

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF DIRECTOR

ACTION REFERRAL

TO <i>Myers</i>	DATE  <i>7-18-08</i>
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DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOC NUMBER  <i>000038</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR  <i>cc: Ms. Forlener, Deps</i>	<input type="checkbox"/> Prepare reply for appropriate signature DATE DUE _____
	<input type="checkbox"/> FOIA DATE DUE _____
	<input checked="" type="checkbox"/> Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1.			
2.			
3.			
4.			

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop S2-14-26  
Baltimore, Maryland 21244-1850



**Center for Medicaid and State Operations**

**JUL 15 2008**

**RECEIVED**

Ms. Emma Forkner

Director

South Carolina Department of Health and Human Services

Post Office Box 8206

Columbia, South Carolina 29202-8206

**JUL 18 2008**  
Department of Health & Human Services  
**OFFICE OF THE DIRECTOR**

Dear Ms. Forkner:

The Centers for Medicare & Medicaid Services (CMS) has reviewed the revised definitions for best price and pharmacy submitted by South Carolina in its Michigan multi-state pooling agreement (MMSPA), also referred to as the National Medicaid Pooling Initiative (NMPI) for drugs provided to Medicaid beneficiaries. CMS has determined that these revised definitions are non-substantive and, therefore, CMS authorizes the State to use the revised NMPI without requiring a State Plan Amendment (SPA). The attached revised NMPI Supplemental Rebate Agreement (SRA) has been authorized for use with pharmaceutical manufacturers for renewal and new agreements, effective January 1, 2008.

Please note that this CMS authorization only extends to the attached SRA, Exhibits, and templates. If changes are subsequently made to the SRA, Exhibits, or templates, a new SPA and any such documents should be submitted to CMS for review and approval. If you have any questions, please contact Bernadette Leeds at (410) 786-9463.

Sincerely,

Deirdre Duzor

Director

Division of Pharmacy

Disabled & Elderly Health Programs Group

*log: Myers*

*N/A*

*cc: Ms. Forkner  
DEPS*

C: Mary Kaye Justis, Acting ARA, Atlanta Regional Office

Elaire Elmore, Atlanta Regional Office

Darlene Noonan, Atlanta Regional Office

## SUPPLEMENTAL DRUG-REBATE AGREEMENT

CONTRACT # NMPI-\_\_\_\_\_

### **PARTIES/PERIOD**

1.1 This Supplemental Drug-Rebate Agreement ("Agreement") is made and entered into this    [start date] by and between the State of Michigan ("State"), represented by the Department of Community Health ("State"), First Health Services Corporation ("First Health"), ("Manufacturer"), Labeler Code \_\_\_\_\_, and such other states that subsequently join into this Agreement upon the terms hereafter set forth ("Participating State(s)"). The parties, in consideration of the covenants, conditions, agreements, and stipulations expressed in this Agreement, do agree as follows:

### **PURPOSE**

2.1 It is the intent of this Agreement that (i) states that have entered into agreements for First Health to provide pharmacy benefit administration services ("PBA Services") to the state Medicaid and other non-Medicaid programs approved by CMS in the Medicaid state plan(s) that do not affect Best Price ("FH Clients"), including the States, ("Participating States"), will receive State Supplemental Rebates, in addition to the rebates received under the CMS Rebate Agreement, pursuant to Section 1927 of the Social Security Act (42 U.S.C. § 1396r-8), for the Manufacturer's Supplemental Covered Product(s) quarterly utilization in the Participating States' Medicaid Programs in which there is Medicaid federal financial participation. It is also the intent of this Agreement that State Supplemental Rebates will be paid for utilization of the Manufacturer's Supplemental Covered Product(s) in other state funded programs that have been approved for inclusion by the Secretary of Health and Human Services ("HHS"). The parties also intend for this Agreement to meet the requirements of federal law at Section 1927 of the Social Security Act (42 U.S.C. §1396r-8).

### **DEFINITIONS**

3.1 'Average Manufacturer Price' (AMP) means Manufacturer's price for the Covered Product(s). AMP will be calculated accordance with 42 U.S.C. 1396r-8(k)(1) and as specified in Manufacturer's CMS Agreement.

3.2 'Best Price' as set forth in the National Drug Rebate Agreement between the Secretary of Health and Human Services and drug manufacturers, 42 U.S.C. §1396r-8, and regulations promulgated by CMS

thereof, if any, as such statute or regulations may be amended from time to time, excluding State Supplemental Rebate amounts.

3.3 [Reserved]

3.4 'Covered Product(s)' means the pharmaceutical product(s) of the Manufacturer pursuant to Section 1927 of the Social Security Act (42 U.S.C. § 1396r-8).

3.5 'CMS Agreement' means the Manufacturer's drug rebate contract with the Centers for Medicare & Medicaid Services (CMS), formerly known as the Health Care Financing Administration, entered pursuant to Section 1927 of the Social Security Act (42 U.S.C. § 1396r-8).

3.6 'CMS Basic Rebate' means, with respect to the Covered Product(s), 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) and 42 U.S.C. § 1396r-8(c)(3)].

3.7 'CMS CPI Rebate' means, with respect to the Covered Product(s), the quarterly payment by Manufacturer pursuant to Manufacturer's CMS Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act [42 U.S.C. § 1396r-8(c)(2)].

3.8 'CMS Rebate' means, with respect to the Covered Product(s), the quarterly payment by Manufacturer pursuant to Sections 4.1 of this Agreement.

3.9 'CMS Unit Rebate Amount' means, the unit amount computed by CMS to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due.

3.10 'Drug Reimbursement Amount' means the total amount per unit allowable as calculated by the Participating States, specific to each drug, that the Participating States reimburse pharmacy providers per unit of drug under their Medicaid (and other state funded, HHS approved) programs, in accordance with applicable state and federal laws and regulations.

3.11 'First Health Client(s)' or 'FH Clients' means those states (including the State) that have entered or subsequently enter into agreements with First Health for the provision of PBA Services to the states'

**Deleted:** 'Best Price' means, in accordance with 42 U.S.C. § 1396r-8(c)(1)(C), with respect to a Single Source Drug or Innovator Multiple Source Drug of a Manufacturer, the lowest price available from the Manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity within the United States, excluding: (a) any price charged on or after October 1, 1992, to the Indian Health Services, the Department of Veterans Affairs, a State home receiving funds under Section 1741 of Title 38, United States Code, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(3)(B) of Section 1927 of the Social Security Act; (b) any prices charged under the Federal Supply Schedule of the General Services Administration; (c) any prices used under a State Pharmaceutical Assistance Program; and (d) any depot prices and single award contract prices, as defined by the Secretary of any agency of the Federal Government. 'Best Price' shall: (a) be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section); (b) be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and (c) not take into account prices that are merely nominal in amount.†

Medicaid and other non-Medicaid programs approved by CMS in the Medicaid state plan(s), subject to the supervision and oversight of such States.

3.12 [Reserved]

3.13 'Manufacturer' means, for purposes of this Agreement, the party identified as such in Section 1.1 of this Agreement, which may be a pharmaceutical manufacturer, labeler or other entity not prohibited by law from entering into this Agreement.

3.14 'Participating State(s)' means the (i) States named in Section 1.1 hereof, and (ii) other states that, subsequent to the execution of this Agreement by the States, elect to participate under this Agreement and have all necessary authorizations and approvals from CMS to do so. Unless otherwise authorized by CMS on a state by state basis, Participating States shall be limited to ones that have a CMS authorized contract under which First Health has been engaged to provide PBA services to that State. For each new Participating State, a unilateral amendment ("New Participating State Amendment") to this Agreement shall be executed by the new Participating State and First Health and sent to the Manufacturer prior to the Participation Commencement Date. A copy of the New Participating State Amendment is attached hereto as Exhibit A.

3.15 'Participating States' Net Price Per Unit' or 'Net Price' means the amount(s) agreed upon by the parties to this Agreement in the attached "Supplemental Rebate Matrix, Schedule 2". 'Net Price' will vary in accordance with Schedule 2 and is dependent upon the factors detailed therein, which includes, but may not be limited to, the number of Medicaid (and other state funded, HHS approved) eligible recipient lives and the number of products in a Preferred Drug List's product category. Per the attached "Supplemental Rebate Matrix, Schedule 2", Net Price will be a factor in the equation that is determinative of the Supplemental Rebate Amount.

3.16 'Participation Commencement Date' is the latter of the date (i) a Manufacturer's Supplemental Covered Product is effectively placed in a Participating State's Preferred Drug List by distribution of the Preferred Drug List (via website or otherwise) to providers and prescribers or (ii) the New Participating State Amendment is fully executed and returned to the Manufacturer, or (iii) the effective date of CMS approval of the Participating State's applicable state plan amendment. It is the date when the Participating State(s)' entitlement to the State Supplemental Rebate(s) from the Manufacturer accrues.

3.17 'Pharmacy Provider' means an entity or person licensed or permitted by law to dispense or administer legend drugs, and enrolled as a State Medicaid Provider.

3.18 'Rebate Summary' means the individual Participating States' reports itemizing the State Utilization Data supporting each Participating State's invoice for Rebates. The Rebate Summary will comply in all respects with requirements for Medicaid Utilization Information in the CMS Agreement.

3.19 'State Supplemental Rebate' means, with respect to the Supplemental Covered Product(s), the quarterly payment by Manufacturer pursuant to Section 4.2 of this Agreement.

3.20 'State Utilization Data' means the data used by Participating States to reimburse pharmacy providers under Participating States' Medicaid Program (and other non-Medicaid programs approved by CMS in the state plan(s) as provided in Section 2.1 hereof). State Utilization Data excludes data from covered entities identified in Title 42 U.S.C. §256b(a)(4) in accordance with Title 42 V.S.C. §256b(a)(5)(A) and 1396r-8(a)(5)(C).

3.21 'Supplemental Covered Product' means the pharmaceutical product(s) of the Manufacturer, as detailed in the attached Supplemental Rebate Matrix, Schedule 2, upon which a State Supplemental Rebate will be paid pursuant to this Agreement.

3.22 'Supplemental Covered Product Category' or 'Product Category' means a defined group of pharmaceutical products considered to compete with one another in the market and that are also thought to be therapeutic alternatives in many situations. First Health Services has determined and defined the Product Categories in which manufacturers will bid. The Product Categories, set forth on the "Product Categories, Schedule 1" hereto, may be changed as deemed appropriate by Participating States.

3.23 'Supplemental Rebate Amount' means, with respect to the Supplemental Covered Product(s), the amount(s) specified in the attached Supplemental Bid Matrix, Schedule 2 and Supplemental Rebate Calculation, Schedule 3 that the Manufacturer has agreed to reimburse Participating States per unit of drug in accordance with the formula detailed in the above Schedules.

3.24 'Wholesale Acquisition Cost' or 'WAC' means the Manufacturer's U.S. Dollar wholesale acquisition price in effect on the last day of a quarter on a unit basis as published by a third party source, such as First Databank, for each product and represents the Manufacturer's published price for a drug product to wholesalers.

#### **MANUFACTURER'S RESPONSIBILITIES**

4.1 Manufacturer will calculate and provide each Participating State a CMS Rebate for the Covered Product(s), which includes the CMS Basic Rebate and CMS CPI Rebate, as appropriate. The CMS Rebate represents the discount obtained by multiplying the units of the Covered Product(s) reimbursed by each Participating State in the preceding quarter by the per unit rebate amount provided to each Participating State by CMS. CMS will calculate the CMS Rebate amount in accordance with Manufacturer's CMS Agreement. Manufacturer's obligation for CMS Rebates will continue for the duration of the Manufacturer's CMS Agreement.

4.2 In addition to the CMS Rebates described in Section 4.1 of this Agreement, Manufacturer will remit to each Participating State a State Supplemental Rebate for the Supplemental Covered Product(s) that are in each Participating States Preferred Drug List Program. The State Supplemental Rebates will be calculated on a calendar quarter basis and provided via invoices to the Manufacturer's CMS financial contact. The State Supplemental Rebates for the quarter will be determined by multiplying the number of units of the Supplemental Covered Product(s) reimbursed by each Participating State in the preceding quarter by its Supplemental Rebate Amount. The Manufacturer's obligation for State Supplemental Rebates will continue for the duration of this Agreement. The Supplemental Rebate calculation is described in "Supplemental Rebate Calculation, Schedule 3".

4.3 The Manufacturer's obligation for State Supplemental Rebates will begin with the Rebate Billing Period for the [enter quarter associate with start date] calendar quarter [year], which begins [start date] (even if this Agreement is not fully executed by such date) and will continue through the Rebate Billing Period that ends [end date], subject to each Participating States' actual Participation Commencement Date as described in Section 3.16, *supra*. Notwithstanding the above, the Participating States reserve the right to solicit annually more favorable State Supplemental Rebates from Manufacturer by giving written notice thereof no less than ninety (90) days prior to the yearly anniversary of the effective date of this Agreement.

4.4 The quarters to be used for calculating the Rebates in Section 4.2 of this Agreement will be those ending on March 31, June 30, September 30, and December 31 of each calendar year during the term of this Agreement.

4.5 The participating Manufacturer will be required to submit each Participating State's State Supplemental Rebate payment within 38 days of the Manufacturer's receipt of the Participating State's Rebate Summary.

4.6 Manufacturer will pay the State Supplemental Rebates, including any applicable interest in accordance with Section 1903 (d)(5) of the Act. Interest on the Rebates payable under Section 4.2 of this Agreement begins accruing 38 calendar days from the postmark date of each Participating State'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. For the rebate programs invoiced under this Agreement, if the date of mailing of a Rebate payable under Section 4.2 of this Agreement is 69 days or more from the date of mailing of the invoice, the interest rate will be calculated as required under federal guidelines for rebates described in Section 4.1 but will be increased by ten percentage points or the maximum allowed by that Participating State's state law. If a Participating State has not received the Rebates payable under Section 4.2 of this Agreement, including interest, within 180 days of the postmark date of said Participating State's invoice and supporting Rebate Summary sent to the Manufacturer, such Participating State may deem the Manufacturer to be in default and Participating State may terminate its participation in this Agreement by giving Manufacturer and First Health ninety (90) days advance written notice.

4.7 Manufacturer agrees to continue to pay State Supplemental Rebates on the Supplemental Covered Product(s) for as long as this Agreement or any of its Addenda are in force, and State Utilization Data shows that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug. Manufacturer's obligation to pay State Supplemental Rebates on the Supplemental Covered Product(s) shall terminate twelve (12) months following the last expiration date of the last lot of Supplemental Covered Product sold by the Manufacturer. Notwithstanding the above, in the event Manufacturer's Supplemental Covered Product(s) is/are sold to another manufacturer, the original Manufacturer shall have no liability for rebates on utilization beyond those required by the Medicaid program. Manufacturer shall provide the State and First Health with notice of the sale of said Supplemental Covered Product(s) concurrent with Manufacturer's notice to CMS.

4.8 Unless notified otherwise, Manufacturer will send Rebate payments by certified mail, return receipt requested, to the address provided to Manufacturer in each individual Participating State's Addendum.

#### **PARTICIPATING STATE(S)' RESPONSIBILITIES**

5.1 Each Participating State will consider the Manufacturer's Supplemental Covered Product(s) for inclusion in the Participating State's Preferred Drug List Program. Each individual Participating State reserves the right to select the products that will be in its Preferred Drug List Program and will only



receive State Supplemental Rebates for Manufacturer's Supplemental Covered Products that are actually included in its Preferred Drug List Program. Manufacturer shall pay Participating States State Supplemental Rebates based upon Participating State(s)' utilization of Manufacturer's Supplemental Covered Product(s) that did not require prior authorization. Participating States shall not be entitled to State Supplemental Rebates for utilization of Manufacturer's Supplemental Covered Product(s) that occurred only subsequent to the obtaining of prior authorization unless the Supplemental Covered Product(s) have been assigned to a Product Category and all products in the Product Category are subject to prior authorization requirements. Each individual Participating State also reserves the right to determine, as a result of a Product Category review, that prior authorization is required for all preferred drugs in a Product Category. If a Participating State determines that prior authorization is required for any Supplemental Covered Product, then the Participating State will comply with all provisions of Section 1927( d) of the Social Security Act applicable to Prior Authorization programs. Each Participating State will notify Manufacturer and First Health, within ten (10) business days of adoption and publication of a new or revised Preferred Drug List, when Manufacturer's Supplemental Covered Product is added to the Participating State's Preferred Drug List by providing Manufacturer and First Health a copy of the Preferred Drug List in accordance with the notice provisions of Section 9.2 hereof.

5.2 The State and/or First Health shall notify the Manufacturer whenever a Participating State adds one of Manufacturer's Supplemental Covered Products to its Preferred Drug List or when one of Manufacturer's Supplemental Covered Products is moved to a prior authorization status.

5.3 Each Participating State will provide aggregate State Utilization Data to the Manufacturer on a quarterly basis. This data will be based on paid claims data (data used to reimburse pharmacy providers) under each Participating State's Medicaid (and other state funded, HHS approved) Program(s), will be consistent with any applicable Federal or State guidelines, regulations and standards for such data, and will be the basis for the Participating State's calculation of the State Supplemental Rebate.

5.4 Each Participating State will maintain those data systems used to calculate the State Supplemental Rebates. In the event material discrepancies are discovered, the Participating State will promptly justify its data or make an appropriate adjustment, which may include a credit as to the amount of the State Supplemental Rebates, or a refund to Manufacturer as the parties may agree.

5.5 Each Participating State shall maintain electronic claims records for the most recent four quarters that will permit Manufacturer to verify through an audit process the Rebate Summaries provided by the Participating State.

5.6 Upon implementation of this Agreement, and from time to time thereafter, Participating States 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 Participating States to Manufacturer are adequate for the purposes of this Agreement.

5.7 First Health, as the pharmacy benefit administrator, may assist the Participating States in fulfilling its responsibilities hereunder and is a party to this Agreement solely in its capacity as agent for, and subject to the supervision and oversight of, the Participating State(s).

5.8 The State and each Participating State shall obtain CMS approval of its state Medicaid plan of which this Agreement forms a part. Manufacturer shall not be obligated to remit any Supplemental Rebates that have accrued and are due under this Agreement until after the affected State or Participating State has obtained CMS approval of its Supplemental Rebate Program of which this Agreement forms a part.

## **DISPUTE RESOLUTION**

6.1 In the event that in any quarter a discrepancy in a Participating State's State Utilization Data is questioned by the Manufacturer, which the Manufacturer and the Participating State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy to the Participating State and First Health.

6.2 If the Manufacturer in good faith believes the Participating State's State Utilization Data is erroneous, the Manufacturer shall pay the Participating State that portion of the rebate claimed, that is not in dispute by the required date. The balance in dispute, if any, will be paid by the Manufacturer to the Participating State by the due date of the next quarterly payment after resolution of the dispute.

6.3 The Participating State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of written notification. Should additional information be required to resolve disputes, the Participating State and First Health will cooperate with the Manufacturer in obtaining the additional information.

6.4 In the event that the Participating State and the Manufacturer are not able to resolve a discrepancy regarding State Utilization Data as provided for in Sections 6.1 through 6.3, the Manufacturer may request a reconsideration of the Participating State's determination within 30 days after the end of the 60 day period identified in Section 6.3. The Manufacturer shall submit with its written request its argument in writing, along with any other materials, supporting its position to the Participating State and First Health. The Participating State shall review the written argument and materials and issue a decision in the matter.

## CONFIDENTIALITY PROVISIONS

7.1 The parties agree that confidential information will not be released to any person or entity not a party to this contract. Confidential information, including trade secrets, will not be disclosed, or used except in connection with this Agreement or as may be required by law or judicial order.

7.2 The Manufacturer will hold Participating State' State Utilization Data confidential. If the Manufacturer audits this information or receives further information on such data from First Health or a Participating State, that information shall also be held confidential. The Manufacturer shall have the right to disclose Participating State(s)'s State Utilization Data to auditors who agree to keep such information confidential.

7.3 Pursuant to 42 USC 1396r-8(b)(3)(D), and other applicable state or federal laws, the parties agree that this Agreement and all information provided pursuant to this Agreement will not be disclosed and that the parties will not duplicate or use the information, except in connection with this Agreement or as may be required by law or judicial order. The parties further agree that any information provided by Manufacturer to the State, First Health, or the Participating State(s) pursuant to this Agreement and this Agreement itself constitute trade secrets and/or confidential or proprietary commercial and financial information not subject to public disclosure. Furthermore, the parties agree that any Manufacturer information received by First Health pursuant to this Agreement and distributed by First Health to the State and/or Participating States shall constitute trade secrets and/or confidential or proprietary commercial and financial information of the Manufacturer not subject to public disclosure, except as otherwise provided for herein. If the services of a third party are used to administer any portion of this Agreement, Sections 7.1 through 7.4 of this Agreement shall apply to the third party. In the event a Participating State cannot give satisfactory assurance that rebate pricing data provided under this

Agreement will be exempt from public disclosure under applicable state law, then First Health (without assuming responsibility for any wrongful disclosure by a Participating State) shall limit the amount of such data made available to the Participating State by not disclosing to the Participating State any NDC-level pricing information. For purposes hereof "satisfactory assurance" shall be deemed given when the Participating State enters the statutory cite of the applicable exemption on its Participating State Addendum. In the event that either party is required by law to disclose any provision of this Agreement or pricing information to any person, such party shall provide advance written notice to the other party sufficiently in advance of the proposed disclosure to allow the other party to seek a protective order or other relief.

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

#### **NON-RENEWAL or TERMINATION**

8.1 This Agreement shall be effective as of start date and shall have the term indicated in Section 4.3, *supra*.

8.2 Any Participating State may terminate its participation in this Agreement by giving Manufacturer and First Health written notice at least (90) days prior to the anniversary date of this Agreement, in which case termination shall become effective on the anniversary date of the date of execution of this Agreement. The termination of this Agreement by one or more Participating States shall not affect the Manufacturer's, First Health's or the other Participating States' obligations under this Agreement, other than any effect the reduction in the number of lives covered by the Agreement may have on the Supplemental Rebate payable hereunder. Manufacturer may terminate this Agreement and all Addenda by giving all Participating States and First Health written notice at least ninety (90) days prior to the anniversary date of this Agreement, in which case termination shall become effective on the anniversary date of the date of execution of this Agreement. Manufacturer's right of termination is limited to the right to terminate the entire Agreement. Manufacturer may not terminate specific Addendum/Addenda of less than all Participating State(s).

8.3 Termination by a FH Client of its PBA Services Agreement with First Health shall, as of the same termination effective date, terminate this Agreement as to that Participating State.

**Deleted: April 1, 2006**

8.4 Notwithstanding any non-renewal or termination of this Agreement, State Supplemental Rebates will still be due and payable from the Manufacturer under Section 4.2 for any Supplemental Covered Products for which Participating State(s)' obligation to reimburse arose prior to the effective date of termination of this Agreement.

8.5 On at least an annual basis or as mutually agreed upon by Manufacturer and First Health, Manufacturer shall have the opportunity to decrease the Net Price of its Covered Products to increase the likelihood of product(s) utilization and/or inclusion in the Participating States Preferred Drug List Programs.

#### GENERAL PROVISIONS

9.1 This Agreement will be governed and construed in accordance with 42 U.S.C. § 1396r-8 and all other applicable federal and state law and regulations.

9.2 Any notice required to be given pursuant to the terms and provisions of this Agreement will be in writing and will be sent by certified mail, return receipt requested. Notice will be mailed to the addressees specified in each individual Participating State's Addendum to this Agreement.

Notice to the State shall be sent to:

State of Michigan  
Department of Community Health Medical Services Administration  
Attn: Dave McLaury  
400 S. Pine Street  
Lansing, MI 48933

Notice to First Health shall be sent to:

First Health Services Corporation  
Attn: Peter Quinn, Chief Operating Officer  
With a copy to: Legal Department  
4300 Cox Road  
Glen Allen, Virginia 23060

Notice to Manufacturer will be sent to:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

9.3 The Manufacturer agrees to be bound by the laws of the United States of America and with respect to each Participating State, the law of that Participating State. Proper venue in any legal action shall be the venue of the Participating State that is party to the proceeding. Any action brought by Manufacturer must be brought separately against individual Participating States or First Health, unless all affected Participating States and First Health consent to joinder of the actions.

9.4 Nothing herein shall be construed or interpreted as limiting or otherwise affecting First Health or Participating State(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.

9.5 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 First Health or any Participating State.

9.6 Manufacturer may not assign this Agreement, either in whole or in part, without the written consent of the Participating States and First Health. However, 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. If the Agreement is assigned pursuant to this Section, Manufacturer shall provide First Health and the Participating States with an update of the information contained in Section 9.2, *supra*.

9.7 Nothing in this Agreement will 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 requirements, this Agreement will be construed in all respects as if any invalid, unenforceable, or inconsistent provision were eliminated, and without any effect on any other provision.

9.8 First Health, Participating State(s) and Manufacturer declare that this Agreement, including attachments, schedules and addenda, contains a total integration of all rights and obligations of the parties. There are no extrinsic conditions, collateral agreements or undertakings of any kind. In regarding this

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

9.9 This Agreement will not be altered except by (i) an amendment in writing signed by all the parties, other than (ii) in the case of the addition of a new Participating State(s), by its execution of the New Participating State Amendment. It is acknowledged that the intent of the previous sentence is that the addition of a new Participating State(s) by amendment shall only require the consent of First Health and the approval of CMS, not Manufacturer. Manufacturer agrees that any Participating State may be added to this Agreement by amendment and that said Participating State's covered Medicaid (and other non-Medicaid programs approved by CMS in the Medicaid state plan(s)) lives shall apply to the provisions of Schedules 2 and 3 and will affect the rebates to all Participating States in accordance with Schedules 2 and 3. The New Participating State Amendment shall be executed by First Health and the new Participating State with a copy provided to Manufacturer for its records. Other than as stated herein, 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 Participating State(s), First Health, and the Manufacturer. Any modification or amendment must be authorized by CMS.

9.10 The parties do not contemplate any circumstances under which indemnification of the other parties would arise. Nevertheless, should such circumstances arise, Manufacturer agrees to indemnify, defend and hold harmless the Participating States and First Health, their 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 in the performance of this Agreement.

9.11 Inasmuch as the State Supplemental Rebates required by this Agreement are for state Medicaid (and non-Medicaid programs approved by CMS in the Medicaid state plan(s)) program beneficiaries, it is agreed, in accordance with Medicaid Drug Rebate Program Release #102 for State Medicaid Directors and other applicable law, that the State Supplemental Rebates do not establish a new 'Best Price' for purposes of participating Manufacturer's CMS Agreement.

9.12 In the event that Participating State(s) require(s) prior authorization of Manufacturer's Supplemental Covered Product(s) as part of a Product Category prior authorization under Section 5.1, State Supplemental Rebates shall nevertheless be payable hereunder.

9.13 If First Health or a Participating State makes changes to a Product Category that are considered to be a material change in the structure of the supplemental rebates program, Manufacturer may be allowed to re-submit bids for the Product Category/Categories affected.

9.14 As evidence of their Agreement to the foregoing terms and conditions, the parties have signed below.

STATE OF MICHIGAN, DEPARTMENT OF COMMUNITY HEALTH:

By: \_\_\_\_\_ Date: \_\_\_\_\_

Name: Sue Moran

Title: Director, Bureau of Medicaid Program Operations and Quality Assurance  
MANUFACTURER

By: \_\_\_\_\_ Date: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

FIRST HEALTH SERVICES CORPORATION

By: \_\_\_\_\_ Date: \_\_\_\_\_

Name: Charles W. Byrd, Jr.

Title: Chief Financial Officer



## SUPPLEMENTAL DRUG-REBATE AGREEMENT

CONTRACT # NMPI-\_\_\_\_\_

### **PARTIES/PERIOD**

1.1 This Supplemental Drug-Rebate Agreement ("Agreement") is made and entered into this [start date], by and between the State of Michigan ("State"), represented by the Department of Community Health ("State"), First Health Services Corporation ("First Health"), \_\_\_\_\_ ("Manufacturer"), Labeler Code \_\_\_\_\_, and such other states that subsequently join into this Agreement upon the terms hereafter set forth ("Participating State(s)"). The parties, in consideration of the covenants, conditions, agreements, and stipulations expressed in this Agreement, do agree as follows:

### **PURPOSE**

2.1 It is the intent of this Agreement that (i) states that have entered into agreements for First Health to provide pharmacy benefit administration services ("PBA Services") to the state Medicaid and other non-Medicaid programs approved by CMS in the Medicaid state plan(s) that do not affect Best Price ("FH Clients"), including the States, ("Participating States"), will receive State Supplemental Rebates, in addition to the rebates received under the CMS Rebate Agreement, pursuant to Section 1927 of the Social Security Act (42 U.S.C. § 1396r-8), for the Manufacturer's Supplemental Covered Product(s) quarterly utilization in the Participating States' Medicaid Programs in which there is Medicaid federal financial participation. It is also the intent of this Agreement that State Supplemental Rebates will be paid for utilization of the Manufacturer's Supplemental Covered Product(s) in other state funded programs that have been approved for inclusion by the Secretary of Health and Human Services ("HHS"). The parties also intend for this Agreement to meet the requirements of federal law at Section 1927 of the Social Security Act (42 U.S.C. §1396r-8).

### **DEFINITIONS**

3.1 'Average Manufacturer Price' (AMP) means Manufacturer's price for the Covered Product(s). AMP will be calculated accordance with 42 U.S.C. 1396r-8(k)(1) and as specified in Manufacturer's CMS Agreement.

3.2 'Best Price' as set forth in the National Drug Rebate Agreement between the Secretary of Health and Human Services and drug manufacturers, 42 U.S.C. §1396r-8, and regulations promulgated by CMS

thereto, if any, as such statute or regulations may be amended from time to time, excluding State Supplemental Rebate amounts.

3.3 [Reserved]

3.4 'Covered Product(s)' means the pharmaceutical product(s) of the Manufacturer pursuant to Section 1927 of the Social Security Act (42 U.S.C. § 1396r-8).

3.5 'CMS Agreement' means the Manufacturer's drug rebate contract with the Centers for Medicare & Medicaid Services (CMS), formerly known as the Health Care Financing Administration, entered pursuant to Section 1927 of the Social Security Act (42 U.S.C. § 1396r-8).

3.6 'CMS Basic Rebate' means, with respect to the Covered Product(s), 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) and 42 U.S.C. § 1396r8(c)(3)].

3.7 'CMS CPI Rebate' means, with respect to the Covered Product(s), the quarterly payment by Manufacturer pursuant to Manufacturer's CMS Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act [42 U.S.C. §1396r-8(c)(2)].

3.8 'CMS Rebate' means, with respect to the Covered Product(s), the quarterly payment by Manufacturer pursuant to Sections 4.1 of this Agreement.

3.9 'CMS Unit Rebate Amount' means, the unit amount computed by CMS to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due.

3.10 'Drug Reimbursement Amount' means the total amount per unit allowable as calculated by the Participating States, specific to each drug, that the Participating States reimburse pharmacy providers per unit of drug under their Medicaid (and other state funded, HHS approved) programs, in accordance with applicable state and federal laws and regulations.

3.11 'First Health Client(s)' or 'FH Clients' means those states (including the State) that have entered or subsequently enter into agreements with First Health for the provision of PBA Services to the states'

Medicaid and other non-Medicaid programs approved by CMS in the Medicaid state plan(s), subject to the supervision and oversight of such States.

3.12 [Reserved]

3.13 'Manufacturer' means, for purposes of this Agreement, the party identified as such in Section 1.1 of this Agreement, which may be a pharmaceutical manufacturer, labeler or other entity not prohibited by law from entering into this Agreement.

3.14 'Participating State(s)' means the (i) States named in Section 1.1 hereof, and (ii) other states that, subsequent to the execution of this Agreement by the States, elect to participate under this Agreement and have all necessary authorizations and approvals from CMS to do so. Unless otherwise authorized by CMS on a state by state basis, Participating States shall be limited to ones that have a CMS authorized contract under which First Health has been engaged to provide PBA services to that State. For each new Participating State, a unilateral amendment ("New Participating State Amendment") to this Agreement shall be executed by the new Participating State and First Health and sent to the Manufacturer prior to the Participation Commencement Date. A copy of the New Participating State Amendment is attached hereto as Exhibit A.

3.15 'Participating States' Net Price Per Unit' or 'Net Price' means the amount(s) agreed upon by the parties to this Agreement in the attached "Supplemental Rebate Matrix, Schedule 2". 'Net Price' will vary in accordance with Schedule 2 and is dependent upon the factors detailed therein, which includes, but may not be limited to, the number of Medicaid (and other state funded, HHS approved) eligible recipient lives and the number of products in a Preferred Drug List's product category. Per the attached "Supplemental Rebate Matrix, Schedule 2", Net Price will be a factor in the equation that is determinative of the Supplemental Rebate Amount.

3.16 'Participation Commencement Date' is the latter of the date (i) a Manufacturer's Supplemental Covered Product is effectively placed in a Participating State's Preferred Drug List by distribution of the Preferred Drug List (via website or otherwise) to providers and prescribers or (ii) the New Participating State Amendment is fully executed and returned to the Manufacturer, or (iii) the effective date of CMS approval of the Participating State's applicable state plan amendment. It is the date when the Participating State(s)' entitlement to the State Supplemental Rebate(s) from the Manufacturer accrues.

3.17 'Pharmacy Provider' means an entity or person licensed or permitted by law to dispense or administer legend drugs, and enrolled as a State Medicaid Provider.

3.18 'Rebate Summary' means the individual Participating States' reports itemizing the State Utilization Data supporting each Participating State's invoice for Rebates. The Rebate Summary will comply in all respects with requirements for Medicaid Utilization Information in the CMS Agreement.

3.19 'State Supplemental Rebate' means, with respect to the Supplemental Covered Product(s), the quarterly payment by Manufacturer pursuant to Section 4.2 of this Agreement.

3.20 'State Utilization Data' means the data used by Participating States to reimburse pharmacy providers under Participating States' Medicaid Program (and other non-Medicaid programs approved by CMS in the state plan(s) as provided in Section 2.1 hereof). State Utilization Data excludes data from covered entities identified in Title 42 U.S.C. §256b(a)(4) in accordance with Title 42 V.S.C. §256b(a)(5)(A) and 1396r-8(a)(5)(C).

3.21 'Supplemental Covered Product' means the pharmaceutical product(s) of the Manufacturer, as detailed in the attached Supplemental Rebate Matrix, Schedule 2, upon which a State Supplemental Rebate will be paid pursuant to this Agreement.

3.22 'Supplemental Covered Product Category' or 'Product Category' means a defined group of pharmaceutical products considered to compete with one another in the market and that are also thought to be therapeutic alternatives in many situations. First Health Services has determined and defined the Product Categories in which manufacturers will bid. The Product Categories, set forth on the "Product Categories, Schedule 1" hereto, may be changed as deemed appropriate by Participating States.

3.23 'Supplemental Rebate Amount' means, with respect to the Supplemental Covered Product(s), the amount(s) specified in the attached Supplemental Bid Matrix, Schedule 2 and Supplemental Rebate Calculation, Schedule 3 that the Manufacturer has agreed to reimburse Participating States per unit of drug in accordance with the formula detailed in the above Schedules.

3.24 'Wholesale Acquisition Cost' or 'WAC' means the Manufacturer's U.S. Dollar wholesale acquisition price in effect on the last day of a quarter on a unit basis as published by a third party source, such as First Databank, for each product and represents the Manufacturer's published price for a drug product to wholesalers.

## MANUFACTURER'S RESPONSIBILITIES

4.1 Manufacturer will calculate and provide each Participating State a CMS Rebate for the Covered Product(s), which includes the CMS Basic Rebate and CMS CPI Rebate, as appropriate. The CMS Rebate represents the discount obtained by multiplying the units of the Covered Product(s) reimbursed by each Participating State in the preceding quarter by the per unit rebate amount provided to each Participating State by CMS. CMS will calculate the CMS Rebate amount in accordance with Manufacturer's CMS Agreement. Manufacturer's obligation for CMS Rebates will continue for the duration of the Manufacturer's CMS Agreement.

4.2 In addition to the CMS Rebates described in Section 4.1 of this Agreement, Manufacturer will remit to each Participating State a State Supplemental Rebate for the Supplemental Covered Product(s) that are in each Participating States Preferred Drug List Program. The State Supplemental Rebates will be calculated on a calendar quarter basis and provided via invoices to the Manufacturer's CMS financial contact. The State Supplemental Rebates for the quarter will be determined by multiplying the number of units of the Supplemental Covered Product(s) reimbursed by each Participating State in the preceding quarter by its Supplemental Rebate Amount. The Manufacturer's obligation for State Supplemental Rebates will continue for the duration of this Agreement. The Supplemental Rebate calculation is described in "Supplemental Rebate Calculation, Schedule 3".

4.3 The Manufacturer's obligation for State Supplemental Rebates will begin with the Rebate Billing Period for the [enter quarter associate with start date] calendar quarter [year], which begins [start date] (even if this Agreement is not fully executed by such date) and will continue through the Rebate Billing Period that ends [end date], subject to each Participating States' actual Participation Commencement Date as described in Section 3.16, *supra*. Notwithstanding the above, the Participating States reserve the right to solicit annually more favorable State Supplemental Rebates from Manufacturer by giving written notice thereof no less than ninety (90) days prior to the yearly anniversary of the effective date of this Agreement.

4.4 The quarters to be used for calculating the Rebates in Section 4.2 of this Agreement will be those ending on March 31, June 30, September 30, and December 31 of each calendar year during the term of this Agreement.

4.5 The participating Manufacturer will be required to submit each Participating State's State Supplemental Rebate payment within 38 days of the Manufacturer's receipt of the Participating State's Rebate Summary.

4.6 Manufacturer will pay the State Supplemental Rebates, including any applicable interest in accordance with Section 1903 (d)(5) of the Act. Interest on the Rebates payable under Section 4.2 of this Agreement begins accruing 38 calendar days from the postmark date of each Participating State'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. For the rebate programs invoiced under this Agreement, if the date of mailing of a Rebate payable under Section 4.2 of this Agreement is 69 days or more from the date of mailing of the invoice, the interest rate will be calculated as required under federal guidelines for rebates described in Section 4.1 but will be increased by ten percentage points or the maximum allowed by that Participating State's state law. If a Participating State has not received the Rebates payable under Section 4.2 of this Agreement, including interest, within 180 days of the postmark date of said Participating State's invoice and supporting Rebate Summary sent to the Manufacturer, such Participating State may deem the Manufacturer to be in default and Participating State may terminate its participation in this Agreement by giving Manufacturer and First Health ninety (90) days advance written notice.

4.7 Manufacturer agrees to continue to pay State Supplemental Rebates on the Supplemental Covered Product(s) for as long as this Agreement or any of its Addenda are in force, and State Utilization Data shows that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug. Manufacturer's obligation to pay State Supplemental Rebates on the Supplemental Covered Product(s) shall terminate twelve (12) months following the last expiration date of the last lot of Supplemental Covered Product sold by the Manufacturer. Notwithstanding the above, in the event Manufacturer's Supplemental Covered Product(s) is/are sold to another manufacturer, the original Manufacturer shall have no liability for rebates on utilization beyond those required by the Medicaid program. Manufacturer shall provide the State and First Health with notice of the sale of said Supplemental Covered Product(s) concurrent with Manufacturer's notice to CMS.

4.8 Unless notified otherwise, Manufacturer will send Rebate payments by certified mail, return receipt requested, to the address provided to Manufacturer in each individual Participating State's Addendum.

## **PARTICIPATING STATE(S)' RESPONSIBILITIES**

5.1 Each Participating State will consider the Manufacturer's Supplemental Covered Product(s) for inclusion in the Participating State's Preferred Drug List Program. Each individual Participating State reserves the right to select the products that will be in its Preferred Drug List Program and will only receive State Supplemental Rebates for Manufacturer's Supplemental Covered Products that are actually included in its Preferred Drug List Program. Manufacturer shall pay Participating States State Supplemental Rebates based upon Participating State(s)' utilization of Manufacturer's Supplemental Covered Product(s) that did not require prior authorization. Participating States shall not be entitled to State Supplemental Rebates for utilization of Manufacturer's Supplemental Covered Product(s) that occurred only subsequent to the obtaining of prior authorization unless the Supplemental Covered Product(s) have been assigned to a Product Category and all products in the Product Category are subject to prior authorization requirements. Each individual Participating State also reserves the right to determine, as a result of a Product Category review, that prior authorization is required for all preferred drugs in a Product Category. If a Participating State determines that prior authorization is required for any Supplemental Covered Product, then the Participating State will comply with all provisions of Section 1927(d) of the Social Security Act applicable to Prior Authorization programs. Each Participating State will notify Manufacturer and First Health, within ten (10) business days of adoption and publication of a new or revised Preferred Drug List, when Manufacturer's Supplemental Covered Product is added to the Participating State's Preferred Drug List by providing Manufacturer and First Health a copy of the Preferred Drug List in accordance with the notice provisions of Section 9.2 hereof.

5.2 The State and/or First Health shall notify the Manufacturer whenever a Participating State adds one of Manufacturer's Supplemental Covered Products to its Preferred Drug List or when one of Manufacturer's Supplemental Covered Products is moved to a prior authorization status.

5.3 Each Participating State will provide aggregate State Utilization Data to the Manufacturer on a quarterly basis. This data will be based on paid claims data (data used to reimburse pharmacy providers) under each Participating State's Medicaid (and other state funded, HHS approved) Program(s), will be consistent with any applicable Federal or State guidelines, regulations and standards for such data, and will be the basis for the Participating State's calculation of the State Supplemental Rebate.

5.4 Each Participating State will maintain those data systems used to calculate the State Supplemental Rebates. In the event material discrepancies are discovered, the Participating State will promptly justify

its data or make an appropriate adjustment, which may include a credit as to the amount of the State Supplemental Rebates, or a refund to Manufacturer as the parties may agree.

5.5 Each Participating State shall maintain electronic claims records for the most recent four quarters that will permit Manufacturer to verify through an audit process the Rebate Summaries provided by the Participating State.

5.6 Upon implementation of this Agreement, and from time to time thereafter, Participating States 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 Participating States to Manufacturer are adequate for the purposes of this Agreement.

5.7 First Health, as the pharmacy benefit administrator, may assist the Participating States in fulfilling its responsibilities hereunder and is a party to this Agreement solely in its capacity as agent for, and subject to the supervision and oversight of, the Participating State(s).

5.8 The State and each Participating State shall obtain CMS approval of its state Medicaid plan of which this Agreement forms a part. Manufacturer shall not be obligated to remit any Supplemental Rebates that have accrued and are due under this Agreement until after the affected State or Participating State has obtained CMS approval of its Supplemental Rebate Program of which this Agreement forms a part.

## **DISPUTE RESOLUTION**

6.1 In the event that in any quarter a discrepancy in a Participating State's State Utilization Data is questioned by the Manufacturer, which the Manufacturer and the Participating State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy to the Participating State and First Health.

6.2 If the Manufacturer in good faith believes the Participating State's State Utilization Data is erroneous, the Manufacturer shall pay the Participating State that portion of the rebate claimed, that is not in dispute by the required date. The balance in dispute, if any, will be paid by the Manufacturer to the Participating State by the due date of the next quarterly payment after resolution of the dispute.



6.3 The Participating State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of written notification. Should additional information be required to resolve disputes, the Participating State and First Health will cooperate with the Manufacturer in obtaining the additional information.

6.4 In the event that the Participating State and the Manufacturer are not able to resolve a discrepancy regarding State Utilization Data as provided for in Sections 6.1 through 6.3, the Manufacturer may request a reconsideration of the Participating State's determination within 30 days after the end of the 60 day period identified in Section 6.3. The Manufacturer shall submit with its written request its argument in writing, along with any other materials, supporting its position to the Participating State and First Health. The Participating State shall review the written argument and materials and issue a decision in the matter.

#### **CONFIDENTIALITY PROVISIONS**

7.1 The parties agree that confidential information will not be released to any person or entity not a party to this contract. Confidential information, including trade secrets, will not be disclosed, or used except in connection with this Agreement or as may be required by law or judicial order.

7.2 The Manufacturer will hold Participating State' State Utilization Data confidential. If the Manufacturer audits this information or receives further information on such data from First Health or a Participating State, that information shall also be held confidential. The Manufacturer shall have the right to disclose Participating State(s)'s State Utilization Data to auditors who agree to keep such information confidential.

7.3 Pursuant to 42 USC 1396r-8(b)(3)(D), and other applicable state or federal laws, the parties agree that this Agreement and all information provided pursuant to this Agreement will not be disclosed and that the parties will not duplicate or use the information, except in connection with this Agreement or as may be required by law or judicial order. The parties further agree that any information provided by Manufacturer to the State, First Health, or the Participating State(s) pursuant to this Agreement and this Agreement itself constitute trade secrets and/or confidential or proprietary commercial and financial information not subject to public disclosure. Furthermore, the parties agree that any Manufacturer information received by First Health pursuant to this Agreement and distributed by First Health to the State and/or Participating States shall constitute trade secrets and/or confidential or proprietary commercial and financial information of the Manufacturer not subject to public disclosure, except as

otherwise provided for herein. If the services of a third party are used to administer any portion of this Agreement, Sections 7.1 through 7.4 of this Agreement shall apply to the third party. In the event a Participating State cannot give satisfactory assurance that rebate pricing data provided under this Agreement will be exempt from public disclosure under applicable state law, then First Health (without assuming responsibility for any wrongful disclosure by a Participating State) shall limit the amount of such data made available to the Participating State by not disclosing to the Participating State any NDC-level pricing information. For purposes hereof "satisfactory assurance" shall be deemed given when the Participating State enters the statutory cite of the applicable exemption on its Participating State Addendum. In the event that either party is required by law to disclose any provision of this Agreement or pricing information to any person, such party shall provide advance written notice to the other party sufficiently in advance of the proposed disclosure to allow the other party to seek a protective order or other relief.

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

#### **NON-RENEWAL OR TERMINATION**

8.1 This Agreement shall be effective as of [start date] and shall have the term indicated in Section 4.3; *supra*.

8.2 Any Participating State may terminate its participation in this Agreement by giving Manufacturer and First Health written notice at least (90) days prior to the anniversary date of this Agreement, in which case termination shall become effective on the anniversary date of the date of execution of this Agreement. The termination of this Agreement by one or more Participating States shall not affect the Manufacturer's, First Health's or the other Participating States' obligations under this Agreement, other than any effect the reduction in the number of lives covered by the Agreement may have on the Supplemental Rebate payable hereunder. Manufacturer may terminate this Agreement and all Addenda by giving all Participating States and First Health written notice at least ninety (90) days prior to the anniversary date of this Agreement, in which case termination shall become effective on the anniversary date of the date of execution of this Agreement. Manufacturer's right of termination is limited to the right to terminate the entire Agreement. Manufacturer may not terminate specific Addendum/Addenda of less than all Participating State(s).

8.3 Termination by a FH Client of its PBA Services Agreement with First Health shall, as of the same termination effective date, terminate this Agreement as to that Participating State.

8.4 Notwithstanding any non-renewal or termination of this Agreement, State Supplemental Rebates will still be due and payable from the Manufacturer under Section 4.2 for any Supplemental Covered Products for which Participating State(s)' obligation to reimburse arose prior to the effective date of termination of this Agreement.

8.5 On at least an annual basis or as mutually agreed upon by Manufacturer and First Health, Manufacturer shall have the opportunity to decrease the Net Price of its Covered Products to increase the likelihood of product(s) utilization and/or inclusion in the Participating States Preferred Drug List Programs.

#### GENERAL PROVISIONS

9.1 This Agreement will be governed and construed in accordance with 42 U.S.C. § 1396f-8 and all other applicable federal and state law and regulations.

9.2 Any notice required to be given pursuant to the terms and provisions of this Agreement will be in writing and will be sent by certified mail, return receipt requested. Notice will be mailed to the addressees specified in each individual Participating State's Addendum to this Agreement.

Notice to the State shall be sent to:

State of Michigan

Department of Community Health Medical Services Administration

Attn: Sue Moran

400 S. Pine Street

Lansing, MI 48933

Notice to First Health shall be sent to:

First Health Services Corporation

Attn: Peter Quinn, Chief Operating Officer

With a copy to: Legal Department

4300 Cox Road  
Glen Allen, Virginia 23060

Notice to Manufacturer will be sent to:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

9.3 The Manufacturer agrees to be bound by the laws of the United States of America and with respect to each Participating State, the law of that Participating State. Proper venue in any legal action shall be the venue of the Participating State that is party to the proceeding. Any action brought by Manufacturer must be brought separately against individual Participating States or First Health, unless all affected Participating States and First Health consent to joinder of the actions.

9.4 Nothing herein shall be construed or interpreted as limiting or otherwise affecting First Health or Participating State(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.

9.5 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 First Health or any Participating State.

9.6 Manufacturer may not assign this Agreement, either in whole or in part, without the written consent of the Participating States and First Health. However, 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. If the Agreement is assigned pursuant to this Section, Manufacturer shall provide First Health and the Participating States with an update of the information contained in Section 9.2, supra.

9.7 Nothing in this Agreement will 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 requirements, this Agreement will be construed in all respects as if any invalid, unenforceable, or inconsistent provision were eliminated, and without any effect on any other provision.

9.8 First Health, Participating State(s) and Manufacturer declare that this Agreement, including attachments, schedules and addenda, contains a total integration of all rights and obligations of the parties. There are no extrinsic conditions, collateral agreements or undertakings of any kind. In regarding this Agreement as the full and final expression of their contract, it is the express intention of the parties that any and all prior or contemporaneous agreements, promises, negotiations or representations, either oral or written, relating to the subject matter and period of time governed by this Agreement which are not expressly set forth herein are to have no force, effect, or legal consequences of any kind.

9.9 This Agreement will not be altered except by (i) an amendment in writing signed by all the parties, other than (ii) in the case of the addition of a new Participating State(s), by its execution of the New Participating State Amendment. It is acknowledged that the intent of the previous sentence is that the addition of a new Participating State(s) by amendment shall only require the consent of First Health and the approval of CMS, not Manufacturer. Manufacturer agrees that any Participating State may be added to this Agreement by amendment and that said Participating State's covered Medicaid (and other non-Medicaid programs approved by CMS in the Medicaid state plan(s)) lives shall apply to the provisions of Schedules 2 and 3 and will affect the rebates to all Participating States in accordance with Schedules 2 and 3. The New Participating State Amendment shall be executed by First Health and the new Participating State with a copy provided to Manufacturer for its records. Other than as stated herein, 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 Participating State(s), First Health, and the Manufacturer. Any modification or amendment must be authorized by CMS.

9.10 The parties do not contemplate any circumstances under which indemnification of the other parties would arise. Nevertheless, should such circumstances arise, Manufacturer agrees to indemnify, defend and hold harmless the Participating States and First Health, their 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 in the performance of this Agreement.

9.11 Inasmuch as the State Supplemental Rebates required by this Agreement are for state Medicaid (and non-Medicaid programs approved by CMS in the Medicaid state plan(s)) program beneficiaries, it is

agreed, in accordance with Medicaid Drug Rebate Program Release #102 for State Medicaid Directors and other applicable law, that the State Supplemental Rebates do not establish a new 'Best Price' for purposes of participating Manufacturer's CMS Agreement.

9.12 In the event that Participating State(s) require(s) prior authorization of Manufacturer's Supplemental Covered Product(s) as part of a Product Category prior authorization under Section 5.1, State Supplemental Rebates shall nevertheless be payable hereunder.

9.13 If First Health or a Participating State makes changes to a Product Category that are considered to be a material change in the structure of the supplemental rebates program, Manufacturer may be allowed to re-submit bids for the Product Category/Categories affected.

9.14 As evidence of their Agreement to the foregoing terms and conditions, the parties have signed below.

STATE OF MICHIGAN, DEPARTMENT OF COMMUNITY HEALTH:

By: \_\_\_\_\_ Date: \_\_\_\_\_

Name: Sue Moran

Title: Director, Bureau of Medicaid Program Operations and Quality Assurance  
MANUFACTURER

By: \_\_\_\_\_ Date: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

FIRST HEALTH SERVICES CORPORATION

By: \_\_\_\_\_ Date: \_\_\_\_\_

Name: Charles W. Byrd, Jr.

Title: Chief Financial Officer

## EXHIBIT A

### New Participating State Amendment to Supplemental Drug-Rebate Agreement Between Participating States; First Health Services Corporation

And  
(Manufacturer Name ("Manufacturer"))

WHEREAS, the State of Michigan, First Health Services Corporation ("First Health"), and Manufacturer have entered into a Supplemental Drug-Rebate Agreement (the "Agreement"), effective as of <<DATE>>; and

WHEREAS, the participating States as named in Section 8 below have become parties to the Agreement as Participating States by previous amendment or addenda; and

Now, therefore, in consideration of the mutual covenants, promises, and conditions contained herein and in the Agreement, the parties agree as follows:

1. The State of Georgia is hereby added as a party to the Agreement as a new Participating State, as defined in Section 3.14 of the Agreement.
2. This Amendment shall become effective upon the date determined in accordance with Section 3.16 of the Agreement; provided that this Amendment shall not become effective until the effective date of the state plan amendment submitted to CMS on June 6, 2006.
3. An executed copy of this Amendment shall be sent via certified mail, return receipt requested to Manufacturer's address of record as set forth in the Agreement within five (5) business days of its execution by the parties.
4. This Addendum adds a new Participating State to the Agreement and does not otherwise change or alter the Agreement. The new Participating State(s) understand(s) and agrees to be bound by the terms of the Agreement.
5. The undersigned State acknowledges that manufacturer rebate pricing information is confidential information under applicable Federal law and shall be exempt from public disclosure pursuant to State Code Section O.C.G.A. 50-18-70, et seq.
6. The undersigned State represents that it has not requested authorization from CMS to include any state pharmaceutical assistance program within the rebate provisions of the Agreement.

**EXHIBIT A**

The above representation shall not prohibit the undersigned State from requesting CMS authorization to include (other) pharmaceutical assistance programs within the Agreement at a later date. Upon receipt of CMS authorization, State shall given written notice to Manufacturer of the date Manufacturer's Supplemental Covered Product is effectively placed on the preferred drug list of the undersigned State's non-Medicaid programs approved by CMS in the Medicaid state plan(s) by completing the attached Exhibit A1.

7. The approximate enrollment in the undersigned State's Medicaid program at the time of execution of this Amendment is 364,000.

8. As of the effective date of this Amendment, the following are all of the Participating States under the Agreement:

<u>Michigan</u>	<u>Alaska</u>
<u>New York</u>	<u>Nevada</u>
<u>New Hampshire</u>	<u>Hawaii</u>
<u>Minnesota</u>	<u>Montana</u>
<u>Kentucky</u>	<u>Tennessee</u>
<u>District of Columbia</u>	<u>Georgia</u>
<u>South Carolina</u>	<u>Rhode Island</u>



**EXHIBIT A**

**STATE OF GEORGIA  
DEPARTMENT OF COMMUNITY  
HEALTH**

**FIRST HEALTH SERVICES CORP**

**By: \_\_\_\_\_**

**By: \_\_\_\_\_**

**Name: \_\_\_\_\_**

**Name \_\_\_\_\_**

**Title: \_\_\_\_\_**

**Title: \_\_\_\_\_**

**Date: \_\_\_\_\_**

**Date: \_\_\_\_\_**

**EXHIBIT A1**

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

Participating State: Georgia

Non-Medicaid programs approved by CMS in the Medicaid State Plan(s) - Date of Approval

- |                |       |       |
|----------------|-------|-------|
| 1. <b>None</b> | _____ | _____ |
| 2.             | _____ | _____ |
| 3.             | _____ | _____ |
| 4.             | _____ | _____ |
| 5.             | _____ | _____ |
| 6.             | _____ | _____ |

**Schedule 1**  
**Product Category Listing**  
**Revision Date:**

Product Category ID	Product Category	Product	Manufacturer Name



## Schedule 2

**Please fill in all shaded boxes**

1000

Product Category: [illegible][illegible]

Net Price Per Unit				
	> 3 PREFERRED	THREE PREFERRED	TWO PREFERRED	ONE PREFERRED
1-2,999,999 Eligible Recipients	N/A	N/A	N/A	N/A
3M-5,999,999 Eligible Recipients	N/A	N/A	N/A	N/A
6M-4,999,999 Eligible Recipients	N/A	N/A	N/A	N/A
Equal to or greater than 9M Eligible Recipients	N/A	N/A	N/A	N/A



### Supplemental Rebate Matrix

#### BID CERTIFICATION

By submitting the attached bid(s) and having a duly authorized representative of ("Manufacturer") sign below, Manufacturer certifies:

- a. that the bid(s) submitted are firm offers that Manufacturer will not retract unless rejected as insufficient by First Health Services Corporation; and
- b. that Manufacturer will enter into binding contract(s) incorporating the Manufacturer's bid(s) that are accepted; and
- c. that Manufacturer understands and agrees that the acceptance of its bid(s) does not require any individual state to include Manufacturer's bidded product(s) on its preferred drug list; and
- d. that the signature below is that of a duly authorized representative of Manufacturer with the authority to execute agreements binding Manufacturer.

MANUFACTURER

Signature

Date

Printed Name

Title





### Supplemental Rebate Matrix

#### BID CERTIFICATION

By submitting the attached bid(s) and having a duly authorized representative of

(Manufacturer) sign below, Manufacturer certifies:

- a. that the bid(s) submitted are firm offers that Manufacturer will not retract unless rejected as insufficient by First Health Services Corporation; and
- b. that Manufacturer will enter into binding contract(s) incorporating the Manufacturer's bid(s) that are accepted; and
- c. that Manufacturer understands and agrees that the acceptance of its bid(s) does not require any individual state to include Manufacturer's bidded product(s) on its preferred drug list; and
- d. that the signature below is that of a duly authorized representative of Manufacturer with the authority to execute agreements binding Manufacturer.

MANUFACTURER

Signature \_\_\_\_\_

Date \_\_\_\_\_

Printed Name \_\_\_\_\_

Title \_\_\_\_\_


**Schedule 3**  
**Supplemental Rebate Calculation**



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF DIRECTOR

ACTION REFERRAL

TO  <i>Myers</i>	DATE  <i>7-18-08</i>
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DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER  <i>000038</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR  <i>cc: Ms. Forkner, Deps</i> 	<input type="checkbox"/> Prepare reply for appropriate signature DATE DUE _____ <input type="checkbox"/> FOIA DATE DUE _____ <input checked="" type="checkbox"/> Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1.			
2.			
3.			
4.			