PART II - CHAPTER 900
SCOPE OF SERVICE

901. General

Effective January 1, 1991, payment for pharmaceutical services is limited to those products of manufacturers who offer rebates to the states as required by the Omnibus Reconciliation Act of 1990. The Division covers the products of all manufacturers who offer such rebates with certain exceptions. The drugs or classes of drugs listed below represent those the Division has elected to exclude from coverage (as allowed by federal law).

901.1 Non-Covered Drugs

(A). Agents used for anorexia or weight gain.
(B). Agents used to promote fertility.
(C). Agents used for cosmetic purposes or hair growth.
(D). Agents used to promote smoking cessation.
(E). Drugs identified by the Health Care Financing Administration (HCFA) as less than effective (DESI), as provided under Section 1927(k)(2)
(F). Barbiturates, except Seconal, Phenobarbital and Mebaral.
(G). Prescription vitamins and mineral products except prenatal vitamins and fluoride preparations that are not in combination with other vitamins and Carnitor. Vitamin E and Coenzyme Q are covered under medical necessity for <21.

Children's multiple vitamins in combination with fluoride will be covered for members 21 years of age or less when documented as medically necessary.

(H). Legend prenatal vitamins are covered for women
(I). Nonprescription drugs with the following exceptions: multi-vitamins and multiple vitamins with iron for members less than 21 years of age (chewable or liquid drops), enteric coated aspirin (covered under per diem for nursing home members), PEN-X, ibuprofen suspension for members <21, OTC folic acid, diphenhydramine, insulin, NIX, iron, KLOUT, Lice-B Gone, meclizine, insulin syringes and urine test strips. Effective April 1, 1995, the following medications are covered **ONLY FOR ESRD PATIENTS** when the physician has certified them for a medically accepted indication through the Prior Approval process. These drugs are exempt from the monthly prescription limit. All strengths and dosage forms of each drug entity are covered with some exceptions. Covered drugs include: Calcium Carbonate, Aluminum Hydroxide, Calcium

STATE OF GEORGIA

SUPPLEMENTAL REBATE AGREEMENT

between

THE GEORGIA DEPARTMENT OF COMMUNITY HEALTH

and

_____

The State of Georgia, acting by and through the Georgia Department of Community Health (hereinafter referred to as "DCH" or "Department") – Division of Medical Assistance (hereinafter referred to as "DMA"), and _____ (hereinafter referred to as "Manufacturer"), hereby enter into the following Supplemental Rebate Agreement (hereinafter referred to as "SRA" or "Agreement") effective this _____ day of _____, 2003.

WHEREAS, DCH is responsible for health care policy, purchasing, planning and regulation pursuant to the Official Code of Georgia Annotated (O.C.G.A.) § 31-5A-4 et. seq.; and

WHEREAS, _____(Manufacturer) is willing to provide supplemental rebates to the Department based on the actual payment for dispensing of Manufacturer's covered products under the Georgia Medicaid Plan; and

WHEREAS, It is the intent of this Agreement that the Department will receive Supplemental Rebates for the Medicaid population, in addition to rebates received under the CMS Rebate Agreement, pursuant to Section 1927 of the Social Security Act (42USC 1396r-8), for Manufacturer's Covered Product(s)' quarterly utilization in the Georgia Plans, the parties also intend for this Agreement to meet the requirements of Federal law at Section 1927 of the Social Security Act (42 USC 1396r-8).

NOW THEREFORE, for and in consideration of the mutual promises and covenants contained herein, it is agreed:

ARTICLE I – DEFINITIONS

1.1 As used in this Agreement, the following terms have the following meanings:" **Average Wholesale Price (AWP)"** shall mean the published price of the Covered Product by National Drug Code ("NDC") as published by First Data Bank on the first day of the calendar quarter that corresponds to the calendar quarter for which the Department utilization data for the Covered Product is reported to Manufacturer

1.2 **"Average Manufacturer Price" ("AMP")** shall mean, with respect to a covered outpatient drug of a Manufacturer for a rebate quarter, the average unit price paid to the Manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts and any other price reductions which reduce the actual price paid. AMP will be calculated as specified in Manufacturer's CMS Agreement. The quarters to be used for calculating the Rebates in this Agreement will be each of those ending March 31, June 30, September 30, and December 31 and corresponding to each of the quarters during which the contract is in effect in the calendar year(s) during the term of this Agreement. If it is determined that the actual AMP rises more than 3% of the reported AMP used to establish the original Supplemental Rebates, the Department reserves the right to adjust the percentage for calculation of the supplemental rebates by an equal percentage. The Department will maintain the data systems and audits as are necessary to ensure the accuracy of the data used to calculate the supplemental rebates. In the event material discrepancies are discovered, the Department will promptly justify its data or make an appropriate adjustment.

1.3 **"Best Price"** shall mean Best Price set forth in 42. U.S.C. 1396r-8, as such may be amended from time to time, excluding State Supplemental Rebate (SSR) amounts.

1.4 **"CMS"** shall mean the Centers for Medicare and Medicaid Services (formerly known as Health Care Financing Administration (HFCA)) of the United States Department of Health and Human Services, or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.

1.5 **"Fiscal Quarter"** shall mean one of the four (4) three-month periods by which the fiscal year is divided, that fiscal year beginning July 1, and ending on the following June 30.

1.6 **"National Rebate"** means, with respect to the Covered Product, the quarterly payment by Manufacturer pursuant to Manufacturer's CMS Agreement made in accordance with Section 1927(c)(1) or Section 1927(c)(3) of the Social Security Act (42 U.S.C. 1396r-8(c)(1) or 42 U.S.C. 1396r-(c)(3).

1.7 **"Georgia Medicaid Program"** or **"Georgia Medicaid"** shall mean the joint federal and state medical assistance program as established and defined pursuant to Title 42 U.S.C. 1396, et. seq., that provides reimbursement for or coverage of prescription drug products to Medicaid Members.

1.8 **"Medicaid Member"** shall mean any person enrolled in the Georgia Medicaid Plan and eligible to receive prescription drug benefits.

1.9 **"New Product"** shall mean any pharmaceutical product of Manufacturer that may be launched or otherwise become available from Manufacturer after the effective date of this Agreement.

1.10 **"Pharmacy"** shall mean a facility licensed in accordance with the laws of the State in which the pharmacy is located or of the State of Georgia as applicable, to dispense legend drugs and enrolled as a Georgia Medicaid provider.

1.11 **"Drug Utilization Review Board" ("DURB")** shall mean the group of health care professionals and other individuals who work with DCH to provide clinical expertise and advice to DCH regarding drug products.

1.12 **"Preferred Drug List"** shall mean the list developed by DCH with the advice of the DURB and assistance of the PBM, and approved by DCH which indicates the current status of the specific drug(s) based on the Department's determination of effectiveness and cost.

1.13 **"Product"** shall mean any prescription drug OTC drug product listed in Attachment A.

1.14 **"State Supplemental Rebate"** or **"SSR"** shall mean any cash rebate that offsets expenditures and that supplements CMS National Rebate. SSR amounts shall be calculated in accordance with Attachment C. In no case may the SSR amount be a negative amount. SSR shall also mean any cash rebate received on any medical device, or medical supplies routinely dispensed through an outpatient pharmacy program

1.15 **"Unit"** means the lowest identifiable dosage form of a drug product (*e.g.*, tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams).

ARTICLE II - TERM AND SCOPE OF AGREEMENT.

2.1 **Term.** The term of this Agreement shall be from_____, through_____, until all obligations set forth in this agreement have been satisfactorily fulfilled, whichever occurs first, unless the Agreement is otherwise terminated. A Manufacturer's obligation for State Supplemental Rebates will begin with the Rebate Billing Period for First full quarter following the completion of the contract and will continue through the quarter that ends the end date of the contract.

2.2 **Entire Agreement.** The terms and conditions of this Agreement along with any applicable Department's Administrative Rules and any documents expressly incorporated herein shall constitute the entire present agreement between the parties. This Agreement constitutes a total integration of all rights, benefits and obligations of the parties, and there exist no other agreements or understandings, oral or otherwise, that binds any of the parties regarding the subject matter of this Agreement.

ARTICLE III - TERMINATION.

3.1 **Termination Without Cause**. Notwithstanding any contrary provision in this Agreement, either party upon sixty (60) days written notice to the other may terminate

this Agreement. Termination shall become effective the first day of the first calendar quarter beginning at least sixty (60) days after a party gives written notice requesting termination.

3.2 **Notice of Change in Circumstances.** In the event Manufacturer, Manufacturer's parent, or a related corporate entity becomes a party to any litigation, investigation or transaction that may reasonably be considered to have a material impact on Manufacturer's ability to perform under this Agreement, Manufacturer will immediately notify the Department in writing.

3.3 **Non-waiver.** Failure of either party to insist on performance of any term or condition of this Agreement or to exercise any right or privilege hereunder shall not be construed as a continuing or future waiver of such term, condition, right or privilege.

3.4 **Breach.** If either party commits a material breach of this Agreement, the non-breaching party shall deliver written notice of the alleged breach to the breaching party, with an opportunity to cure the breach during the succeeding thirty (30) day period. Failure to cure shall give the non-breaching party the right to cancel this Agreement at the end of the thirty (30) day period. The non-breaching party shall give the breaching party final written notice of the cancellation of this Agreement.

3.5 **Accrued Obligations/Remedies.** The expiration or termination of this Agreement shall not affect any rights or obligations of the parties that have accrued prior to the effective date of such termination. The fact that either party exercises any right of termination it may have under this Agreement shall not prevent such party from pursuing any other remedy it may be entitled to in law or equity. Any remedy provided herein shall not be deemed an exclusive remedy unless expressly provided for as such.

ARTICLE IV - AGREEMENT MANAGEMENT AND NOTICES.

4.1. **Agreement Management.** The Department shall designate a Rebate Vendor who will facilitate communication between Manufacturer and various administrative units within the Department. All communications from Manufacturer to the Department pertaining to this Agreement are to be directed to the Rebate Vendor at the address and telephone number set forth herein, unless otherwise directed by the Department. Nothing in this section shall be construed to prevent the Department's counsel from contacting Manufacturer or Manufacturer's counsel.

4.2. **Notices.** All written notices, requests and communications, unless specifically required to be given by a specific method, may be: (i) delivered in person, obtaining a signature indicating successful delivery; (ii) sent by a recognized overnight delivery service, obtaining a signature indicating successful delivery; (iii) sent by certified mail, obtaining a signature indicating successful delivery; or (iv) transmitted by facsimile, producing a document indicating the date and time of successful transmission, to the address or facsimile number set forth below. All telephonic communications between the parties

shall be made to the telephone number(s) set forth below. Either party may at any time give notice in writing to the other party of a change of name, address, or telephone or facsimile number.

To Manufacturer:

Telephone
Facsimile

To Department: Department of Community Health
Division of Medical Assistance
_____, Rebate Vendor

Telephone
Facsimile

ARTICLE V - MANUFACTURER'S RIGHTS AND RESPONSIBILITIES.

5.1. **State Supplemental Rebate Payment.** Manufacturer agrees to provide a State Supplemental Rebate to the Department for each product identified in this agreement in Attachment A that is dispensed to a Medicaid Member and reimbursed to a Pharmacy for each Fiscal Quarter as indicated above. Manufacturer shall pay to the Department the State Supplemental Rebate amount in accordance with the formula set forth in Attachment C. Nothing in this Agreement shall be construed to relieve Manufacturer from its obligation to pay National Rebates under contracts, if any, with CMS for utilization by Medicaid Members. The Department shall remit State Supplemental Rebate payments made under this Agreement to CMS as required under its approved state plan.

A. ***Payment Timeframe.*** Manufacturer shall pay to the Department the State Supplemental Rebate amount to which the Department is entitled in accordance with the formula set forth in Attachment C, within thirty-eight (38) days after receipt of the Department's report described in Attachment B of this Agreement. At a minimum a detailed itemization per NDC, Rebate Summary, must accompany the payment. A 'Rebate Summary' means the report itemizing the Department Utilization Data supporting the Department's invoice for Rebates. The Rebate Summary will comply in all respects with requirements for Medicaid Utilization Information in the CMS Agreement

B. ***Timeliness.*** Manufacturer's failure to remit the State Supplemental Rebate amount within the 38 day period may result in a change in status of the drug pursuant to the application of the dispute resolution process set forth in Paragraph D, below. The participating Manufacturer will pay the supplemental rebates, including

any applicable interest in accordance with Section 1903 (d)(5) of the Act. Interest on the Rebates is payable and begins accruing 38 calendar days from the postmark date of the Department's invoice and supporting Rebate Summary sent to the Manufacturer and interest will continue to accrue until the postmark date of the Manufacturer's payment. Interest will be calculated in accordance with the method set by CMS for National Rebates.

C. ***Incomplete Submission.*** Manufacturer shall have no obligation for claims that are not submitted as part of an invoice in accordance with Section 6.4 of this Agreement. Manufacturer shall notify the Department or its designee of any incomplete submission within fifteen (15) calendar days after Manufacturer's receipt of such submission pursuant to Section 6.4.

D. ***Over/Underpayment.*** If either party discovers an error in the payment of State Supplemental Rebates by Manufacturer, it shall notify the other of such error within forty-eight (48) hours upon discovery of such error. The parties shall attempt to reconcile all differences through discussion and negotiation; if that attempt fails, the parties will resolve their dispute in accordance with generally acceptable procedures followed by the Department or CMS in disputes concerning National Rebates. Manufacturer shall deduct any overpayment from subsequent State Supplemental Rebates payable under this Agreement after notification, verification of the amount and mutual agreement. In the event that no further State Supplemental Rebates are payable, the Department and Manufacturer will determine a mutually agreeable method of settlement. Manufacturer will remit any underpayment to the Department within thirty (30) days after Manufacturer' s acknowledgment of such underpayment.

E. ***Product Utilization Eligible for Rebate.*** Product utilization as identified by the drug rebate vendor for the specific products as agreed to in Attachment A shall be eligible for State Supplemental Rebates pursuant to Attachment C only if and when it meets one of the following conditions:

1. **Own Use.** The Product shall have been dispensed and used in connection with this Agreement only for DCH Medicaid Members, for their own use.

2. **New Products**. Products have been added to this agreement through an amendment.

3. **Duration** Manufacturer has agreed to continue to pay supplemental rebates on the Covered Product(s) for as long as this Agreement is in force, and Department Utilization Data shows that payment was made for the specific drug, regardless of whether the Manufacturer continues to market the drug.

5.2. **Discretion to Market.** Nothing in this Agreement shall be construed to prohibit the Manufacturer from discontinuing production, marketing or distribution of any Product or from transferring or licensing any Product to a third party. It is understood that Manufacturer is liable for the payment of Supplemental Rebates only on Products as identified by their 11-digit NDC codes and indicated on Attachment A. In the event of a transfer in ownership of the Manufacturer, the Agreement is automatically assigned to the new owner subject to the conditions in this Agreement. Manufacturer agrees that it will not sell Products for re-packaging or re-labeling by a third party for the purpose of influencing the Best Price or National Rebate for any Product. If Manufacturer elects to discontinue production, marketing or distribution of any Product or to transfer or license any Product to a third party, Manufacturer shall make every reasonable effort to notify the Department as soon as practicable of such action so that the Department can negotiate with such third party for State Supplemental Rebates on such Product or change the status of such product, or other restrictions as deemed appropriate by the Department.

5.3. **Best Price Contingency.** Performance under this Agreement shall be contingent on Manufacturer's Best Price and AMP not being affected by State Supplemental Rebates.

ARTICLE VI - DEPARTMENT'S RIGHTS AND RESPONSIBILITIES.

6.1. **Covered Benefit.** The Department shall provide or arrange for the provision of outpatient pharmacy services to Medicaid Members.

6.2 **Providers.** The Department or its designee shall enroll Pharmacies as providers to dispense pharmaceutical products to Medicaid Members in accordance with the Medicaid Policies and Procedures Manual.

6.3 **Preferred Drug List**. The Department shall adopt and maintain a Preferred Drug List. Products included in Attachment C of this agreement will be listed as preferred on the Preferred Drug List.

A. ***The Department's Preferred Drug List Documentation and Publication.*** The Department shall publish the Abbreviated Preferred Drug List on the Department's website within thirty (30) days after it is adopted in total or for a specific therapeutic class following DURB recommendations. DCH shall update the website quarterly or after each therapeutic class review and upon the final DCH decision.

B. ***Notice of Preferred Drug List Review.*** The Department or its designee shall notify Manufacturer of any scheduled review of its Product and shall provide Manufacturer the opportunity to present information on the Product's merits for inclusion on the Preferred Drug List. Viewing of the DCH website (www.dch.state.ga.us) by the Manufacturer is recommended for updated PDL and Manufacturers' Forum information]:

C. ***Preferred Drug List Distribution.*** The Abbreviated Preferred Drug List may be found on DCH's website at www.dch.state.ga.us.

D. ***Addition of New Products to Preferred Drug List.*** Manufacturer shall notify the Department of any New Product and the State Supplemental Rebate available on such New Product. Provided that the price of such product, less any National Rebate or State Supplemental Rebate available on such New Product, is acceptable to the Department, the Department may, after review, add such New Product by amendment.

6.4 **Invoicing.** The Department shall invoice State Supplemental Rebates separately from National Rebates, using the format set forth in Attachment B. The Department will provide aggregate utilization data to the participating Manufacturer on a quarterly basis. This data will be based on paid claims data (data used to reimburse pharmacy providers) for the Georgia Medicaid Program. The Department shall submit the State Supplemental Rebate invoice to the Manufacturer within sixty 60) days after the Fiscal Quarter in which the Department paid for the Product. Any amended invoice shall be submitted by the Department within twelve (12) months after the Fiscal Quarter in which the Department paid for the Product. The Manufacturer may not submit adjusted rates less than those in the initial agreement. The Department will not accept any rate changes beyond 12 calendar or fiscal quarters.. The Department shall comply with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") regarding any patient identifiable information or protected health information or any other information the disclosure of which is prohibited or regulated by laws or regulations governing confidentiality of medical or other information that may be provided to the Manufacturer.

6.5. **Competitive Circumstances.** The Department will make a reasonable effort to ensure that the State Supplemental Rebates provided herein by the Manufacturer have been negotiated under circumstances which render the net prices of the Covered Products competitive with the net prices of pharmaceutical products that are used to treat the same conditions. Upon implementation of this Agreement, and from time to time thereafter, the Department and Manufacturer will meet to discuss any data or data system improvements which are necessary or desirable to ensure that the data and any information provided by the Department to Manufacturer are adequate for the purposes of this Agreement.

6.6 **Approval of Generic [insert name of drug class].** If within the duration of this Agreement a generic equivalent of any Competitive Product should become available, the Department will allow the Covered Product to remain on the Preferred Drug List as long as the net cost to the Department is not more than the net cost of the generic product.

6.7 **Fraud & Abuse.** It is the Department's belief that the business arrangement contemplated by this Agreement is not subject to the provisions of 42 U.S.C. 1320a-7b(b) prohibiting illegal remunerations. Should the above provisions apply, it is the Department's belief that the business arrangement contemplated by this Agreement meets the discount exception found in 42 U.S.C. 1320a-7b(b)(3)(A), which excludes from prohibited activities the practice of discounting or other reductions in price obtained by a

provider of services or other entity under a Federal health care program, if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program. The Department currently provides CMS full and unfettered access to all information held by the Department regarding the implementation of the Georgia Medicaid Program, and shall continue to do so throughout the implementation of the State Supplemental Rebate.

ARTICLE VII - GENERAL TERMS.

7.1. **Agreement to Obey All Laws.** Manufacturer shall at all times observe, comply with, and perform all obligations hereunder in accordance with, all laws, ordinances, codes and regulations of Federal, State, County and local governmental agencies which in any manner affect the terms of this Agreement.

7.2. **Amendments and Change Orders.** This Agreement may be amended or modified by the parties at any time during its term. Amendments must be in writing and signed by the parties. No change in, addition to, or waiver of any term or condition of this Agreement shall be binding on the Department unless approved in writing by an authorized representative of the Department.

7.3. **Amendments Necessary for Statutory or Regulatory Compliance.**

A. Manufacturer shall, upon request by the Department and receipt of a proposed amendment to this Agreement, negotiate in good faith with the Department to amend the Agreement if and when required, in the opinion of the Department, to comply with Federal or State laws or regulations. If the parties are unable to agree upon an amendment within sixty (60) days, or such shorter time required by Federal or State law or regulation, the Department may terminate this Agreement.

B. Manufacturer acknowledges that this Section 7.3 specifically includes, without limitation, reference to the Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191, and regulations promulgated thereunder; and Manufacturer agrees that this Agreement will be amended prior to the Compliance Date specified in those regulations if the Department determines, in its sole discretion, that amendment is necessary to ensure compliance with the regulations.

7.4. **Audits and Records**.

A. ***Right of Audit.*** This Agreement, and all books, records, and supporting documents related thereto, shall be available for review or audit by the Department, the Office of Inspector General for the Department, the Medicaid Fraud Control Unit of the Georgia State Police, the United States Department of Health and Human Services, the Georgia Auditor General and other State and

Federal agencies with monitoring authority related to the subject matter of this Agreement ("Authorized Persons"), and Manufacturer agrees to cooperate fully with any such review or audit. Upon reasonable notice by any Authorized Person, Manufacturer shall provide, in Georgia, or any other location designated by the Authorized Person, during normal business hours, full and complete access to the relevant portions of Manufacturer's books and billing records as they relate to payments under this Agreement. If the audit findings indicate underpayment(s) by Manufacturer, Manufacturer shall adjust future payments otherwise due to the Department and pay within 48 hours if it is a final payment. If an overpayment is noted and no SSR payments are due and owing, or if the overpayment(s) exceed(s) the amount otherwise due to Department, a mutually agreeable method of settlement will be determined by the Department and Manufacturer

B. ***Retention of Records.*** Manufacturer shall maintain all business, professional, and other records in accordance with State law, 45 CFR Part 74, the specific terms and conditions of this Agreement, and pursuant to generally accepted accounting practice. Manufacturer shall maintain, during the life of the Agreement and for a minimum of three (3) years after the completion of the Agreement, adequate books, records, and supporting documents to verify the amounts, Members, and uses of all disbursements of funds passing in conjunction with the Agreement. If an audit, litigation, or other action involving the records is begun before the end of the three-year period, the records must be retained until all issues arising out of the action are resolved. Failure to maintain the books, records, and supporting documents required by this Article shall establish a presumption in favor of the Department for the recovery of any funds due under the Agreement for which adequate books, records, and other documents are not available to support the purported disbursement.

7.5. **Choice of Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of Georgia. The Department shall not enter into binding arbitration to resolve any Agreement dispute. The State of Georgia does not waive sovereign immunity by entering into this Agreement.

7.6. **Confidentiality.**

A. ***Proprietary Information.*** Performance of the Agreement may require Manufacturer to have access to and use of documents and data which may be confidential or considered proprietary to the Department or to a Department contractor, or which may otherwise be of such a nature that its dissemination or use, other than in performance of the Agreement, would be adverse to the interest of the Department or others. Any documents or data obtained by Manufacturer from the Department in connection with carrying out the services under this Agreement shall be kept confidential and not provided to any third party unless disclosure is approved in writing by the Department. The Manufacturer will hold the Utilization Information confidential. If the Manufacturer audits this

information or receives further information on such data, that information shall also be held confidential. The Manufacturer shall have the right to disclose Utilization Information to auditors who agree to keep such information confidential. Each party shall protect the confidentiality of information provided by the other party, or to which the receiving party obtains access by virtue of its performance under this Agreement, that either has been reasonably identified as confidential by the disclosing party or by its nature warrants confidential treatment. The receiving party shall use such information only for the purpose of this Agreement and shall not disclose it to anyone except those of its employees who need to know the information. These nondisclosure obligations shall not apply to information that is or becomes public through no breach of this Agreement, that is received from a third party free to disclose it, that is independently developed by the receiving party, or that is required by law to be disclosed. Confidential information shall be returned to the disclosing party upon request.

B. ***Confidentiality of Program Recipient Identification.*** Manufacturer shall ensure that all information, records, data, and data elements pertaining to applicants for and Members of public assistance, or to providers, facilities, and associations, shall be protected from unauthorized disclosure by Manufacturer and Manufacturer's employees, by Manufacturer's corporate affiliates and their employees.

C. ***Maintenance of Confidentiality.*** Notwithstanding the non-renewal or termination of this Supplemental Rebate Agreement for any reason, these confidentiality provisions will remain in full force and effect.

7.7 **Dispute Resolution** In the event that the Department and Manufacturer have a dispute as to the meaning of a requirement solely included as a result of a Federal regulation applicable to or referred to in this Agreement, the Department will request an interpretation from the appropriate Federal agency or agencies and that interpretation, if received, will be adopted by the Department and Manufacturer.

A. If the Manufacturer in good faith believes the Department's Utilization Information is erroneous, the Manufacturer shall pay the Department that portion of the rebate claimed which is not disputed by the required date. The balance in dispute, if any, will be paid or credited by the Manufacturer or the Department by the due date of the next quarterly payment after resolution of the dispute.

B. The Department and the Manufacturer will use their best efforts to resolve discrepancies within 60 days of receipt of written notification. Either party may, at any time and at its own expense, hire a mutually agreed upon independent auditor to verify the accuracy of the Department's Utilization Information or the Manufacturer's calculations and payment figures. Should an audit of pharmacy records be required to resolve disputes, the Department will cooperate with the Manufacturer and provide information regarding pharmacy providers upon the

Manufacturer's request the Department will verify, through its rebate vendor, calculations for payments and interest.

7.8. **Fraud and Abuse.** Manufacturer shall report to the Department's Legal Department, who will forward to the Office of Inspector General (OIG), and any other applicable agency, State or federal, on any suspected financial fraud and abuse in the Georgia Medicaid Program or suspected misconduct of Department employees, as soon as Manufacturer learns of the suspected fraud and abuse or misconduct. Manufacturer shall not conduct any investigation of the suspected fraud and abuse or misconduct without being specifically directed to do so by the OIG. Manufacturer shall cooperate with all investigations of suspected fraud and abuse or Department employee misconduct.

7.9. **Gifts.** Manufacturer and Manufacturer's principals, employees and subcontractors are prohibited from giving gifts to Department employees, and from giving gifts to, or accepting gifts from, any person who has a contemporaneous contract with the Department involving duties or obligations related to this Agreement.

7.10. **Nondiscrimination.** In compliance with the State and Federal Constitutions, the Georgia Human Rights Act, the U. S. Civil Rights Act, and Section 504 of the Federal Rehabilitation Act, the Department does not unlawfully discriminate in employment, contracts, or any other activity. Manufacturer and Manufacturer's principals, employees and subcontractors shall abide by all Federal and State laws, regulations and orders which prohibit discrimination because of race, creed, color, religion, sex, national origin, ancestry, age, or physical or mental disability, including but, not limited to, the Federal Civil Rights Act of 1964, the Americans with Disabilities Act of 1990, the Federal Rehabilitation Act of 1973, the Georgia Human Rights Act, and Executive Orders 11246 and 11375. Manufacturer further agrees to take affirmative action to ensure that no unlawful discrimination is committed in any manner, including, but not limited to, in the delivery of services under this Agreement.

7.11 **Non-solicitation of Employees**. Manufacturer shall give notice to the Department's Ethics Officer, or such other person as the Department may designate, if Manufacturer solicits or intends to solicit for employment any Department employee during any part of the term of this Agreement and for one (1) year after its termination or expiration. This notice shall be given in writing at the earliest possible time. Manufacturer shall not employ any person or persons employed by the Department at any time during the term of this Agreement for any work required by the terms of this Agreement.

7.12. **Rules of Construction**. Unless the context otherwise requires or unless otherwise specified, the following rules of construction apply to this Agreement:

A. Provisions apply to successive events and transactions;

B. "Or" is not exclusive;

C. References to statutes and rules include subsequent amendments and successors thereto;

D. The various headings of this Agreement are provided for convenience only and shall not affect the meaning or interpretation of this Agreement or any provision hereof;

E. If any payment or delivery hereunder shall be due on any day, which is not a business day, such payment or delivery shall be made on the next succeeding business day;

F. "Days" shall mean calendar days; "business day" shall mean a weekday (Monday through Friday), excepting State holidays, between the hours of 8:00 a.m. Eastern Standard Time and 5:00 p.m Eastern Standard Time;

G. Use of the male gender (*e.g.*, "he", "him", "his") shall be construed to include the female gender (*e.g.*, "she", "her"), and vice versa; and

H. Words in the plural which should be singular by context shall be so read, and vice versa.

7.13. **Sale or Transfer**. Manufacturer shall provide the Department with the earliest possible advance notice of any sale or transfer of Manufacturer's business. The Department has the right to terminate this Agreement without cause upon notification of such sale or transfer.

7.14. **Severability**. In the event that any provision, term or condition of this Agreement is declared void, unenforceable, or against public policy, then said provision, term or condition shall be construed as though it did not exist and shall not affect the remaining provisions, terms, or conditions of this Agreement, and this Agreement shall be interpreted as far as possible to give effect to the parties' intent.

7.15 **Survival of Obligations**. Those obligations under this Agreement, which by their nature are intended to continue beyond the termination or expiration of this Agreement, shall survive the termination or expiration of this Agreement.

7.16 **Force Majeure.** Noncompliance with any obligations hereunder due to force majeure, such as acts of God, laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers, and any other causes beyond the reasonable control of the parties, shall not constitute breach of contract.

7.17 **Assignment.** Neither party shall have the right to assign this Agreement to a third party without the written consent of the other party, which consent shall not be unreasonably withheld. Any permitted assignee shall assume all obligations of its assignor under this

Agreement. No assignment shall relieve any party of responsibility for the performance of any obligations that have accrued prior to such assignment.

7.18 **No Waiver of Rights.** The failure of either party to insist upon the strict observation or performance of any provision of this Agreement or to exercise any right or remedy shall not impair or waiver any such right or remedy in the future. Every right and remedy given by this Agreement to the parties may be exercised from time to time as often as appropriate.

7.19 **Entire Agreement.** This Agreement contains the entire agreement and understanding of the parties. This Agreement (including Attachments) shall not be amended or modified except upon the written agreement of both parties.

7.20 **Governing Law, Jurisdiction And Venue.** This contract, and amendments and supplements thereto, will be governed by the laws of the State of Georgia. Venue for all legal proceedings arising out of this contract, or breach thereof, will be in the state or federal court with competent jurisdiction in Fulton County, Georgia.

7.21 **Effect of Future Laws.** In the event of any enactment, promulgation, rescission, modification or interpretation of any law or regulation after the date hereof which would (a) materially adversely affect the manner in which either party is obligated to perform under this Agreement, (b) adversely affect for either party the net prices of State Supplemental Rebates or other terms applicable under this Agreement, or (c) have the effect of requiring the net prices or State Supplemental Rebates or other terms applicable under this Agreement to be extended or offered to any third party, each party shall have the right to enter into good faith negotiations with the other in order to seek to agree on reasonable terms for maintaining the intent of this Agreement affected by such enactment, promulgation, etc. Agreement on any such terms shall be in the sole discretion of each party. If the parties do not agree within sixty (60) days of a party's written request for negotiations, either party may terminate this Agreement with respect to the affected Covered Products upon expiration of the sixty (60) day period, with immediate effect.

7.22 **Compliance with Law.** In connection with its respective obligations under this agreement, each party shall comply with all applicable federal, state and local laws and regulations, including without limitation any disclosure or consent requirements.

7.23 **Authority.** Department and Manufacturer each represent and warrant to the other that the person signing below has all requisite legal power and authority to execute this Agreement on behalf of each party and each party shall thereby be bound. The terms of this agreement does not allow for the sale or use of any data acquired under the terms of this agreement for purposes on than stated herein.

7.24 **CMS Approval Contingency.** The effectiveness of this Agreement shall be contingent on receipt of CMS approval by the Department, as evidenced by correspondence from

CMS approving State Plan Amendment TN 03-007 and the model contract, a copy of which will be furnished to Manufacturer.

7.25 **Authorized Representatives.** Manufacturer's authorized representative for the purposes of administration of this agreement is _____or his/her successor. The Department's authorized representative for the purposes of administration of this agreement is _____or his/her successor. Each representative shall have final authority for acceptance of services of the other party and shall have responsibility to insure that all payments due to the other party are made pursuant to the terms of this agreement.

ARTICLE VIII - MANUFACTURER CERTIFICATIONS

By signing this Agreement, Manufacturer makes the following certifications and warranties. The Department in its sole discretion upon Manufacturer's failure to maintain these certifications and warranties may terminate this Agreement immediately or upon notice.

8.1 **Bid Rigging, Bid Rotating and Inducement Manufacturer** has not paid any money or other valuable thing to any person or entity to induce that person or entity not to bid on a Department contract or to recompense that person or entity for not having bid on a Department contract. Manufacturer will report to the Georgia Attorney General and the Chief Procurement Officer any suspected collusion or other anticompetitive practice among any bidders, offerors, contractors or employees of the State.

8.2. **Federal Taxpayer Identification Number and Legal Status Disclosure.** Manufacturer certifies, under penalties of perjury, that the Federal taxpayer identification number and legal status that appear below Manufacturer's signature are correct.

8.3. **Lobbying.**

A. Manufacturer certifies to the best of Manufacturer's knowledge and belief, that no Federally appropriated funds have been paid or will be paid by or on behalf of Manufacturer, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal loan or grant, or the entering into of any cooperative agreement, or the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan or cooperative agreement.

B. If any funds other than Federally appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan or cooperative agreement, Manufacturer shall complete and submit Standard Form LLL, "Disclosure Forms to Report

Lobbying," in accordance with its instructions. Such Form is to be obtained at Manufacturer's request from the Department's Bureau of Fiscal Operations.

C. Manufacturer shall require that the language of this certification be included in the award document for sub-awards at all tiers (including subcontracts, sub-grants, and contracts under grants, loans, and cooperative agreements) and that all sub-Members shall certify and disclose accordingly.

D. This certification is a material representation of fact upon which reliance was placed when this Agreement was executed. Submission of this certification is a prerequisite for making or entering into the transaction imposed by Section 1352, Title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

8.4. **Exclusions**

A. This is affirmation that neither Manufacturer, Manufacturer's principals, shareholders or subcontractors owning at least five percent (5%) of Manufacturer, nor any employee of Manufacturer, is currently barred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal or State department or agency, or is currently barred or suspended from contracting with

B. If Manufacturer knows or learns of any person who was in the past but is not currently, or who during the term of this Agreement becomes, excluded from participation in this transaction as provided in Section (A), above, Manufacturer shall, within thirty (30) days after signing this Agreement or within thirty (30) days after learning of such exclusion, provide to the Department a written description of each offense causing the exclusion, including the name of the offender, the date of the offense, the action causing the offense, any penalty assessed or sentence imposed, and the date any penalty was paid or sentence completed.

Signatures on following page

SIGNATURE PAGE

IN WITNESS WHEREOF, the parties state and affirm that they are duly authorized to bind the respected entities designated below as of the day and year indicated.

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

_____
Gary B. Redding, Commissioner

NAME OF MANUFACTURER

_____ _____
Signature Date

_____ _____
(Please Print/Type Name Here) FEIN or SSN*

_____ _____
Title AFFIX CORPORATE SEAL HERE
(Corporations without a seal, attach a Certificate of Corporate Resolution)

***Manufacturer's FEIN:** _____

If Manufacturer is an individual, enter the Social Security Number (SSN) as it appears on the Manufacturer's Social Security Card. If Manufacturer is a sole proprietorship, enter the owner's SSN. For all other entities, enter the Federal Employer Identification Number (FEIN).

Manufacturer's Legal Status:

__ Individual
__ Sole Proprietorship
__ Partnership
__ Corporation
__ Non-Resident Alien
__ Real Estate Agent
__ Other:
__ Governmental Entity
__ Trust or Estate
__ Not-For-Profit Corporation
__ Medical and Health Care Services Provider Corporation
__ Foreign Corporation, Partnership, Trust, or Estate
__ Tax Exempt Organization (IRC 501(a) Only)

ATTACHMENT A

COVERED PHARMACEUTICALS

The pharmaceuticals to which this Supplemental Rebate Agreement shall apply are the following:

NDC	Product Description

ATTACHMENT B
REBATE SUMMARY

ATTACHMENT C
REBATE FORMULA

Drug Name	NDC	Discount

State Supplemental Rebates shall be calculated according to the following formula:

% x AMP = SSR