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State/Territory: Indiana

State Plan Amendment (SPA)#: 20-014

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form
- 3) Approved SPA Pages

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 CHIP Services

Disabled and Elderly Health Programs Group

September 28, 2020

Ms. Allison Taylor
Medicaid Director
Indiana Office of Medicaid Policy and Planning
402 W Washington St Rm W382
Indianapolis, IN 46204-2776

Dear Ms. Taylor:

The CMS Division of Pharmacy team has reviewed Indiana State Plan Amendment (SPA) 20-0014 received in the Division of Program Operations North Branch on September 1, 2020. This SPA proposes to make technical changes to the template utilized in administering the State's supplemental drug rebate program.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 20-0014 is approved with an effective date of September 1, 2020. A copy of the updated signed CMS-179 form, as well as the pages approved for incorporation into Indiana's state plan will be forwarded by the Division of Program Operations North Branch.

If you have any questions regarding this request, please contact Justin Aplin at (410) 786-6901 or Justin.Aplin@cms.hhs.gov.

Sincerely,

/s/

Cynthia R. Denemark, R.Ph.
Deputy Director
Division of Pharmacy
DEHPG/CMCS/CMS

cc: James G. Scott, Director Division of Program Operations
Mai Le-Yuen Division of Program Operations North Branch
Sara Albertson Indiana Office of Medicaid Policy and Planning

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL	1. TRANSMITTAL NUMBER: 20-014	2. STATE Indiana
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
FOR: HEALTH CARE FINANCING ADMINISTRATION		4. PROPOSED EFFECTIVE DATE: September 1, 2020
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES		

5. TYPE OF PLAN MATERIAL (Check One):

NEW STATE PLAN AMENDMENT TO BE CONSIDERED AS NEW PLAN AMENDMENT

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

6. FEDERAL STATUTE/REGULATION CITATION: 42 CFR 447.505	7. FEDERAL BUDGET IMPACT (thousands): a. FFY 2020 \$ 0 b. FFY 2021 \$ 0
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.19 page 7 Attachment 3.1-A page 7	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Attachment 3.19 page 7 Attachment 3.1-A page 7

10. SUBJECT OF AMENDMENT:

This State Plan Amendment makes technical changes to the template utilized in administering the State's supplemental drug rebate program. In addition, the State is updating the date on an affected page within the state's State Plan. These changes are being made in order to bring about greater transparency pertaining to the supplemental drug rebate processes and procedures and to fully comply with applicable state requirements for supplemental rebates.

11. GOVERNOR'S REVIEW (Check One):

GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED:
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

Indiana's Medicaid State Plan does not require the Governor's review. See Section 7.4 of the State Plan

12. SIGNATURE OF STATE AGENCY OFFICIAL: 	16. RETURN TO: Allison Taylor Medicaid Director Indiana Office of Medicaid Policy and Planning 402 West Washington Street, Room W382 Indianapolis, IN 46204 ATTN: Sara Albertson, Federal Relations Lead
13. TYPED NAME: Allison Taylor	
14. TITLE: Medicaid Director	
15. DATE SUBMITTED: September 1, 2020	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: September 1, 2020	18. DATE APPROVED: September 28, 2020
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: September 1, 2020	20. SIGNATURE OF REGIONAL OFFICIAL:  Digitally signed by James G. Scott -S Date: 2020.10.01 13:25:42 -05'00'
21. TYPED NAME: James G. Scott	22. TITLE: Director, Division of Program Operations

23. REMARKS:

The state is authorizing Pen & Ink changes to Boxes 8 & 9 to read:
"Attachment 3.1-A page 7"

12.a. Prescribed Drugs

Provided with limitations.

Reimbursement is available for prescribed drugs subject to the limitations set out in 405 IAC 5. The following are not covered: anorectics or any agent used to promote weight loss; topical minoxidil preparations; fertility enhancement drugs; drugs used to treat sexual or erectile dysfunction, as set forth in section 1927(d)(2)(K) of the Act, unless such drugs are used to treat conditions other than sexual or erectile dysfunction and such uses have been approved by the Food and Drug Administration; drugs prescribed solely or primarily for cosmetic purposes. All over-the-counter and non-legend items are subject to the limitations set out in 405 IAC 5-24.

In accordance with Section 4401 of P.L. 101-508 (Omnibus Budget Reconciliation Act of 1990), Indiana Medicaid will fully participate in the manufacturer rebate program. In doing so, all applicable provisions and restrictions of the legislation, as well as that of any subsequent rules and/or regulations, will be strictly adhered to. Specifically, Indiana Medicaid will reimburse for all rebating manufacturers' (as identified to the agency by CMS) products fully in accordance with the specifications of the legislation. The program will also adhere to all reporting requirements of the legislation.

Supplemental Rebates--The State is in compliance with section 1927 of the Social Security Act. The state will cover drugs of federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.

The state will be negotiating supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates. A rebate agreement between the State and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on September 1, 2020 and entitled, State of Indiana Supplemental Rebate agreement, has been authorized by CMS.

Supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the federal government on the same percentage basis as applied under the national rebate agreement.

All drugs covered by the program, irrespective of prior authorization requirement, will comply with the provisions of the national rebate agreement.

STATE OF INDIANA SUPPLEMENTAL REBATE AGREEMENT
CONTRACT # _____

This Supplemental Rebate Agreement (“Agreement”) is entered into by and between the State of Indiana, Office of Medicaid Policy and Planning (“OMPP”) and **[Labeler’s Legal Name]** (“Labeler”), a **[Type of business entity, e.g., corporation]**, under the laws of the State of **[Identify the state of organization or incorporation]**, whose business address and taxpayer identification number are as follows:

Business Address:

Taxpayer Identification Number:

WHEREAS, OMPP desires to negotiate and collect rebates in addition to the Federal Rebates provided for in Title XIX, Section 1927 of the Social Security Act (42 U.S.C. 1396r-8) for Covered Products utilized Quarterly by Indiana Medicaid Members.

WHEREAS, Labeler desires to provide OMPP with Supplemental Rebates for the utilized Covered Products.

WHEREAS, this Agreement between OMPP and Labeler shall be separate and distinct from the Federal Rebate Agreement between Labeler and the Federal Secretary of Health and Human Services.

WHEREAS, the parties hereto intend for this Agreement to comply with the requirements of Title XIX, Section 1927 of the Social Security Act (42 U.S.C. 1396r-8).

WHEREAS, this Agreement, entitled “State of Indiana Supplemental Rebate Agreement”, was submitted to CMS by OMPP on **[Month/Day/Year revised Agreement template submitted to CMS]** and has been authorized by CMS. A true and accurate copy of the authorization from CMS is set out in Exhibit A, which is attached hereto and incorporated herein by reference.

NOW, THEREFORE, OMPP and Labeler agree as follows:

Article 1 — Definitions

- 1.1 “Average Manufacturer Price” or “AMP” shall mean the Average Manufacturer Price as defined in 42 U.S.C. 1396r-8 and shall exclude rebates paid to all states under CMS approved Supplemental Rebate Agreements.
- 1.2 “Best Price” or “BP” shall mean the Best Price as defined in 42 U.S.C. 1396r-8 and shall exclude rebates paid to all states under CMS authorized Supplemental Rebate Agreements.
- 1.3 “Centers for Medicare & Medicaid Services” or “CMS” (formerly known as the Health Care Financing Administration of HCFA) shall mean the agency within the Federal Department of Health and Human Services that is charged with overseeing the Medicaid programs administered by states.
- 1.4 “Consumer Price Index-Urban” or “CPI-U” shall have the same meaning as set forth in the Federal Rebate Agreement.
- 1.5 “Covered Product” shall mean the pharmaceutical products listed in Exhibit B, which is attached hereto and incorporated herein by reference.
- 1.6 “CPI-U Adjustment” or “Consumer Price Index-Urban Adjustment” shall mean the additional unit rebate amount calculated pursuant to 42 U.S.C. 1396r-8(c)(2).

- 1.7 “Drug Utilization Review Board” shall mean the entity established by IC 12-15-35-19.
- 1.8 “Federal Rebate” shall mean any monetary payment remitted by Labeler pursuant to the Federal Rebate Agreement and in accordance with 42 U.S.C. 1396r-8(c).
- 1.9 “Federal Rebate Agreement” shall mean the contractual agreement between Labeler and the Federal Secretary of Health and Human Services entered into pursuant to 42 U.S.C. 1396r-8.
- 1.10 “Indiana Medicaid” or “Indiana Medicaid Program” shall mean the joint Federal- state medical assistance program as established, defined and administered pursuant to Title XIX, Section 1927 of the Social Security Act (42 U.S.C. 1396, et seq.) in the State of Indiana.
- 1.11 “Indiana Medicaid Member” shall mean any person enrolled in the Indiana Medicaid Program and eligible to receive fee-for-service prescription drug benefits.
- 1.12 “Labeler” shall mean the entity identified above that is a party to this Agreement. For the purposes of this Agreement, Labeler shall also have the meaning set forth in 42 U.S.C. 1396r-8(k)(5), and also mean the entity holding legal title to or possession of the NDC for the Covered Products.
- 1.13 “NDC Number” or “NDC” shall mean the identifying drug number maintained by the Federal Food and Drug Administration (FDA). For the purposes of this Agreement, NDC shall mean the complete eleven (11) digit number including the labeler code (first segment of 5 digits), the product code (middle segment of 4 digits) and the package code (last segment of 2 digits).
- 1.14 “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 Indiana, as applicable, to dispense legend drugs, and enrolled as an OMPP provider. The definition of Pharmacy shall not include any pharmacy located outside of the United States.
- 1.15 “Pricing Information” shall include Average Manufacturer Price, Best Price, CPI- U Adjustment, Unit Rebate Amount, Rebate Per Unit, Rebate Amount Per Unit and any methodology utilized to calculate a Supplemental Rebate pursuant to this Agreement as set out in Exhibit C, which is attached hereto and incorporated herein by reference.
- 1.16 “Quarter” shall mean calendar quarter unless otherwise specified.
- 1.17 “State Utilization Data” shall mean the information provided on the total number of Units of each dosage form and strength, as identified by National Drug Code (NDC) of Labeler’s Covered Products dispensed by Pharmacies and reimbursed by OMPP during a Quarter. This information will be based on claims of each Covered Product reimbursed by OMPP during a Quarter and not each Covered Product dispensed during a Quarter and the definition of State Utilization Data shall include the former type of claims. State Utilization Data shall exclude claims from covered entities identified in 42 U.S.C. 256b(a)(4) in accordance with 42 U.S.C. 256b(a)(5)(A) and 42 U.S.C. 1396r-8(a)(5)(C).
- 1.18 “Supplemental Rebate” shall mean any monetary payment remitted by Labeler, pursuant to this Agreement, that supplements the Federal Rebate.
- 1.19 “Supplemental Rebate Invoice” shall mean the report that itemizes and aggregates, by NDC, the Units for claims reimbursed by OMPP for each Covered Product during a Quarter and any cover letter that accompanies said report. The Supplemental Rebate Invoice shall comply with the requirements for Medicaid Utilization Information as set forth in the Federal Rebate Agreement.
- 1.20 “Therapeutics Committee” shall mean the subcommittee of the Drug Utilization Review Board

established by IC 12-15-35-20.5.

- 1.21 “Unit” shall mean the drug unit in the lowest identifiable amount on which the Federal Rebate is calculated (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams) as reported by Labeler to CMS.
- 1.22 “Unit Rebate Amount” or “URA” shall mean the computed Unit amount to which the State Utilization Data is applied for the Federal Rebate or Supplemental Rebate payment due. For the purposes of this Agreement, Unit Rebate Amount shall be synonymous with the terms Rebate Per Unit (RPU) and Rebate Amount Per Unit and encompass said terms.
- 1.23 “Wholesale Acquisition Cost” or “WAC” shall mean the Labeler’s list price for the Covered Product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, that was in effect on the last day of the subject Quarter as reported by First Data Bank, Medi-Span or other publications of drug pricing data.

Article 2 — Responsibilities of Labeler

- 2.1 Labeler shall pay a Supplemental Rebate per Unit to OMPP for each of the Covered Products dispensed by Pharmacies to Indiana Medicaid Members and reimbursed by OMPP for each quarter, or any part thereof, that the Covered Product is preferred. Preferred status does not exclude the utilization of prior authorization or step therapy as permitted by IC 12-15-35-28(g). Labeler shall pay to OMPP the Supplemental Rebate per unit as calculated in accordance with the formula set out in Exhibit C, which is attached hereto and incorporated herein by reference.
- 2.2 Nothing in this Agreement shall be construed to relieve Labeler of its obligation to pay Federal Rebates for utilization by Indiana Medicaid Members . Furthermore, at no time shall the Supplemental Rebates paid by Labeler, pursuant to this Agreement, diminish the amount of Federal Rebates due and owing pursuant to the Federal Rebate Agreement and 42 U.S.C. 1396r-8.
- 2.3 If applicable, Labeler shall submit AMP or Best Price information for each Covered Product to OMPP or its designee within thirty (30) days of the last day of each Quarter. The Pricing Information shall be submitted in a format and via a medium mutually agreed upon by OMPP or its designee and Labeler. Labeler shall report any adjustments to AMP or Best Price for all prior Quarters for which Labeler was obligated to remit Supplemental Rebates pursuant to this Agreement.
- 2.4 Labeler shall remit Supplemental Rebate payments to OMPP or its designee within thirty (30) days of Labeler’s receipt of the Supplemental Rebate Invoice. Labeler shall mail Supplemental Rebate payments to the address specified by the Supplemental Rebate Invoice.
- 2.5 Interest on Supplemental Rebates due begins to accrue on the thirty-eighth (38th) day from the postmark date of the Supplemental Rebate Invoice. Interest stops accruing and is calculated up to the postmark date of Labeler’s mailed check. Interest will be calculated in accordance with the CMS’ guidelines that apply to Federal Rebates. Labeler’s failure to remit Supplemental Rebate payments in a timely manner may result in Labeler’s termination in accordance with Article 5.3 of this Agreement.
- 2.6 If OMPP or its designee does not receive Supplemental Rebates as set forth in this section, including interest due and owing, within ninety (90) days of the postmark date of the Supplemental Rebate Invoice, and Labeler does not file a dispute in accordance with Article 4 of this Agreement, Labeler will be deemed to be in breach of this Agreement and the Agreement may be terminated by OMPP in accordance with Article 5.3 of this Agreement.

- 2.7 Labeler shall continue to pay Supplemental Rebates for so long as this Agreement is in force and State Utilization Data evidences that OMPP has paid for the Covered Product, regardless of whether Labeler continues to market and sell the Covered Product. In the event Labeler sells or otherwise transfers a Covered Product to another manufacturer, Labeler shall continue to be responsible for the payment of Supplemental Rebates for the Covered Product for the duration of the term of this Agreement. Nothing in this Agreement shall be construed to prohibit Labeler from discontinuing the production of a Covered Product. In the event Labeler elects to discontinue production of a Covered Product, Labeler shall make a reasonable effort to notify OMPP or its designee prior to the discontinuance of the Covered Product.
- 2.8 During the term of this Agreement and for a minimum of five (5) years after termination of this Agreement, Labeler shall maintain records that will permit OMPP to verify Pricing Information. If an audit, litigation, or other action involving the records is begun before the end of the five (5) year period, Labeler shall retain all records until all issues of the action are finally resolved. Labeler shall cooperate with OMPP in any such verification that may be required to resolve issues regarding Pricing Information. Any such verification will be at OMPP's expense and only upon reasonable notice to Labeler.
- 2.9 Payment of rebates under this Agreement is contingent on Labeler's Best Price and AMP not being affected by such rebates.

Article 3 — Responsibilities of OMPP

- 3.1 All Supplemental Rebates collected by OMPP, pursuant to this Agreement, which are in excess of those required by the Federal Rebate Agreement will be reported to and shared with the Federal government on the same percentage basis as the Federal Rebate under the Federal Rebate Agreement.
- 3.2 OMPP represents and warrants that it is in compliance with Title XIX, Section 1927 of the Social Security Act (42 U.S.C. 1396, et seq.) and the Federal Rebate Agreement.
- 3.3 OMPP or its designee shall invoice Supplemental Rebates separately from the Federal Rebates, on a Quarterly basis, utilizing an invoice format substantially similar to that of the Federal Rebate invoice, that provides at a minimum for each Covered Product reimbursed by OMPP during the Quarter: (i) NDC number; (ii) name of Covered Product, including strength and dosage form; (iii) Units paid for by during the Quarter by NDC number; (iv) total number or prescriptions paid for during the Quarter by NDC number; and (v) total reimbursed amount paid during the Quarter by NDC number. OMPP, at its option, may compute the total Supplemental Rebate anticipated but it shall remain the responsibility of Labeler to correctly calculate the Supplemental Rebate amount based on the applicable methodology set out in Exhibit C. OMPP or its designee shall submit the Supplemental Rebate invoice to Labeler within sixty (60) days of the last day of the Quarter in which OMPP provided reimbursement for the Covered Product or if applicable, within sixty (60) days after this Agreement is executed by both of the parties hereto. Any amended invoice shall be submitted by OMPP or its designee within fifteen (15) months of the last day of the Quarter in which OMPP provided reimbursement for the Covered Product.
- 3.4 During the term of this Agreement and for a minimum of five (5) years after the termination of this Agreement, OMPP or its designee shall maintain State Utilization Data and the supporting paid claims for the most recent four (4) Quarters that will permit Labeler to verify, through an audit process, the Supplemental Rebate invoices submitted by OMPP or its designee. If an audit, litigation, or other action involving the records is begun before the end of the five (5) year period, OMPP or its designee shall retain all records until all issues of the action are finally resolved. OMPP or its designee shall cooperate with Labeler in any such audit that may be required to resolve issues regarding State Utilization Data. Any such audit will be at Labeler's expense and only upon reasonable notice to OMPP and its designee.

Article 4 — Dispute Resolution

- 4.1 If either party discovers an error in the payment of Supplemental Rebates by Labeler, the discovering party shall notify in writing the other party of such error. Labeler shall deduct any overpayment from subsequent Supplemental Rebates due and owing pursuant to this Agreement. In the event no subsequent Supplemental Rebates become due and owing, OMPP or its designee shall refund the overpayment within thirty (30) days of OMPP's acknowledgement of such overpayment. In the event of any underpayment, Labeler shall remit payment to OMPP or its designee within thirty (30) days of Labeler's acknowledgement of such underpayment.
- 4.2 Disputes regarding State Utilization Data shall be resolved in accordance with the applicable policies and procedures established by CMS for resolution of disputes of the Federal Rebate.
- 4.3 The parties hereto shall attempt to reconcile all disputes related to Pricing Information or WAC data through discussion and negotiation within (30) thirty days of the postmark date of the Supplemental Rebate invoice. In the event that OMPP and Labeler are not able to resolve a dispute regarding Pricing Information through said procedure, Labeler, if it desires to contest the position of the OMPP may appeal in writing. In accordance with IC 4-21.5-3-6(d), OMPP's position regarding Pricing Information will be deemed to be final on the fifteenth day after notice is sent to Labeler. A petition for review must comply with IC 4-21.5-3-7 and be filed within fifteen days after notice is given. Such appeals shall be held in accordance with IC 4-21.5-3.
- 4.4 If Labeler in good faith believes that the State Utilization and /or Pricing Information is erroneous, Labeler shall remit payment for the portion of the Supplemental Rebate which is not disputed within the timeframe set out in Article 2.4 above. The balance due, if any, plus a reasonable rate of interest as set forth herein, will be paid or credited by the Labeler by the due date of the next Quarterly payment under this Agreement after resolution of the dispute.

Article 5 — Term and Termination

Unless terminated pursuant to the terms of this Agreement, the parties hereto are bound by this Agreement from **[Effective Date]** through **[Termination Date]**.

- 5.1 Renewal Option – This Agreement may be renewed under the same terms and conditions, subject to the approval of the Commissioner of the Department of Administration and the State Budget Director in compliance with IC § 5-14-3.5-2 and IC § 12-15-30-4 and with authorization from CMS.
- 5.2 Termination for Convenience – Either party may terminate this Agreement by providing the other party with notice at least sixty (60) days prior to the effective date of the termination. Termination shall become effective the first day of the first Quarter beginning at least sixty (60) days after a party provides notice requesting termination.
- 5.3 Bankruptcy and Insolvency – OMPP shall have the right to immediately terminate this Agreement, without prior notice, in the event Labeler is adjudicated bankrupt or makes an assignment for the benefit of creditors without OMPP's prior express written consent or if a receiver is appointed for Labeler.
- 5.4 Termination for Breach – In the event of an alleged breach of this Agreement, the non-breaching party shall give the breaching party written notice of the alleged breach. The breaching party shall have fifteen (15) days from the receipt of notice in which to cure the alleged breach to the satisfaction of the non-breaching party. Failure to cure the breach within such fifteen (15) day period shall give the non- breaching party the right to terminate this Agreement immediately. The non- breaching party shall provide the breaching party express written notice of the termination.

- 5.5 Governmental Action – If any governmental entity, other than the Indiana Family and Social Services Administration, whether state or Federal, demands, requests or advises the parties hereto, or either party, to suspend, materially alter or otherwise materially revise its performance under this Agreement so as to be in compliance with any governmental law, action, regulation, or opinion, that party may take whatever action its deems necessary, in its sole discretion, including termination of the Agreement, to comply with the demand, request, or advice, and such action shall not constitute a breach of this Agreement or otherwise give rise to any liability of any nature whatsoever, Each party hereto agrees to notify the other party of such demand, request or advisory with seven (7) days upon learning of the demand, request or advisory.
- 5.6 Effect on Accrued Obligations – Termination of this Agreement shall have no effect on the rights and responsibilities of the parties hereto arising out of any transactions that occurred prior to the effective date of such termination.
- 5.7 Remedies – The fact that either party exercises any right of termination it may be entitled to under this Agreement shall not prevent such party from seeking any other remedy it may have in law or equity, nor shall any provision under this Agreement which provides a remedy to a party for the other party's non-performance be deemed to be a sole and exclusive remedy, unless specifically stated as such.
- 5.8 Effect of Termination or Non-Renewal – At the sole discretion of OMPP, termination or non-renewal of this Agreement may result in Labeler's Covered Product(s) being available to Indiana Medicaid Members only through prior authorization.

Article 6 — Confidentiality

- 6.1 To the extent required by law (42 U.S.C. 1396r-8(b)(3)(D), IC 12-15-35-43.5 and any other applicable Federal and state law), the parties to this Agreement agree to maintain the confidentiality of this Agreement and not to disclose its terms, conditions and Pricing Information to third parties without the express written consent of the other party except that OMPP may share Pricing Information with any of OMPP's agents, designees, consultants or other persons, including but not limited to the Therapeutics Committee members, who participate: (i) in the review of Labeler's bid to enter into this Agreement or negotiation of this Agreement; or (ii) in the development and administration of the preferred drug list, prior authorization program, supplemental rebate program or as may be required by court order.
- 6.2 Labeler shall hold State Utilization Data confidential. If Labeler audits this information or receives additional information on such data, all information obtained shall also be held confidential.
- 6.3 For the purposes of this Article 6, "third party" shall include, but is not limited to: (i) any person or entity that is not an employee of a party to this Agreement or under contract with a party to this Agreement, and (ii) any individual or entity, including an employee or contracted party, who does not have a reasonable need to know the confidential information involved.
- 6.4 The confidentiality obligations set out in this Agreement 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 said information, that is independently developed by the receiving party, or that is required by law to be disclosed.
- 6.5 Notwithstanding the non-renewal or termination of this Agreement for any reason, the provisions of Article 6 shall remain in full force and effect and survive the termination of this Agreement.

Article 7 — Notices

Any notice required or permitted pursuant to the terms of this Agreement shall be in writing and shall be sent by certified mail, return receipt requested.

Notice to OMPP shall be sent to:

Marc Shirley, R.Ph.
Pharmacy Operations Manager
Office of Medicaid Policy and Planning
Indiana Family and Social Services Administration
Room W-382
Indiana State Government Center South
402 W. Washington Street
Indianapolis, IN 46204-2739

Notice to Labeler will be sent to:

Labeler Notice Contact Name
Labeler Notice Contact Name Title
Labeler Legal Name
Mailing Street Address
City, State, Zip Code

Article 8 — General Provisions

- 8.1 Relationship of the Parties - The relationship of the parties is that of independent entities contracting for the sole purpose of carrying out the provisions of this Agreement. Nothing herein or otherwise shall be construed to create any other relationship, including without limitation, that of employee, agent or representative.
- 8.2 Agreement Rights and Remedies - This Agreement is between the parties hereto and is not intended to create any rights or remedies in favor of any other person or entity, including without limitation, any person who has received, or is eligible to receive, benefits from the OMPP.
- 8.3 Choice of Law and Venue - This Agreement shall be governed by the laws of the State of Indiana without regard to choice of law provisions. The parties hereby submit to the jurisdiction of the state and Federal courts in Indiana. The parties further agree that any action to enforce or interpret the provisions of this Agreement shall be filed in a court of competent jurisdiction in Indianapolis, Indiana.
- 8.4 Amendment - This Agreement may not be amended or modified by either party without the express written consent of the other party. Any amendment or modification must be authorized by CMS.
- 8.5 Force Majeure - A party shall not be deemed to have breached this Agreement if its delay or failure to perform all or any part of its obligations hereunder results from a condition beyond its reasonable control, including without limitation, acts of God or the public enemy, acts of terrorism, fire, earthquake, flood, storm, strike or other labor unrest, power or communication line failure, or statute, or rule or action of any federal, state or local government or agency.
- 8.6 Use of Names and Trademarks - Neither party shall use the name of the other in any type of promotional or advertising material without the express, written consent of the other party. Labeler agrees to not use the name of the State of Indiana, the Indiana Medicaid Program or OMPP in any manner without the express, written consent of OMPP. OMPP may use the

trade name of any Covered Product(s) to communicate whether or not the Covered Product(s) requires prior approval.

- 8.7 Entire Agreement - This Agreement constitutes the entire agreement and understanding between the parties hereto with respect to the subject matter contained herein and supersedes any and all prior agreements or understandings between the parties.
- 8.8 Waiver - No waiver of any provision of this Agreement shall be deemed to constitute or shall constitute a waiver of any other provision hereof, whether or not similar, nor shall any waiver constitute a continuing waiver. No waiver shall be binding unless executed in writing by the party making the waiver.
- 8.9 Severability - In the event any term or provision contained in this Agreement shall be determined to be invalid or unenforceable, such invalidity or unenforceability shall not affect the validity or enforcement of any other term or provision in this Agreement.
- 8.10 Agreement Headings - The headings used in this Agreement are solely for convenience and shall have no effect on the interpretation of this Agreement.
- 8.11 Indemnification – Labeler shall indemnify, defend and hold harmless OMPP, its officers, agents and employees from any and all claims and losses accruing or resulting to any person, firm or corporation who may be injured or damaged by Labeler in its performance or breach of this Agreement.
- 8.12 Assignment – This Agreement shall not be assigned in whole or in part without the express written consent of OMPP.
- 8.13 Word Usage – The singular shall include the plural and the plural shall include the singular except where the contrary intention is manifest.
- 8.14 The Labeler and its agents shall abide by all ethical requirements that apply to persons who have a business relationship with the State, as set forth in Indiana Code § 4-2-6 et seq., the regulations promulgated thereunder, and Executive Order 04-08, dated April 27, 2004. If the Labeler is not familiar with these ethical requirements, the Labeler should refer any questions to the Indiana State Ethics Commission, or visit the Indiana State Ethics Commission website at [<<<http://www.in.gov/ethics/>>>](http://www.in.gov/ethics/). If the Labeler or its agents violate any applicable ethical standards, the State may, in its sole discretion, terminate this Agreement immediately upon notice to the Labeler. In addition, the Labeler may be subject to penalties under Indiana Code § 4-2-6-12.
- 8.15 The Labeler certifies by entering into this Agreement that neither it nor its principal(s) is presently in arrear in payment of taxes, permit fees or other statutory, regulatory or judicially required payments to the State of Indiana.
- 8.16 The Labeler affirms that, if it is an entity as described in Indiana Code Title 23, it is properly registered and owes no outstanding reports to the Indiana Secretary of State.
- 8.17 The signatory for the Labeler represents that he/she has been duly authorized to execute this Agreement on behalf of the Labeler and has obtained all necessary or applicable approvals to make this Agreement fully binding upon the Labeler when his/her signature is affixed and accepted by the State.

Non-Collusion and Acceptance

The undersigned attests, subject to the penalties for perjury, that the undersigned is the Labeler, or that the undersigned is the properly authorized representative, agent, member or officer of the Labeler. Further, to the undersigned's knowledge, neither the undersigned nor any other member, employee, representative, agent or officer of the Labeler, directly or indirectly, has entered into or been offered any sum of money or other consideration for the execution of this Agreement other than that which appears upon the face hereof. **Furthermore, if the undersigned has knowledge that a state officer, employee, or special state appointee, as those terms are defined in Indiana Code § 4-2-6-1, has a financial interest in the Agreement, the Labeler attests to compliance with the disclosure requirements in Indiana Code § 4-2-6-10.5.**

Agreement to Use Electronic Signatures

I agree, and it is my intent, to sign this Agreement by electronically submitting this Agreement to the State of Indiana. I understand that my signing and submitting this Agreement in this fashion is the legal equivalent of having placed my handwritten signature on the submitted Agreement and this affirmation. I understand and agree that by electronically signing and submitting this Agreement in this fashion I am affirming to the truth of the information contained therein. I understand that this Agreement will not become binding on the State until it has been approved by the Department of Administration, the State Budget Agency, and the Office of the Attorney General.

In Witness Whereof, Labeler and the State of Indiana have, through their duly authorized representatives, entered into this Amendment. The parties, having read and understood the foregoing terms of this Agreement, do by their respective signatures dated below agree to the terms thereof.

[Labeler's Legal Name] **Indiana Family and Social Services Administration**
 Labeler Code(s): _____ **Office of Medicaid Policy and Planning**

By:\s1\ By:\s2\
 Title:\t1\ Title:\t2\
 Date:\d1\ Date:\d2\

	Electronically Approved by: Department of Administration By: _____ (for) Lesley A. Crane, Commissioner
Electronically Approved by: State Budget Agency By: _____ (for) Zachary Q. Jackson, Director	Electronically Approved as to Form and Legality: Office of the Attorney General By: _____ (for) Curtis T. Hill, Jr., Attorney General

EXHIBIT A
CENTERS FOR MEDICARE AND MEDICAID SERVICES APPROVAL

[Reserved for CMS correspondence approving this revised Agreement template]

EXHIBIT B
COVERED PRODUCTS

The pharmaceutical products to which this Supplemental Rebate Agreement shall apply are as follows:

Brand Name (Registered Trademark Name)	Generic Name	Strength	Dosage Form

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EXHIBIT C
SUPPLEMENTAL REBATE CALCULATION METHODOLOGY

This Exhibit C to the Indiana Supplemental Rebate Agreement between the **State of Indiana, Office of Medicaid Policy and Planning** (“OMPP”), and **[Labeler’s Legal Name]**, is in effect as of **[Effective Date]**, through **[Termination Date]** and will utilize the Supplemental Rebate Calculation Methodology as set forth in the table below:

NDC Number (11 digits required)	Product Name, Strength & Dosage Form	CMS Unit Type	Pricing Reference (AMP, BP, WAC)	Supplemental Rebate Per Unit (SRPU) Calculation Methodology (One-of-One)	Supplemental Rebate Per Unit (SRPU) Calculation Methodology (One-of-Two)	Supplemental Rebate Per Unit (SRPU) Calculation Methodology (One-of-Three)	Supplemental Rebate Per Unit (SRPU) Calculation Methodology (One-of-Many)	Comments and Conditions

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