

Tony Evers
Governor



DIVISION OF MEDICAID SERVICES
DIVISION OF PUBLIC HEALTH

DRUG REBATE PROGRAM
313 BLETTNER BLVD
MADISON WI 53784

Karen E. Timberlake
Secretary

State of Wisconsin
Department of Health Services

Telephone: 800-947-9627
Fax: 608-221-4567
TTY: 711

Dear Manufacturer:

The Wisconsin Chronic Disease Program (WCDP) is a state-funded program that offers assistance to low-income Wisconsin residents who have chronic renal disease, hemophilia, or adult cystic fibrosis. WCDP pays health care providers for disease-related services and supplies provided to WCDP-enrolled participants after all other sources of payment have been exhausted.

The program has a drug formulary for each of the following programs: Chronic Renal Disease, Hemophilia Home Care, and the Adult Cystic Fibrosis. Participation in these program formularies requires that your product is accepted by the program and there is a signed WCDP Drug Rebate Agreement on file.

Each formulary contains products that are directly related to each program. The ForwardHealth Drug Search tool may be used to identify specific information about a drug covered by the WCDP and is available on the ForwardHealth Portal at <https://www.forwardhealth.wi.gov/WIPortal/Subsystem/Provider/DrugSearch.aspx>.

Wis. Stat. § 49.687(3)(a) requires the Wisconsin Department of Health Services (DHS) to have a drug rebate program for WCDP, modeled after the national Medicaid Drug Rebate Program.

Some drug manufacturers have expressed concern that participating in WCDP's Drug Rebate Program could compromise their "best price" under the Centers for Medicare and Medicaid Services (CMS) Medicaid Drug Rebate Program. DHS has received confirmation from CMS that WCDP qualifies as a State Pharmacy Assistance Program (SPAP). Therefore, the WCDP Drug Rebate Program is eligible for the same rebates as the national Medicaid Drug Rebate Program, and any rebates paid to WCDP can be excluded from your Average Manufacturer Pricing (AMP) and Best Price (BP) calculations.

Before you choose to participate, please read the rebate agreement in its entirety. This is a standard rebate agreement being offered to all manufacturers who are currently participating in the national Medicaid Drug Rebate Program. You may not alter, modify, or otherwise change the agreement.

In order for the product(s) that you manufacture to be covered by WCDP, you must sign and submit the Wisconsin Chronic Disease Drug Rebate Agreement, F-13185. In addition, you must complete and submit the WCDP Drug Rebate Labeler Attachment, F-13187. Please indicate all labeler codes that are to be covered by your WCDP Rebate Agreement on this Attachment and indicate the National Drug Code(s) (NDC) for WCDP disease-related drugs and drug products manufactured by labeler codes being included under your WCDP Rebate Agreement that you wish to request consideration of WCDP coverage for.

You will receive notification regarding the approval or denial of a submitted WCDP Rebate Agreement in approximately 10 business days through your Manufacturer Drug Rebate ForwardHealth Portal account. If your WCDP Rebate Agreement is approved, the WCDP Program shall review the submitted NDC(s) and determine coverage and formulary inclusion for program selected disease-related drugs and drug products manufactured by the Manufacturer that has entered into a WCDP Rebate Agreement.

Failure to participate in WCDP's Drug Rebate Program will result in the exclusion of your drugs from the formulary and make your products unavailable to WCDP members.

If you have any questions, click the Contact a Drug Rebate Analyst link on the Drug Rebate Manufacturer home page of the ForwardHealth Portal.

Sincerely,

<SIGNATURE>
Medicaid Director

Enclosure

F-13186A (09/2017)

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WISCONSIN CHRONIC DISEASE PROGRAM DRUG REBATE AGREEMENT

Wisconsin Chronic Disease Program Rebate Agreement Between Wisconsin Department of Health Services and The Manufacturer

This rebate agreement (Agreement) is made and entered into by and between the Manufacturer identified in this Agreement and the State of Wisconsin, Department of Health Services (DHS) for its Wisconsin Chronic Disease Program (Program). DHS and the Manufacturer may be referred to collectively herein as the "Parties."

BACKGROUND

The Program is a state-funded program that offers assistance to Wisconsin residents with chronic renal disease, adult cystic fibrosis, and hemophilia, which is described in Wis. Stat. §§ 49.68, 49.683, and 49.685, funded solely by Wisconsin State General Purpose Revenue. In addition to state laws, the Program is also governed by a set of regulations known as the Wisconsin Administrative Code, Health Services; chapters DHS 152-154. The Program pays health care providers for disease-related services, drugs, and supplies provided to eligible program members after all other sources of payment have been exhausted.

The Program qualifies as a State Pharmaceutical Assistance Program (SPAP) according to the federal Centers for Medicare and Medicaid Services (CMS) and any rebates paid under the Program can be excluded from the Best Price and Average Manufacturers Price calculations.

Under the terms of this Agreement, the Manufacturer agrees to provide the Program with rebate payments associated with the prescription drugs dispensed to participants for whom the Program has made a payment and the Program agrees to use the rebated funds to assist the Program.

In order for the manufacturer to enter into a rebate agreement for Wisconsin's Chronic Disease Program, the Manufacturer must also have entered into a rebate agreement with the national Medicaid Drug Rebate Program.

Under the terms of this Agreement, the Program will utilize the identical drug rebate terms, definitions, dispute resolution, and reporting guidelines used by the national Medicaid Drug Rebate Program unless otherwise specified.

1. The Manufacturer's Responsibilities

- 1.1 Following receipt of separately identified Wisconsin Chronic Disease Rebate Program quarterly invoices indicating pharmacy reimbursement utilization data by National Drug Code (NDC) during the prior quarter, the Manufacturer will make a rebate payment within the same timeframes as the national Medicaid Drug Rebate Program. The Manufacturer shall identify and remit separate rebate payments directly to DHS to the address indicated on the State of Wisconsin's Chronic Disease Program Drug Rebate invoices or via the secure Drug Rebate Manufacturer area of the ForwardHealth Portal developed and maintained by the Program under section 2.4 of this Agreement.
- 1.2 The Manufacturer agrees to allow DHS to access and use information included on the CMS quarterly Medicaid Rebate Program file that is necessary for the creation of invoices for the Program. Any information about the Manufacturer that the Program obtains from the CMS file will be treated as confidential and will not be used or disclosed by the Program except in connection with this Agreement.
- 1.3 The rebate per unit (RPU) used by the Program to determine the rebate amount due shall be identical to the RPU included in DHS's quarterly national Medicaid Drug Rebate Program file received from CMS during that same quarterly period. If the actual RPU is different from the one invoiced by the Program, the Manufacturer must change the RPU and report the correct RPU to DHS.
- 1.4 The Manufacturer understands that payment of rebates as required under section 1.1 of this Agreement is a condition of coverage of the Manufacturer's drugs under the Program.
- 1.5 For each quarterly rebate payment, the Manufacturer is required to separately document the Program rebates from the national Medicaid Drug Rebate Program rebates using the Medicaid Drug Rebate Program-mandated Reconciliation of State Invoice form, CMS-304. For explanation of any adjusted rebate payments to the Program, the Prior Quarter Adjustment Statement form, CMS-304a, must be used.
- 1.6 Payment of Rebates: Subject to the Manufacturer's right to offset any requested Rebate and the Manufacturer's right to dispute product utilization amounts pursuant to section 1.5 of the Agreement, payment of any Rebate shall become due 30 days after receipt by the Manufacturer of the DHS invoice from the Program. Interest on unpaid rebates begins accruing 38 days after whichever date comes first: the postmark date of a DHS paper invoice, the date of an emailed invoice, or the date of an emailed notification that an invoice is ready to be downloaded. The Manufacturer is required to continue to make a rebate payment

on all the covered drugs for which claims have been paid while the Agreement is in force.

- 1.7 If the Manufacturer questions quarterly invoiced units received from the Program, the Manufacturer can only withhold payment for the disputed units and must pay rebates for all undisputed units. After receipt of the Manufacturer's dispute, the dispute resolution process is initiated between DHS and the Manufacturer and will be conducted using the same dispute resolution procedures and timelines as indicated in the Best Practices Guide for Dispute Resolution under the national Medicaid Drug Rebate Program.

2 Program Responsibilities

- 2.1 The Program shall provide coverage for Program-selected disease-related drugs and drug products manufactured by the Manufacturer that has entered into this Agreement.
- 2.2 The Program shall furnish separate quarterly invoices to the Manufacturer within the same timeframes as required under the national Medicaid Drug Rebate Program and in the same format as specified under the national Medicaid Drug Rebate Program using the Medicaid Drug Rebate Invoice form, CMS-R-144. The Program will create invoices for labelers identified by the manufacturer's labeler codes indicated in the Wisconsin Chronic Disease Program Drug Rebate Labeler Attachment included with this Agreement. Invoices will be submitted using the labeler invoice contact name and address included in DHS's quarterly national Medicaid Drug Rebate Program file received from CMS or via the secure Drug Rebate Manufacturer area of the Portal developed and maintained by the Program under section 2.4 of this Agreement.
- 2.3 The Program shall keep and maintain records to ensure the accuracy of the dispenser level data and the information contained in each invoice submitted to the Manufacturer. Upon request, the Manufacturer will be allowed to review this information as it relates to the Program. However, under no circumstances will the Program be required to disclose information contrary to applicable law or in violation of patient confidentiality.
- 2.4 The Program may make available a secure Drug Rebate Manufacturer area of the ForwardHealth Portal to DHS-approved manufacturers to enhance electronic rebate collections, operations, and invoicing processes that may be used by the Manufacturer and the Program for all drug rebate invoicing activities and other information and notices transmitted between the Parties under the terms of this Agreement.

3 Agreement Duration – Nonrenewal and Termination

- 3.1 This Agreement shall become effective upon the date both Parties have signed the Agreement. Rebates will begin to accrue on eligible utilization beginning on the effective date of this Agreement, even if copies of signed Agreements are not received until after that date. The Agreement shall continue to be in effect until otherwise terminated by either Party or the Manufacturer is terminated by CMS from the national Medicaid Drug Rebate Program.
- 3.2 This Agreement shall be effective for an initial period of one year and will automatically be renewed for additional successive terms of one year unless the Manufacturer or DHS gives written notice of intent not to renew this Agreement at least 90 days before the end of the current period.
- 3.3 Upon written notice, either Party may terminate this Agreement for any reason. The effective date of termination will be effective the first day of the first calendar quarter, beginning 60 days after notice requesting termination, or the ending date of the term of the Agreement if the 90-day notice has been given, whichever date is later.

A written notice for termination of this Agreement must be sent in writing or transmitted via the secure Drug Rebate Manufacturer area of the Portal developed and maintained by the Program under section 2.4 of this Agreement. Written notice shall be mailed to the following address:

Wisconsin Chronic Disease Program Drug Rebate Unit
313 Blettner Blvd
Madison WI 53784

- 3.4 In the event of a violation of the terms and provisions of this Agreement by either Party, written notice to the other Party alleging the violation shall be given. If the violation is not resolved within 30 days following the receipt of the notice, the nonviolating Party may terminate this Agreement immediately upon written notice; however, any nonrenewal or termination will not affect rebates due on drugs that were dispensed prior to the effective date of termination.

Any written notice required to be given by the Manufacturer regarding violation of terms and provisions of this Agreement must be sent in writing to the following address:

Wisconsin Chronic Disease Program Drug Rebate Unit
313 Blettner Blvd
Madison WI 53784

4. Miscellaneous

4.1 This Agreement is intended to comply fully with all applicable State of Wisconsin laws and regulations. In the event that this Agreement or any transactions included in this Agreement are determined by either Party not to be in compliance, the Manufacturer and DHS shall negotiate in good faith to modify the terms and provisions of this Agreement to remedy any prior and future noncompliance. This Agreement will not be altered, except by an amendment in writing signed by both Parties. No person is authorized to alter or vary the terms unless the alteration appears by a written amendment that is signed by duly appointed representatives of DHS and the Manufacturer.

If compliance cannot be achieved, either Party may elect to terminate this Agreement and neither Party shall have any further rights or obligations thereafter. However, if possible, the Manufacturer and DHS shall take all possible action to remedy any noncompliance.

4.2 To enter into this Agreement and to perform its obligations, each Party represents and warrants that it has full power and authority to enter into this Agreement and to perform all of its obligations. The execution, delivery, and performance of this Agreement have been duly and validly authorized and approved by all necessary action, and the Agreement is a binding obligation, enforceable by each Party against the other. The execution, delivery, and performance of this document by the Parties does not violate, contravene, or conflict with any law or regulation of the State of Wisconsin or any agreement to which DHS may be a Party.

4.3 The Program has not and will not permit the resale of drugs for which rebates are sought to other providers or for use by persons who are not Program beneficiaries.

4.4 This Agreement constitutes the entire understanding between the Parties with respect to the transactions contemplated and supersedes all prior written or oral agreements, commitments, or understandings with respect to the matters provided for herein.

4.5 This Agreement, the rights and obligations of the Parties hereto, and any claims or disputes relating thereto shall be governed by and construed in accordance with the laws of the State of Wisconsin (but not including the choice of law rules thereof). The location of any petition brought under this Agreement will be Dane County, Wisconsin.

4.6 The Agreement to conduct transactions by electronic means. The Parties to this Agreement agree that this Agreement and all transactions under this Agreement are subject to the Uniform Electronic Transactions Act, Wis. Stat. ch. 137, subch. II, and agree that any transactions under this Agreement conducted by electronic means will be conducted within the meaning of Wis. Stat. § 137.13. Without

limitation by way of enumeration, this Agreement to allow transactions conducted by electronic means includes that:

- i. An electronic signature satisfies any requirement that a signature be affixed to this Agreement or any other document under this Agreement, within the meaning of Wis. Stat. § 137.15(4);
 - ii. Any requirement that a Party send, or deliver information in writing to another Party, is satisfied if the information is provided, sent, or delivered, in an electronic record capable of retention by the recipient at the time of receipt, within the meaning of Wis. Stat. § 137.16(1);
 - iii. Any electronic signature purporting to be by any representative of either Party was created by the act of that person and is attributable to that person, within the meaning of Wis. Stat. § 137.17;
 - iv. Any requirement that a record be retained is satisfied by retaining the information set forth in the record as an electronic record that accurately reflects the information set forth in the record after it was first generated in its final form, and remains accessible for later reference, within the meaning of Wis. Stat. § 137.20;
 - v. An electronic record is sent when it is addressed properly or otherwise directed properly to the secure Drug Rebate Manufacturer area of the Portal developed and maintained by the Program under section 2.4 of this Agreement and is in a form capable of being processed by that system, within the meaning of Wis. Stat. § 137.23.
- 4.7 This Agreement is subject to any changes in the Medicaid statutes or regulations that affect the rebate program.
- 4.8 The headings of the sections in this Agreement are inserted for convenience of reference only and are not intended to be a part of or affect the meaning or interpretation.

SIGNATURES

For the Administrator of the Department of Health Services
Wisconsin Chronic Disease Rebate Program
State of Wisconsin

SIGNATURE – Administrator
Division of Medicaid Services
Department of Health Services

Date Signed

ACCEPTED FOR THE MANUFACTURER – LABELER CODE

I certify that I have made no alterations, amendments, or other changes to this Rebate Agreement.

SIGNATURE

Date

Name (Print)

Title

Please indicate all labeler codes that are to be covered by this Agreement on the Wisconsin Chronic Disease Program Drug Rebate Labeler Attachment, F-13187. Manufacturers with access to the secure Drug Rebate Manufacturer area of the Portal developed and maintained by the Program under section 2.4 of this Agreement should submit the electronically signed rebate Agreement and completed attachment via the Portal. Non-Portal users may return the signed rebate Agreement and completed attachment by certified or registered mail to the address indicated on the attachment.

F-13185 (09/2017)

**WISCONSIN CHRONIC DISEASE PROGRAM
DRUG REBATE LABELER ATTACHMENT**

Instructions: Indicate the requested information below.

This form must be completed and submitted with the Wisconsin Chronic Disease Program (WCDP) Rebate Agreement, F-13185. Indicate all labeler codes that are to be covered by the WCDP Rebate Agreement on this form.

In addition, indicate the National Drug Code(s) (NDC) for WCDP disease-related drugs and drug products manufactured by labeler codes being included under your WCDP Rebate Agreement that you wish to request consideration of WCDP coverage for. WCDP shall review the submitted NDC(s) and consider coverage for program selected disease-related drugs and drug products.

Manufacturers with access to the secure Drug Rebate Manufacturer area of the ForwardHealth Portal developed and maintained by the Wisconsin Medicaid Drug Rebate Program under section 2.4 of the WCDP Rebate Agreement should complete and submit the signed rebate agreement and this completed attachment via the Portal.

Manufacturers that do not have access to the secure Portal may return the signed WCDP Rebate Agreement and this completed attachment by certified or registered mail to the following address:

Wisconsin Department of Health Services
Drug Rebate Unit
313 Blettner Blvd
Madison WI 53784

Name – Manufacturer

Address (Street, City, State, ZIP Code)

Attention To

Name – Invoice Contact Person	Telephone Number
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Fax Number	Email Address
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Labeler Codes Covered Under this Rebate Agreement

Labeler Code	Labeler Code	Labeler Code
Labeler Code	Labeler Code	Labeler Code
Labeler Code	Labeler Code	Labeler Code
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Labeler Code	Labeler Code	Labeler Code
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Labeler Code	Labeler Code	Labeler Code

Continued

Indicate the NDC(s) that you are requesting for inclusion in the WCDP formulary below.

Note: Inclusion of NDCs on this form does not guarantee WCDP coverage. WCDP shall determine the specific NDCs that the program will include in the WCDP formulary.

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SAMPLE