

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVE
OMB NO. 0938-0

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL**

1. TRANSMITTAL NUMBER:
03-001

2. STATE
OHIO

FOR: CENTERS FOR MEDICAID AND MEDICAID SERVICES

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE
SOCIAL SECURITY ACT (MEDICAID) MEDICAID

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
1/1/03

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:

Section 1927 of the Social Security Act

7. FEDERAL BUDGET IMPACT:

- a. FFY 03 \$ (12.4 million)
- b. FFY 04 \$ (13.7 million)

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

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Page 1 and 1a-10a

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION
OR ATTACHMENT (If Applicable):

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Ohio (03-001)
Approved: 10/10/03
effective: 01/01/03

10. SUBJECT OF AMENDMENT:

Supplemental Rebate

11. GOVERNOR'S REVIEW (Check One):

- GOVERNOR'S OFFICE REPORTED NO COMMENT
- COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
- NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

X OTHER, AS SPECIFIED:

Governor has delegated signature to ODJFS
Director

12. SIGNATURE OF STATE AGENCY OFFICIAL:

Tom Hayes

13. TYPED NAME: Tom Hayes

14. TITLE: Director

16. RETURN TO:

Becky Jackson
ODJFS/OHP
30 East Broad St, 27th fl
Columbus, OH 43215-3414

15. DATE SUBMITTED:

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:

JAN 17 2003

18. DATE APPROVED:

10/10/03

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:

January 1, 2003

20. SIGNATURE OF REGIONAL OFFICIAL:

Ala Freund, acting RRA 10/10/03

21. TYPED NAME:

Cheryl A. Harris

22. TITLE: Associate Regional Administrator
Division of Medicaid and Children's Health

23. REMARKS:

*Rec'd
1/17/03*

STATE OF OHIO

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12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

a. Prescribed drugs

Coverage of prescription drugs meets all reporting requirements and provisions of section 1927 of the social security act.

Long term care pharmacy best practices management incentive payment program

The long term care pharmacy best practices management incentive payment program will be in effect for SFY 2003 (July 1, 2002-June 30, 2003) and SFY 2004 (July 1, 2003-June 30, 2004) with final payments being made by March 31, 2005 to test the assumption that incentive based drug utilization management can reduce pharmacy expenditures for medicaid consumers living in nursing facilities and ICF-MR facilities without compromising patient care. It will be implemented in accordance with rule 5101:3-9-08.

SUPPLEMENTAL REBATES

SUPPLEMENTAL REBATES WILL BE ACCEPTED FROM MANUFACTURERS ACCORDING TO THE SUPPLEMENTAL DRUG-REBATE AGREEMENT. SUPPLEMENTAL REBATES RECEIVED UNDER THIS AGREEMENT WILL BE SHARED WITH THE FEDERAL GOVERNMENT ON THE PERCENTAGE BASIS REQUIRED BY LAW.

b. Dentures

Requires prior authorization.

c. Prosthetic devices

Requires prior authorization.

Hearing aid procurement depends on a physician's prescription and a report of hearing loss, if a hearing aid is recommended.

d. Eyeglasses

No spare eyeglasses or replacements due to personal preference. No trimmed frames. Certain other items require prior authorization.

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STATE OF OHIO DEPARTMENT OF JOB AND FAMILY SERVICES SUPPLEMENTAL DRUG-
REBATE AGREEMENT
CONTRACT # _____

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1 PARTIES/PERIOD

1.1 This Supplemental Drug-Rebate Agreement ("Agreement") is made and entered into this _____ day of _____ 2003, by and between the State of Ohio ("State"), represented by the Department of Job and Family Services ("Department"), and _____ ("Manufacturer"), Labeler Code _____. The parties, in consideration of the covenants, conditions, agreements, and stipulations expressed in this Agreement, do agree as follows:

2 PURPOSE

2.1 It is the intent of this Agreement that the Department will receive a State Supplemental Rebate, 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 Covered Outpatient Drug(s) quarterly utilization in the Ohio Medicaid Program in which there is Medicaid federal financial participation. 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).

3 DEFINITIONS

3.1 'Average Manufacturer Price' (AMP) means Manufacturer's price for the Covered Outpatient Drug(s). AMP will be calculated as specified in Manufacturer's CMS Agreement.

3.2 'Best Price' means, 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)(5)(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.

- 3.3 'Covered Outpatient Drug(s)' means the pharmaceutical product(s) [REGISTERED TRADEMARK NAME*™™ (CHEMICAL ENTITY), DOSAGE FORM, STRENGTH] of the Manufacturer pursuant to Section 1927 of the Social Security Act (42 U.S.C. §1396r-8).
- 3.4 '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).
- 3.5 'CMS Basic Rebate' means, with respect to the Covered Outpatient Drug(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)].
- 3.6 'CMS CPI Rebate' means, with respect to the Covered Outpatient Drug(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)].
- 3.7 '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.
- 3.8 'Drug Reimbursement Amount' means the most recent per unit allowable as calculated by the Department in accordance with OAC 5101:3-9 for the quarter being invoiced.
- 3.9 'Manufacturer' means, for purposes of this Agreement, the non-state party to this Agreement, which may be a pharmaceutical manufacturer, labeler or other entity not prohibited by law from entering into this Agreement.
- 3.10 'Departmental Net Cost' is the amount the Department will pay, pursuant to this agreement, per unit of Covered Outpatient Drug.

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- 3.11 'Pharmacy Provider' means an entity licensed or permitted by state law to dispense legend drugs, and enrolled as a State Medicaid Provider.
- 3.12 'CMS Rebate' means, with respect to the Covered Outpatient Drug(s), the quarterly payment by Manufacturer pursuant to Sections 3.5 and 3.6 of this Agreement.
- 3.13 'State Utilization Data' means the data used by the Department to reimburse pharmacy providers under the Ohio Medicaid Program. State Utilization Data excludes data from covered entities identified in Title 42 U.S.C. §256b(a)(4) in accordance with Title 42 U.S.C. §256b(a)(5)(A) and 1396r-8(a)(5)(C).
- 3.14 'Supplemental Covered Outpatient Drug' means the pharmaceutical product(s) [REGISTERED TRADEMARK NAME® or ™ (CHEMICAL ENTITY), DOSAGE FORM, STRENGTH] of the Manufacturer, as detailed in the attached Addendum/Addenda, that have been negotiated through this Agreement.
- 3.15 'Supplemental Rebate Amount' means, with respect to the Supplemental Covered Outpatient Drug(s), the amount(s) specified in the attached Addendum/Addenda that the Manufacturer has agreed to reimburse the Department per unit of drug in accordance with the formula detailed in the attached Addendum/Addenda.
- 3.16 'Rebate Summary' means the report itemizing the State Utilization Data supporting the Department's invoice for Rebates. The Rebate Summary will comply in all respects with requirements for Medicaid Utilization Information in the CMS Agreement.
- 3.17 'State Supplemental Rebate' means, with respect to the Supplemental Covered Outpatient Drug(s), the quarterly payment by Manufacturer pursuant to Section 4.2 of this Agreement.

4 MANUFACTURER'S RESPONSIBILITIES

4.1 Manufacturer will calculate and provide the Department a CMS Rebate for the Covered Outpatient Drug(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 Outpatient Drug(s) reimbursed by the Department in the preceding quarter by the per unit rebate amount provided to the Department 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

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duration of the Manufacturer's CMS Agreement.

- 4.2 In addition to the CMS Rebates described in Sections 3.5 and 3.6 of this Agreement, Manufacturer will remit to the Department a State Supplemental Rebate for the Supplemental Covered Outpatient Drug(s). The State Supplemental Rebate will be calculated on a calendar quarter basis and provided via an invoice to the Manufacturer's CMS financial contact. The State Supplemental Rebate for the quarter will be determined by multiplying the number of units of the Supplemental Covered Outpatient Drug(s) reimbursed by the Department in the preceding quarter by its Supplemental Rebate Amount, as specified in each Supplemental Covered Outpatient Drug's Addendum. The Manufacturer's obligation for State Supplemental Rebates will continue for the duration of this Agreement.
- 4.3 The Manufacturer's obligation for State Supplemental Rebates will begin with the Rebate Billing Period for the second calendar quarter 2003, which begins April 1, 2003 and will continue through the quarter that ends March 31, 2004.
- 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 Manufacturer agrees to submit the State Supplemental Rebate payment within 30 days of the Manufacturer's receipt of the Rebate Summary from the Department. In the event the Manufacturer requests dispute resolution pursuant to Section 6 of this agreement, the amounts due will be due in the time frames set forth in Section 6. Failure to submit the State Supplemental Rebate payment within the required time frames as specified in this agreement will result in the amount payable being certified to the Ohio Attorney General for collection pursuant to Section 131.02 of the Ohio Revised Code.
- 4.6 Manufacturer agrees to continue to pay State Supplemental Rebates on the Supplemental Covered Outpatient Drug(s), regardless of whether prior authorization is required, for as long as this Agreement is in force, and State Utilization Data shows that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug.
- 4.7 Unless notified otherwise, Manufacturer will send Rebate payments by certified mail, return receipt requested, to the following address:

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*****INSERT PAYMENT ADDRESS*****

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5 DEPARTMENT RESPONSIBILITIES

- 5.1 The Department will classify the Manufacturer's Supplemental Covered Outpatient Drug(s) as "preferred" in the Ohio's Preferred Drug List, however the Department may determine, as a result of a therapeutic class review, that prior authorization is required for all preferred drugs in a therapeutic class. If prior authorization is required for any Supplemental Covered Outpatient Drug, the Department will comply with all provisions of section 1927(d) of the Social Security Act applicable to Prior Authorization programs.
- 5.2 The Department 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 the Ohio Medicaid Program, will be consistent with any applicable Federal or State guidelines, regulations and standards for such data, and will be the basis for the Department's calculation of the State Supplemental Rebate.
- 5.3 The Department will maintain those data systems used to calculate the State Supplemental Rebates. In the event material discrepancies are discovered, the Department 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 the Manufacturer as the parties may agree.
- 5.4 The Department 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 Department.
- 5.6 Upon implementation of this Agreement, and from time to time thereafter, the Department and Manufacturer will meet to discuss any data or data system improvements which are necessary or desirable to ensure that the data and any information provided by the Department to Manufacturer are adequate for the purposes of this Agreement.

6 DISPUTE RESOLUTION

- 6.1 In the event that in any quarter a discrepancy in State Utilization Data is noted by the Manufacturer, which the Manufacturer and the Department in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy to the Department.

6.2 If the Manufacturer in good faith believes the State Utilization Data is erroneous, the Manufacturer shall pay the Department that portion of the rebate claimed, that is not in dispute by the required date in Section 4.5.

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

6.4 If the Department and Manufacturer are able to resolve the dispute as provided for above, the Manufacturer shall pay the balance due by the due date of the next quarterly payment. In the event that the Department 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 Department will notify the Manufacturer that they may request a reconsideration of the Department's determination, provided they request it within 30 days of receipt of that notice. The Manufacturer shall submit with its written request its argument in writing, along with any other materials, supporting its position. The Deputy Director for the Office of Medicaid shall review the written argument and materials and issue a decision in the matter. Payment, if applicable, will be due within 30 days of this decision.

7. CONFIDENTIALITY PROVISIONS

7.1 Pursuant to 42 U.S.C. 1396r-8(b)(3)(D), 1 V.S.A. 317 (c) and other relevant federal and state laws, 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 the State Utilization Data confidential. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. The Manufacturer shall have the right to disclose State Utilization Data to auditors who must agree to keep such information confidential.

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

8. NON-RENEWAL or TERMINATION

8.1 This Agreement shall be effective upon execution and shall have the term indicated in Section 4.3, 01/07/03 Drug Rebate Agreement

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supra.

8.2 This Agreement may be terminated by either party by giving written notice to the other party at least ninety (90) days prior to the effective date of the termination. Termination shall become effective the first day of the first calendar quarter beginning at least ninety (90) days after a party gives written notice requesting termination. Termination of this Agreement may result in Manufacturer's Supplemental Covered Outpatient Drug(s) being available to Ohio's Medicaid Program beneficiaries only through prior authorization.

8.3 Notwithstanding any renewal or termination of this Agreement, State Supplemental Rebates will still be due and payable from the Manufacturer under Section 4.2 for any Covered Outpatient Drugs for which the Department's obligation to reimburse arose prior to the effective date of termination of this Agreement.

9 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 to the Department will be sent to:

INSERT STATE AGENCY INFORMATION

9.3 Notice to Manufacturer will be sent to:

_____ (Name)

_____ (Title)

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(Company Name)
(Address)

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- 9.4 The Manufacturer agrees to be bound by the laws of the State of Ohio and agrees that this Agreement shall be construed and interpreted in accordance with Ohio law.
- 9.5 Nothing herein shall be construed or interpreted as limiting or otherwise affecting the Department'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.
- 9.6 Manufacturer and the agents and employees of Manufacturer in the performance of this Agreement, will act in an independent capacity and not as officers, employees or agents of the State of Ohio.
- 9.7 This Agreement is not assignable either in whole or in part without the written consent of the Department. 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 the Department with an update of the information contained in Section 9.3, *supra*.
- 9.8 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. The parties agree to negotiate replacement provisions, to afford the parties as much of the benefit of their original intent as is possible.
- 9.9 The Department and Manufacturer declare that this Agreement, including attachments and addenda/addendum, contains a total integration of all rights and obligations of both 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 both 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.

9.10 This Agreement will not be altered except by an amendment in writing signed by both parties. No

individual is authorized to alter or vary the terms or make any representation or inducement relative to it, unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Department and Manufacturer.

9.11 Neither party contemplates any circumstances under which indemnification of the other party would arise. Nevertheless, should such circumstances arise, Manufacturer agrees to indemnify, defend and hold harmless the State of Ohio, its officers, agents and employees from any and all claims and losses accruing or resulting to any person, firm or corporation who may be injured or damaged by the Manufacturer in the performance of this Agreement.

9.12 Inasmuch as the State Supplemental Rebate required by this Agreement is for Ohio Medicaid Program beneficiaries, it is agreed that the State Supplemental Rebate does not establish a new 'Best Price' for purposes of participating Manufacturer's CMS Agreement.

9.13 In the event that the Department requires prior authorization of preferred drugs consistent with section 5.1, this Agreement remains in force. If, however, a Covered Outpatient Drug(s) of the Manufacturer should require prior authorization and not the whole class, the parties agree that the terms of Section 8.2 shall apply.

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

STATE OF OHIO, DEPARTMENT OF JOB AND FAMILY SERVICES:

By: _____ Date: _____

Name: _____

Title: _____

MANUFACTURER

By: _____ Date: _____

Name: _____

Title: _____

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ADDENDUM A

This Addendum A dated the _____ day of _____, 2003, to Supplemental Drug-Rebate Agreement Contract # _____ dated the _____ day of January, 2003 (the "Agreement") between State of Ohio ("State"), represented by the Department of Job and Family Services ("Department"), and _____ (Manufacturer), Labeler Code _____ provides as follows:

The Supplemental Rebate Amount per unit of Name of Drug, Strength, NDC# is calculated according to the following formula:

Supplemental Rebate Amount = Drug Reimbursement Amount - (CMS Unit Rebate Amount + Departmental Net Cost)

Where the number of units reimbursed refers to the number of units of _____ reimbursed to pharmacy providers during the applicable quarter; and

Where the CMS Unit Rebate Amount is as determined by CMS for the applicable quarter; and

Where the Departmental Net Cost equals the per unit cost negotiated and Agreed to by Department and Manufacturer.

Department and Manufacturer agree that the Departmental Net Cost per unit of (Name of Drug, Strength, NDC) during the term of the Agreement shall be \$ _____.

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

STATE OF OHIO, DEPARTMENT OF JOB AND FAMILY SERVICES:

By: _____ Date: _____

Name: _____

Title: _____

Department of Job and Family Services

MANUFACTURER

By: _____ Date: _____

Name: _____

Title: _____

Company: _____

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