

3.5 Not less than 30 calendar days before the end of the calendar quarter covered by a Supplemental Rebate Invoice, Manufacturer shall provide the Department with Manufacturer's CMS financial contact's name and address, and the Department shall send the Supplemental Rebate Invoice and supporting Rebate Summary to such address to the attention of the identified CMS financial contact. Transmission of the Supplemental Rebate Invoice and supporting Rebate Summary is not the provision of a notice within the meaning of Appendix G to this Agreement. If Manufacturer does not provide the Department with the name and address of its CMS financial contact before the thirtieth calendar day preceding the end of such calendar quarter, the Department may send the Supplemental Rebate Invoice and supporting Rebate Summary to the individual identified in the then-current Appendix G, and Manufacturer shall be obligated to pay the Supplemental Rebate Invoice as if it had been sent to its CMS financial contact.

3.6 If, for any quarter covered by this Agreement, Manufacturer provides to CMS a CMS Unit Rebate Amount for any ~~Preferred Supplemental~~ Covered Product NDC which the Department in good faith thinks is incorrect, the Department may calculate such NDC's Supplemental Rebate Amount Per Unit by using said CMS Unit Rebate Amount or by using either the last CMS Unit Rebate Amount Manufacturer submitted which the Department considers valid or a CMS Unit Rebate Amount Manufacturer provides to the Department verbally or otherwise. The Manufacturer shall correct the CMS Unit Rebate Amount on the Supplemental Rebate Invoice it receives from the Department and shall remit to the State payment for Supplemental Rebates owing for such quarter calculated using the corrected CMS Unit Rebate Amount.

3.7 Manufacturer shall remit to the State the Supplemental Rebate payment in full within 37 calendar days of the Postmark Date of the Department's Supplemental Rebate Invoice and supporting Rebate Summary.

3.8 Interest will accrue on unpaid invoiced amounts of Supplemental Rebates at the rate allowed by paragraph (d)(5) of Section 1903 of the Act, 42 U.S.C. § 1396b(d)(5). Interest on unpaid Supplemental Rebates begins accruing 38 calendar days after the Postmark Date of the Supplemental Rebate Invoice and supporting Rebate Summary, and interest will continue to accrue on any remaining unpaid balance until the Postmark Date of the Manufacturer's payment in full of the invoiced amount and all accrued interest. If the Postmark Date of Manufacturer's Supplemental Rebate remittance is 69 calendar days or more from the Postmark Date of the Supplemental Rebate Invoice, the interest rate will be calculated as required under federal guidelines for CMS Rebates, but will be increased by ten percentage points, not to exceed the maximum rate allowed by State law.

3.9 Except with respect to any unpaid portion of a Supplemental Rebate Invoice about which Manufacturer has submitted a written notice of disputed State Utilization Data pursuant to Section 5.1, which dispute has not been resolved in accordance with Section 5~~.1 through and including Section 5.7~~, Manufacturer shall be deemed to be in default of this Agreement, and the State may terminate this Agreement, if Manufacturer does not send the State payment in full of the amount of Supplemental Rebates billed on a Supplemental Rebate Invoice, as amended in accordance with Section 3.~~4~~ 6 where relevant, including any applicable interest accrued in accordance with Section 3.~~6~~ 8, within 180 calendar days following the Postmark Date of the Supplemental Rebate Invoice and supporting Rebate Summary. Whether Manufacturer is in default shall be determined by the Postmark Date of its transmission of its payment(s).

3.10 Upon a default as described in Section 3.~~7~~ 9, the Department, in its sole discretion and in lieu of terminating this Agreement immediately, may give Manufacturer written notice it is in default and the conditions Manufacturer must meet in order to cure such default. If Manufacturer does not comply fully with such conditions, the Department, in is sole discretion, may terminate this Agreement. Termination of the Agreement in accordance with this Section or Section 3.~~7~~ 9 shall be effective on the Postmark Date on which the Department sends a written notice of termination to Manufacturer. The Department's notice of termination of the Agreement shall cite this Section and/or Section 3.~~7~~ 9 of the Agreement, and the termination shall not affect Manufacturer's obligation to remit Supplemental Rebates for State Utilization of the ~~Preferred~~ Supplemental Covered Products which occurred prior to the termination of this Agreement.

3.11 Unless the Department notifies Manufacturer in writing to use a different method of transmission or addressee, Manufacturer shall send Supplemental Rebate payments by certified mail, return receipt requested, or via overnight courier, to the following address:

Bank of America Lockbox Services
NYS Department of Health (33594)

99 Founders Plaza
3rd Floor Mailroom
East Hartford, CT 06108

4 DEPARTMENT RESPONSIBILITIES

4.1 When Medicaid MCO Covered Products on the Net Cost Schedule are identified for which standard clinical criteria apply, as mutually agreed upon by the State and the Medicaid MCOs, the State shall notify all Medicaid MCOs that such utilization shall not be included in any Medicaid MCO supplemental rebate programs peripheral to this Agreement.

4.2 Except ~~when~~ for (i) Covered Products that, in accordance with the procedures and criteria set out in NY Public Health Law § 270 through and including § 273 and in Section 4.10, the Commissioner determines ~~that a Supplemental Covered Product~~ do~~es~~ not meet the standard for a Preferred Drug on the NY PDL; and (ii) Covered Products that are Medicaid MCO Covered Products, the Commissioner shall designate ~~each Supplemental~~ a Covered Product as a Preferred Drug on the NY PDL, making each such Covered Product a Preferred Supplemental Covered Product. The Department may remove any such Preferred Supplemental Covered Product from the NY PDL, making it a Non-preferred Drug in the NY PDP, upon the occurrence of any event described in Subsection A, B, or C ~~or D~~ of this Section.

A. The Commissioner, acting in accordance with NY Public Health Law § 270 through and including § 273, requires NY PDP Prior Authorization for the previously designated Preferred Supplemental Covered Product, regardless of whether the Commissioner requires NY PDP Prior Authorization for all drugs in its Therapeutic Class;

~~B. With respect to a previously designated Preferred Supplemental Covered Product that is exempt from NY PDP Prior Authorization pursuant to NY Public Health Law § 272(12), the Commissioner, acting in accordance with NY Public Health Law § 270 through and including § 273, designates such previously designated Preferred Supplemental Covered Product as a Nonpreferred Drug in the NY PDP;~~

B. The previously designated Preferred Supplemental Covered Product is no longer a Covered Product and, as permitted by Section ~~9~~ 8.6, Manufacturer has assigned its obligation to pay CMS Rebates for such Drug; or

C. The Agreement is not renewed or it otherwise terminates and the Commissioner, in accordance with NY Public Health Law § 272(10)(b) and after receiving the ~~P&T Committee~~ DUR Board's recommendation, does not determine that the previously designated Preferred Supplemental Covered Product is the one Drug that is significantly more clinically effective and safe than the other Drugs in its Therapeutic Class.

4.3 If the Department requires NY PDP Prior Authorization for any Covered Product, the Department shall comply with all provisions of Paragraph (d)(5) of Section 1927

of the Act, 42 U.S.C. § 1396r–8(d)(5).

4.4 At or about the Contract Date and not less than 120 calendar days before every third anniversary of the Contract Date, the Department may, by transmitting a Manufacturer Bid Sheet to Manufacturer, solicit Net Costs from Manufacturer for all of its Covered Product NDCs that are Brand Drugs, irrespective of whether such Covered Product is, at that time, ~~a Supplemental Covered Product or~~ a Preferred Drug on the NY PDL. Manufacturer shall respond to such solicitation within 45 calendar days of its Postmark Date by returning the Manufacturer Bid Sheet with the requested information for the Net Costs Manufacturer is offering. (A blank copy of an exemplar Manufacturer Bid Sheet is annexed to this Agreement as Appendix B. The Department may employ other formats for the Manufacturer Bid Sheets it transmits to Manufacturer.)

4.5 Subject to Subsection D of this Section, at any time after the Department solicits Net Costs in accordance with Section 4.~~3~~ 4:

A. The Department may notify Manufacturer that, unless, within a time period specified in such notice, Manufacturer responds to such solicitation with Net Costs for the Covered Products identified in such notice or offers Net Costs for identified Covered Products that are lower or in addition to those it has already offered, the Commissioner may designate Manufacturer as a pharmaceutical manufacturer with which "the Commissioner is negotiating . . . a manufacturer agreement" within the meaning of NY Public Health Law § 272(11)(b). References in this Agreement to a solicitation initiated pursuant to Section 4.~~3~~ 4 include the notice described in this Subsection, to which a Manufacturer Bid Sheet will be attached, if such a notice has been transmitted to Manufacturer.

B. If, with respect to some or all of the Covered Products identified in the notice described in Subsection A of this Section, Manufacturer does not, within the time specified in such notice, offer lower, new or additional Net Costs, or the Commissioner is not satisfied with the Net Costs Manufacturer offers after such notice, the Commissioner may at any time designate Manufacturer as a pharmaceutical manufacturer with which "the Commissioner is negotiating . . . a manufacturer agreement" within the meaning of NY Public Health Law § 272(11)(b) and give Manufacturer notice of such designation and that such a "manufacturer agreement" has not been reached.

C. Upon the Postmark Date of the notice described in Subsection B of this Section, any or all of Manufacturer's Drugs shall be Non-preferred Drugs in the NY PDP, unless, pursuant to NY Public Health Law § 272(10)(b), ~~the Commissioner, after receiving the P&T Committee's recommendation, determines that a Covered Product shall be a Preferred Drug on the NY PDL because it is the one Drug that~~ the covered product is significantly more clinically effective and safe than the other ~~Drugs~~ products in its Therapeutic Class.

D. The Department may not send the notices described in Subsection A or B of this Section between the Postmark Date of a Net Cost Schedule the Department sends Manufacturer following a Net Cost solicitation described in Section 4.~~3~~ 4 and the Postmark Date of a new Net Cost solicitation pursuant to Section 4.~~3~~

4 which the Department sends Manufacturer in connection with a subsequent triennial anniversary of the Contract Date.

4.6 Not less than 60 calendar days before the annual anniversary of the Contract Date, other than a triennial anniversary addressed in Section 4.~~3~~ 4, and at any other time that the Department in its sole discretion determines it is appropriate to do so, the Department may solicit a new, lower or additional Net Cost for any or all ~~Supplemental Covered Product NDCs and~~ Covered Product NDCs by transmitting a Manufacturer Bid Sheet to Manufacturer. Manufacturer shall respond to such solicitation within 30 calendar days of its Postmark Date by returning the Manufacturer Bid Sheet with the requested information for the Net Costs Manufacturer is offering. Subject to the last sentence of this Section, the Department shall not send Manufacturer a Net Cost solicitation pursuant to this Section within 120 calendar days before it sends Manufacturer a Net Cost solicitation pursuant to Section 4.~~3~~ 4, except with respect to a Drug that becomes a Covered Product during such 121-day period. The Department shall solicit a lower, new or additional Net Cost whenever~~, as part of a Prospective DUR, the Commissioner decides to require Step Therapy for a Preferred Supplemental~~ new or revised clinical criteria is applied to the Covered Product.

4.7 The Department shall transmit to Manufacturer a Net Cost Schedule that contains the final Net Costs Manufacturer offers the Department in response to each solicitation described in Section 4.~~3~~ 4 or 4.~~5~~ 6, provided that the Department shall not transmit such a Net Cost Schedule if, pursuant to Subsection C of Section 4.~~4~~ 5, any or all Covered Products are Non-preferred Drugs, ~~except for those the Commissioner determines, after receiving the P&T Committee 's recommendation, are Preferred Drugs because each~~ unless the covered product is significantly more clinically effective and safe than the other ~~Drugs~~ products in its Therapeutic Class, as provided by NY Public Health Law § 272(10)(b). (A blank copy of an exemplar Net Cost Schedule is annexed to this Agreement as Appendix C. The Department may transmit to Manufacturer Net Cost Schedules that employ other formats.)

4.8 Each Net Cost Schedule shall include only one Net Cost for each ~~Supplemental~~ Covered Product NDC, except where Manufacturer offers more than one Condition-Limited Net Cost for such NDC on the Manufacturer Bid Sheet that contains its final Net Cost offer for such NDC. Each Net Cost Schedule shall include each of the following, as relevant, and may include other information the Department deems appropriate:

A. the Price Effective Date for each Net Cost listed on the Net Cost Schedule;

B. the final Net Cost(s) that Manufacturer offered the Department for the ~~Supplemental Covered Product NDCs and~~ Covered Product NDCs in Manufacturer's response to solicitations the Department transmitted to Manufacturer pursuant to Section 4.~~3~~ 4 or Section 4.~~5~~ 6, subject to the following conditions:

i. Net Costs contained on prior Net Cost Schedules shall not be carried forward on the Net Cost Schedule the Department transmits to Manufacturer following a Section 4.~~3~~ 4 solicitation, unless all the following conditions exist: the

contract is renewed, Manufacturer does not respond to the Section 4.~~3~~ 4 solicitation and the Department does not exercise the option described in Subsections B and C of Section 4.~~4~~ 5; and

ii. with respect to Net Cost Schedules the Department transmits to Manufacturer following a Section 4.~~5~~ 6 solicitation, and subject to the remainder of this Paragraph, the Department may, in its sole discretion, (a) carry forward on such Net Cost Schedule any Net Costs which were contained on the Net Cost Schedule in effect when the Department sent such solicitation and (b) omit any new or additional Net Costs contained in Manufacturer's response to the Section 4.~~5~~ 6 solicitation. The Department may not, however, carry forward any Net Costs for ~~Supplemental~~ Covered Products identified in a Section 4.~~5~~ 6 solicitation as Drugs for which Prospective DUR Step Therapy will be required; and

C. the conditions under which the Department may use each Condition-Limited Net Cost to calculate Supplemental Rebates if a ~~Supplemental~~ Covered Product NDC becomes or is retained as a Preferred Supplemental Covered Product.

4.9 The Department may exclude specified conditions from those for which Manufacturer may offer Condition-Limited Net Costs in response to a Section 4.~~3~~ 4 or Section 4.~~5~~ 6 solicitation, except that the Department may not exclude as such a condition that Prospective DUR Step Therapy has been required for the ~~Supplemental~~ Covered Product.

4.10 Within 20 calendar days following the Postmark Date of each Net Cost Schedule, Manufacturer shall provide the Department with: (a) a paper copy of such Net Cost Schedule, which contains the requested information describing Manufacturer's receipt of the Net Cost Schedule, (b) the original paper Certificate of Authenticity applicable to such paper copy of the Net Cost Schedule, (c) an electronic file that contains the Net Cost(s) set out in such Net Cost Schedule, which shall be in the format the Department specifies and (d) the original paper Certificate of Authenticity applicable to such electronic file. Such electronic file shall accurately and completely reflect only the content of the relevant Net Cost Schedule with respect to the following subjects: each ~~Supplemental~~ Covered Product NDC's Net Cost(s) and Price Effective Date(s), whether a Net Cost is a Condition-Limited Net Cost, and the conditions under which each such Condition-Limited Net Cost may be used to calculate Supplemental Rebates if and when the Drug to which it pertains is designated a Preferred Supplemental Covered Product. A copy of the required Certificate of Authenticity pertaining to the paper copy of the Net Cost Schedule is annexed to this Agreement as Appendix D, and a copy of the required Certificate of Authenticity pertaining to the electronic file containing the information from the Net Cost Schedule is annexed to this Agreement as Appendix E.

4.11 A. Except when a Covered Product is a Non-preferred Drug pursuant to Subsection C of Section 4.~~4~~ 5, the ~~P&T Committee~~ DUR Board shall recommend and the Commissioner shall determine whether a ~~Supplemental~~ Covered Product will become or remain a Preferred Drug or a Non-preferred Drug in the NY PDP when they review its Therapeutic Class. When such determination is based in part on the Supplemental

Covered Product's cost effectiveness, the ~~P&T Committee~~ DUR Board and Commissioner shall consider its Net Cost(s) that, as of the date of such consideration, was listed on the Net Cost Schedule the Department most recently transmitted to Manufacturer.

B. If, during the term of this Agreement, a generic equivalent of a Preferred Supplemental Covered Drug should become available and no Federal Upper Limit is established pursuant to Section 1927(e), 42 U.S.C. §1396r-8(e), the ~~P & T Committee~~ DUR Board may recommend, and the Commissioner may determine, that the applicable Preferred Supplemental Covered Drug shall remain a Preferred Drug on the NY PDL as long as the net cost to the Department for the Preferred Supplemental Covered Drug is not more than the net cost to the Department for a generic equivalent, and Manufacturer continues to pay Supplemental Rebates for the Preferred Supplemental Covered Drug. For purposes of this subparagraph, a Preferred Supplemental Covered Drug has a generic equivalent when it is a multiple source drug within the meaning of Section 1 927(k)(7)(i), 42 U.S.C. § 13 96r-8(k)(7)(i).

4.12 Following the Commissioner's determination made pursuant to Subsection C of Section 4.~~4~~ 5 or to Section 4.1~~0~~ 1, the Department shall revise the NY PDL posted on the Department's Web site to reflect the Commissioner's determination whether a Covered Product will become or remain a Preferred Drug or Non-preferred Drug in the NY PDP.

4.13 For six years following the termination of this Agreement, the Department shall retain a paper copy or an electronic image in PDF format, or other format to which the parties agree in writing, of each NY PDL posted on the Department's Web site, which shall contain the date on which such NY PDL is first effective.

4.14 The Department shall calculate the Supplemental Rebate for a quarter by multiplying the number of units of each Preferred Supplemental Covered Product NDC reimbursed by the Department for State Utilization in such quarter by the relevant Supplemental Rebate Amount Per Unit for such NDC, as determined based on the NDC's Price Effective Date, and summing the products of said multiplication(s).

4.15 The Department shall use the quarters ending on March 31, June 30, September 30, and December 31 to calculate Supplemental Rebates.

4.16 On a quarterly basis, the Department shall provide Manufacturer with aggregate State Utilization Data by NDC number for all Covered Products that were ~~Preferred Supplemental~~ Covered Products for any part of the quarter. The Department shall base these data on paid claims data (data used to reimburse Pharmacy Providers) under the New York Medicaid Program and all other State programs included in this Agreement pursuant to Section 4.2~~0~~ 1. The State Utilization Data shall be consistent with any applicable Federal or State guidelines, regulations and standards for such data.

4.17 The Department shall maintain those data systems necessary to calculate the Supplemental Rebates.

4.18 The Department shall maintain electronic or other claims records for not less than six years to permit Manufacturer to verify through an audit process the Rebate Summaries provided by the Department. Any audit conducted pursuant to this Section shall be conducted by independent auditors, at Manufacturer's expense, during regular business hours and not more often than one time per calendar year. The independent auditors shall provide at least 30 calendar days prior written notification of their intent to audit. The Department shall make available to the independent auditors such records as are required to demonstrate the accuracy of the claims submitted to Manufacturer under this Agreement. The independent auditors shall be required to enter into confidentiality agreements with the State and Manufacturer as necessary to comply with state and federal laws and regulations governing the privacy of individual or other health information or information that is proprietary and/or confidential. The Department shall not provide the independent auditors with access to information related to other manufacturers.

4.19 The State shall obtain CMS's approval of any changes to its state Medicaid plan that pertain to subjects within the scope of this Agreement as described in Section 2.2, the NY PDP, or this Agreement. Manufacturer shall not be required to remit any Supplemental Rebates that this Agreement would otherwise obligate it to pay the State until the State has obtained the applicable CMS approvals provided for in this Section. The Department shall provide Manufacturer, within 30 calendar days of receipt, a copy of the CMS document authorizing the State to enter into this Agreement.

4.20 The Department may seek CMS's approval to include in this Agreement any State program, in addition to Medicaid, that reimburses Pharmacy Providers for Drugs that are Preferred Supplemental Covered Products only when all the conditions set out in Subsections A and B of this Section are met.

A. The program utilizes the NY PDL and NY PDP Prior Authorization or an alternative that is an exact duplicate of the NY PDL and NY PDP Prior Authorization;

B. The prices the program pays for Covered Products are exempt from the determination of Best Price in accordance with Subparagraph (c)(1)(C) of Section 1927 of the Act, 42 U.S.C. § 1396r-8(c)(1)(C).

4.21 If, in accordance with Section 4.~~19~~ 20, the Department seeks and receives approval from CMS to include a State program in addition to Medicaid in this Agreement, the Department shall transmit to Manufacturer a copy of such approval. Said State program shall be included in this Agreement unless, within 30 calendar days from the Postmark Date of such transmission, Manufacturer objects in writing to such inclusion. Where Manufacturer does not transmit a timely written objection, such program shall be included in this Agreement beginning on the thirtieth calendar day after the Postmark Date of the Department's transmission of CMS's approval or on an earlier date to which Manufacturer agrees in writing. Beginning on such effective date, Manufacturer is obligated to pay Supplemental Rebates for such program's State Utilization of Preferred Supplemental Covered Products in accordance with the terms and conditions set forth in this Agreement or in any amendment to this Agreement

entered into pursuant to Section ~~9~~ 8.9.

4.22 To the extent the Department utilizes the services of a third-party to develop and maintain the PDL, or to administer any part of this Agreement, all provisions of this Agreement shall apply to the third-party, and the Department shall have the third-party sign a written agreement which assures that the third-party shall comply with all aspects of this Agreement.

5 DISPUTE RESOLUTION

5.1 In the event that in any quarter Manufacturer questions the accuracy of the State Utilization Data, the Department shall cooperate with Manufacturer in obtaining relevant information to support the State's data or make an adjustment the Department deems appropriate, which may include a credit applied to the amount of the Supplemental Rebates Manufacturer would otherwise owe the State or a refund to Manufacturer, as the parties may agree. If Manufacturer and the Department in good faith are unable to resolve such a dispute, the Manufacturer may provide written notice of the disputed State Utilization Data to the Department.

5.2 If the Manufacturer in good faith believes the State Utilization Data are erroneous, the Manufacturer shall pay the Department that portion of the Supplemental Rebates claimed that is not in dispute within 37 calendar days of the Postmark Date of the Department's Supplemental Rebate Invoice and supporting Rebate Summary.

5.3 Within 37 calendar days following the Postmark Date of the first Supplemental Rebate Invoice the Department sends to Manufacturer following resolution of the dispute, Manufacturer shall pay to the State the balance that said resolution determined Manufacturer owes the State (the "previously disputed balance") and any applicable interest that has accrued on such balance. Interest will accrue in accordance with the provisions of Section 3.~~6~~ 8 on any previously disputed balance beginning 38 calendar days after the Postmark Date of the Supplemental Rebate Invoice on which such previously disputed Supplemental Rebates originally appeared.

5.4 Manufacturer shall be deemed to be in default of this Agreement, and the State may terminate this Agreement in accordance with the procedures described in Sections 3.~~7~~ 9 and 3.~~8~~ 10 if Manufacturer does not send the State payment in full of the previously disputed balance, and any interest that has accrued on such balance, within 180 calendar days following the Postmark Date of the first Supplemental Rebate Invoice the Department sends to Manufacturer following resolution of such dispute.

5.5 The Department and Manufacturer shall use their best efforts to resolve any disputed State Utilization Data within 60 calendar days of the Department's receipt of Manufacturer's written notification of such dispute, which shall be accompanied by Manufacturer's argument in writing and all relevant materials supporting its position. Should additional information be required to resolve such a dispute, the Department and Manufacturer shall cooperate to obtain the additional information.

5.6 In the event the Department and Manufacturer are not able to resolve a dispute

regarding State Utilization Data as provided for in Section 5.1 through and including Section 5.7, Manufacturer may request a reconsideration of the Department's determination within 30 calendar days after the end of the 60-day period identified in Section 5.5.

5.7 In the event the Department and Manufacturer are unable to resolve a dispute regarding State Utilization Data as provided for in Section 5.1 through and including Section 5.7, the parties shall utilize the same State procedure that is used to resolve disputes under the Medicaid Drug Rebate Program, consistent with CMS's then-current Best Practices Guide for Dispute Resolution under the Medicaid Drug Rebate Program.

6 CONFIDENTIALITY PROVISIONS

6.1 Information the Manufacturer discloses pursuant to a requirement of this Agreement or a written request from the Department is confidential and shall not be disclosed, except as required by State or Federal law.

6.2 The Manufacturer shall maintain the confidentiality of State Utilization Data and use such information only for purposes approved by the Department. If Manufacturer audits the State Utilization Data or receives additional information concerning State Utilization, that information shall also be held confidential. Manufacturer agrees to abide by applicable State confidentiality statutes, regulations and other properly promulgated policies of the State.

6.3 The Manufacturer herewith applies to the Department for a determination under NY Public Officers Law, Article 6 (Freedom of Information), in accordance with Section 89.5(a)(1), that the information Manufacturer supplies to the Department for the Department's calculation of Supplemental Rebate amounts under this Agreement are exempt from disclosure because their disclosure would cause substantial injury to Manufacturer's competitive position. In addition, the Department is authorized by NY Public Officers Law Section 87.2(c) to withhold the information because their disclosure would impair recurring present or imminent contract awards.

6.4 Manufacturer and the Department shall each inform and train, if necessary, its respective employees, agents, advisors, consultants and officials regarding the confidential nature of information described in Sections 6.1 and 6.2 and shall cause such persons (including any board or committee) to keep such data and information confidential.

6.5 In the event an attempt is made to compel either Manufacturer or the Department to disclose information described in Sections 6.1 and 6.2, said party shall notify the other party to this Agreement in a prompt manner to allow the other party to seek injunctive or other relief prohibiting the disclosure of such information or data.

6.6 The Department shall not duplicate or use the information described in Section 6.1, and Manufacturer shall not duplicate or use the State Utilization Data, except in connection with this Agreement or as may be required by judicial order.

6.7 Manufacturer shall comply with the Federal Health Insurance Portability and Accountability Act ("HIPAA") Business Associate Agreement Governing Privacy and Security, annexed to this Agreement as Appendix H, as applicable to any Protected Health Information Manufacturer receives from or on behalf of the State.

6.8 Notwithstanding the termination of this Agreement for any reason, these confidentiality provisions (Sections 6.1 through and including 6.7) shall remain in full force and effect.

~~7 CONTRACTUAL PENALTY~~

~~7.1 Where Manufacturer does not respond to a solicitation it receives pursuant to Section 4.3 or 4.5 within the time specified in such Section ("specified time"), the Department, in its sole discretion, may impose a penalty on Manufacturer, which shall begin to accrue on the sixth calendar day following the expiration of the specified time and stop accruing on the earlier of when the Agreement terminates or Manufacturer responds to such solicitation. Such penalty shall not exceed: one thousand dollars ($1,000.00) per day for the sixth through and including the tenth calendar day following the expiration of the specified time, five thousand dollars($5,000.00) per day for the eleventh through and including the fifteenth calendar day following the expiration of the specified time, and ten thousand dollars ($10,000.00) per calendar day from the sixteenth day following the expiration of the specified time until the penalty stops accruing in accordance with this Section.~~

7 NON-RENEWAL AND TERMINATION OF THE AGREEMENT

7.1 The State may terminate this Agreement with or without cause upon 60 days prior written notice.

7.2 Between the 120th and 90th day immediately preceding the third anniversary of the Contract Date, and every third anniversary of the Contract Date thereafter, Manufacturer may notify the Department that it will not renew this Agreement, in which case the Agreement will terminate upon such anniversary of the Contract Date.

7.3 The State reserves the right to terminate this Agreement in the event it is found that the certificate(s) filed by Manufacturer in accordance with the Tax Laws of 2004, Chapter 60, Part N, was false or incomplete.

8 GENERAL PROVISIONS

8.1 Whenever this Agreement adopts any aspect of a federal or state statute by reference, such reference shall be read as though it includes the phrase, "as said statute(s) may be amended."

8.2 Any notice required to be given pursuant to the terms and provisions of this Agreement shall be transmitted in accordance with the document entitled "NOTICES," annexed to

this Agreement as Appendix G. By written notification to the other party, the Department and Manufacturer may each modify its addressee or information pertaining to such addressee contained in Appendix G. Provisions of this Agreement that require an action to be taken within a time period that begins with a Postmark Date do not constitute a modification to the description in Appendix G of when written materials are "received," but instead constitute a different method of measuring time not addressed by Appendix G.

8.3 That the State does not seek to enforce a provision of this Agreement shall not preclude it from subsequently enforcing such provision or constitute a waiver by the State of any other provision of this Agreement.

8.4 Nothing in this Agreement shall be construed or interpreted as limiting or otherwise affecting the State's or Manufacturer's ability to pursue its rights arising out of the terms and conditions of the Agreement in the event that a dispute between the parties is not otherwise resolved. Proper venue and jurisdiction for any legal action relating to this Agreement shall be in the State of New York, County of Albany or the United States District Court for the Northern District of New York, Albany Division, as applicable.

8.5 Manufacturer and the agents and employees of Manufacturer in the performance of this Agreement, will act in an independent capacity and not as officers, employees or agents of the State.

8.6 If Manufacturer's obligation to pay CMS Rebates for any or all Drugs that were or became Covered Products as of or after the Contract Date is transferred to another entity (the "transferee") pursuant to Clause two of Appendix A to this Agreement, Manufacturer shall, within 30 days of such transfer, request in writing the Department's consent, and, if consistent with Clause two of Appendix A to this Agreement, the Department shall consent in writing, to Manufacturer's assignment to the transferee of its rights and obligations, if any, under this Agreement with respect to such previously designated Covered Products. If any of Manufacturer's rights or obligations under this Agreement are assigned pursuant to this Section, Manufacturer shall provide the Department with the information required by Appendix G for the person or entity to which such assignment is made.

8.7 Nothing in this Agreement shall be construed so as to require the commission of any act contrary to law. If any provision of this Agreement is found to be invalid or illegal by a court of law, or inconsistent with federal or state requirements, this Agreement shall be construed in all respects as if any invalid, unenforceable, or inconsistent provision were eliminated, and without any effect on any other provision. The parties agree to attempt to negotiate replacement provisions, to afford the parties as much of the benefit of their original bargain as is possible.

8.8 The Department and Manufacturer declare that this Agreement, including any attached materials, contains a total integration of all rights and obligations of both with respect to the subject matter that is within the scope of the Agreement as described in Section 2.2. There are no extrinsic conditions, collateral agreements or undertakings of any kind that pertain to the subject matter within the scope of the Agreement as described

in Section 2.2. In regarding this Agreement as the full and final expression of their contract, it is the express intention of both parties that any and all prior or contemporaneous agreements, promises, negotiations or representations, either oral or written, relating to the subject matter within the scope of the Agreement as described in Section 2.2 and period of time governed by this Agreement which is not expressly set forth herein, are to have no force, effect, or legal consequences of any kind.

8.9 Except as expressly provided in this Agreement, this Agreement cannot be altered except by an amendment in writing signed by both parties. No individual is authorized to alter or vary the terms or make any representation or inducement relative to it, unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Department and Manufacturer and approved by the Office of the New York State Comptroller. Nothing contained herein shall prevent Manufacturer and the Department from mutually agreeing to amend the Agreement at any time. Any modification or amendment to this Agreement must be authorized by CMS.

8.10 Neither party contemplates any circumstances under which indemnification of the other party would arise. Nevertheless, should such circumstances arise, Manufacturer agrees to indemnify, defend and hold harmless the State, its officers, agents and employees from any and all claims and losses accruing or resulting to any person, firm or corporation who may be injured or damaged by the Manufacturer's negligent or willful misconduct in the performance of this Agreement. The State must provide Manufacturer with prompt written notice of any claim or action alleging such liability and the State must cooperate fully in the defense of such claim or action. Any defense of the Department that Manufacturer undertakes pursuant to this Section requires and is subject to the approval and consent of the New York State Attorney General and, except to the extent due to a claim arising from the Department's negligence or wilful misconduct, will be at Manufacturer's sole cost and expense.

8.11 Inasmuch as the Supplemental Rebates required by this Agreement are for New York Medicaid Program beneficiaries, it is agreed, in accordance with Medicaid Drug Rebate Program Release #102 For State Medicaid Directors and other applicable law, that the Supplemental Rebates do not establish a new "Best Price" for purposes of Manufacturer's HHS Agreement.

8.12 Manufacturer agrees to comply with the provisions of the New York State Information Security Breach and Notification Act (General Business Law Section 899-aa; State Technology Law Section 208). Manufacturer shall be liable for the costs associated with such breach if caused by Manufacturer's negligent or willful acts or omissions, or the negligent or willful acts or omissions of Manufacturer's agents, officers, employees or subcontractors.

9 APPENDICES

9.1 Appendix A is attached hereto and is made part of this Agreement. Appendix A, "Standard Clauses for all New York State Contracts," supersedes any and all of its prior versions. If there is a conflict between Appendix A and any terms and conditions in this Letter of Agreement, then Appendix A shall control.

9.2 Appendix B is a blank copy of an exemplar Manufacturer Bid Sheet.

9.3 Appendix C is a blank copy of an exemplar Net Cost Schedule.

9.4 Appendix D is attached hereto and is made part of this Agreement. Appendix D is the "Certificate of Authenticity of Paper Net Cost Schedule."

9.5 Appendix E is attached hereto and is made part of this Agreement. Appendix E is the "Certificate of Authenticity of Electronic File Containing Information from a Net Cost Schedule."

9.6 Appendix G, "NOTICES" is attached hereto and is made part of this Agreement.

9.7 Appendix H is attached hereto and is made part of this Agreement. Appendix H, "Federal Health Insurance Portability and Accountability Act ("HIPAA") Business Associate Agreement Governing Privacy and Security," supersedes any and all of its prior versions.

9.8 Appendix I is attached hereto and is made part of this Agreement. Appendix I lists the non-Medicaid programs approved by CMS in the State Plan, which, as of the Contract Date, is no such programs.