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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**[CMS-2397-PN]**

**RIN-0938-ZB29**

### **Medicaid Program; Announcement of Medicaid Drug Rebate Program National Rebate Agreement**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Proposed notice.

**SUMMARY:** This proposed notice with comment period announces changes that would be made to the Medicaid National Drug Rebate Agreement (NDRA) for use by the Secretary of the Department of Health and Human Services (HHS) and manufacturers under the Medicaid Drug Rebate Program (MDRP). We are updating the NDRA to incorporate legislative and regulatory changes that have occurred since the agreement was published in the February 21, 1991 **Federal Register** (56 FR 7049). We are also updating the NDRA to make editorial and structural revisions, such as references to the updated Office of Management and Budget (OMB)-approved data collection forms and electronic data reporting.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [Insert date **90** days after date of publication in the **Federal Register**].

**ADDRESSES:** In commenting, refer to file code CMS-2397-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways

listed):

1. Electronically. You may submit electronic comments on this regulation to **<http://www.regulations.gov>**. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:  
Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-2397-PN,  
P.O. Box 8016,  
Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:  
Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-2397-PN,  
Mail Stop C4-26-05,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses:
  - a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Room 445-G, Hubert H. Humphrey Building,  
200 Independence Avenue, SW,  
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

**FOR FURTHER INFORMATION CONTACT:** Terry Simananda, (410) 786-8144.

**SUPPLEMENTARY INFORMATION:** Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received:

<http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

## **I. Background**

Under the Medicaid Program, states may provide coverage of outpatient drugs furnished to eligible individuals as an optional benefit under section 1905(a)(12) of the Social Security Act (the Act). Section 1903(a) of the Act provides for federal financial participation (FFP) in state expenditures for these drugs. In general, for payment to be made available under section 1903 of the Act for most drugs, manufacturers must enter into, and have in effect, a Medicaid National Drug Rebate Agreement (NDRA) with the Secretary of the Department of Health and Human Services (HHS) as set forth in section 1927(a) of the Act.

Authorized under section 1927 of the Act, the Medicaid Drug Rebate Program (MDRP) is a program that includes CMS, State Medicaid Agencies, and participating drug manufacturers

that helps to partially offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. Currently there are more than 600 drug manufacturers who participate in the MDRP. The NDRA provides that manufacturers are responsible for notifying states of a new drug's coverage. Additionally, manufacturers are required to report all covered outpatient drugs under their labeler code to the MDRP and may not be selective in reporting their NDCs to the program. Manufacturers are then responsible for paying a rebate on those drugs for which payment was made under the state plan. These rebates are paid by manufacturers on a quarterly basis to states and are shared between the states and the federal government to partially offset the overall cost of prescription drugs under the Medicaid Program.

## **II. Provisions of the Proposed Notice**

We are updating the NDRA to reflect the changes in the Covered Outpatient Drug final rule with comment period that was published in the February 1, 2016 **Federal Register** (81 FR 5170), as well as operational and other legislative changes that have occurred over the last 20 plus years since the NDRA was first issued in 1991. A sample of the finalized NDRA would be posted on the CMS Web site after we have considered the public comments and published the final notice. Once finalized, the updated NDRA would need to be signed by all participating manufacturers, as well as new manufacturers joining the program. Manufacturers with an active NDRA at the time the updated NDRA is to be executed would not be subject to verification of their proposed covered outpatient drug list. However, prospective manufacturers that request a new NDRA, or reinstatement of a previously active NDRA once the updated NDRA is available, would be subject to the current process of data submission and verification prior to the execution

of an NDRA. We intend to provide additional instructions and guidance pertaining to how to execute new and renewal signatures of the finalized NDRA.

In the Addendum to this notice with comment period, we provide a draft of the updated NDRA that we would use in the MDRP. If adopted, a drug manufacturer that seeks Medicaid coverage for its drugs would need to enter into the NDRA with the Secretary agreeing to provide the applicable rebate on those drugs for which payment was made under the state plan. We intend to use the updated NDRA as a standard agreement that will not be subject to further revisions based on negotiations with individual manufacturers.

### **III. Collection of Information Requirements**

As stated in section 4711(f) of the Omnibus Budget Reconciliation Act of 1990, Chapter 35 of title 44, United States Code, and Executive Order 12291 shall not apply to information and regulations required for purposes of carrying out this Act and implementing the amendments made by this Act. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

### **IV. Response to Comments**

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

**ADDENDUM – Draft Agreement:**

**National Drug Rebate Agreement Between the Secretary of Health and Human Services  
(Hereinafter referred to as "the Secretary") and the Manufacturer**

The Secretary, on behalf of the U.S. Department of Health and Human Services and all states which have a Medicaid State Plan approved under 42 U.S.C. 1396a, and the manufacturer, on its own behalf, for purposes of section 1927 of the Social Security Act ("the Act"), 42 U.S.C. 1396r-8, hereby agree to the following:

**I. Definitions**

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in section 1927 of the Act and implementing Federal regulations, as interpreted and applied herein:

(a) "Average Manufacturer Price (AMP)" will have the meaning set forth in section 1927(k)(1) of the Act as implemented by 42 CFR 447.504.

(b) "Base Consumer Price Index-Urban (CPI-U)" is the CPI-U for September, 1990. For drugs approved by the Food and Drug Administration (FDA) after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

(c) "Base Date AMP" will have the meaning set forth in sections 1927(c)(2)(A)(ii)(II) and 1927(c)(2)(B) of the Act.

(d) "Best Price" will have the meaning set forth in section 1927(c)(1)(C) of the Act as implemented by 42 CFR 447.505.

(e) "Bundled Sale" will have the meaning set forth in 42 CFR 447.502.

(f) "Centers for Medicare & Medicaid Services (CMS)" means the agency of the U.S.

Department of Health and Human Services having the delegated authority to operate the Medicaid Program.

(g) "Consumer Price Index-Urban (CPI-U)" will have the meaning set forth in 42 CFR 447.502.

(h) "Covered Outpatient Drug" will have the meaning set forth in sections 1927(k)(2), (k)(3) and (k)(4) of the Act as implemented by 42 CFR 447.502.

(i) "Innovator Multiple Source Drug" will have the meaning as set forth in section 1927(k)(7)(A)(ii) of the Act as implemented by 42 CFR 447.502.

(j) "Manufacturer" will have the meaning as set forth in section 1927(k)(5) of the Act as implemented by 42 CFR 447.502.

(k) "Marketed" means that a covered outpatient drug is available for sale by a manufacturer in the states.

(l) "Monthly AMP" will have the meaning as set forth in 42 CFR 447.510.

(m) "Multiple Source Drug" will have the meaning as set forth in section 1927(k)(7)(A)(i) of the Act as implemented by 42 CFR 447.502.

(n) "National Drug Code (NDC)" will have the meaning as set forth in 42 CFR 447.502.

(o) "Non-innovator Multiple Source Drug" will have the meaning as set forth in section 1927(k)(7)(A)(iii) of the Act as implemented by 42 CFR 447.502.

(p) "Quarterly AMP" will have the meaning as set forth in 42 CFR 447.504.

(q) "Rebate period" will have the meaning as set forth in 42 CFR 447.502.

(r) "Secretary" means the Secretary of the U.S. Department of Health and Human Services, or any successor thereto, or any officer or employee of the U.S. Department of Health and

Human Services or successor agency to whom the authority to implement this agreement has been delegated. In this agreement, references to CMS indicate such successor authority.

(s) "Single Source Drug" will have the meaning set forth in section 1927(k)(7)(A)(iv) of the Act as implemented by 42 CFR 447.502.

(t) "State Drug Utilization Data" means the total number of both fee-for-service (FFS) and managed care organization (MCO) units of each dosage form and strength of the manufacturer's covered outpatient drugs reimbursed during a rebate period under a Medicaid State Plan, other than units dispensed to Medicaid beneficiaries that were purchased by covered entities through the drug discount program under section 340B of the Public Health Service Act; state utilization data is supplied on the CMS-R-144 form (that is, the state rebate invoice).

(u) "States" will have the meaning as set forth in 42 CFR 447.502.

(v) "State Medicaid Agency" means the agency designated by a state under sections 1902(a)(5) to administer or supervise the administration of the Medicaid program.

(w) "Unit" means drug unit in the lowest dispensable amount. The manufacturer will specify the unit information associated with each covered outpatient drug per the instructions provided in CMS-367c.

(x) "Unit Rebate Amount (URA)" means the computed amount to which the state drug utilization data is applied by states in invoicing the manufacturer for the rebate payment due.

(y) "United States" will have the meaning as set forth in 42 CFR 447.502.

(z) "Wholesaler" will have the meaning as set forth in section 1927(k)(11) of the Act as implemented by 42 CFR 447.502.

## II. Manufacturer's Responsibilities

In order for the Secretary to authorize that a state receive payment for the manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the manufacturer agrees to the requirements as implemented by 42 CFR 447.510 and the following:

(a) The manufacturer shall identify an individual point of contact at a United States address to facilitate the necessary communications with states with respect to rebate invoice issues.

(b) Beginning with the quarter in which the National Drug Rebate Agreement (rebate agreement) is signed, calculate, and report all required pricing data on every covered outpatient drug by NDC in accordance with section 1927 of the Act and as implemented by 42 CFR 447.510. Furthermore, except as provided under section V(b) of this agreement, manufacturers are required to make a rebate payment in accordance with each calculated URA to each State Medicaid Agency for the manufacturer's covered outpatient drug(s) by NDC paid for by the state during a rebate period.

(c) In accordance with the specifications pursuant to Office of Management and Budget (OMB)-approved CMS-367c form, report all covered outpatient drugs and corresponding drug product, pricing, and related data to the Secretary, upon entering into this agreement. This information is to be updated as necessary to include new NDCs and updates to existing NDCs. CMS uses drug information listed with FDA, such as Marketing Category and Drug Type, to be able to verify in some cases that an NDC meets the definition of a covered outpatient drug, therefore, manufacturers should ensure that their NDCs are electronically listed with FDA. Reports to CMS should include all applicable NDCs identifying the drug product which may be dispensed to a beneficiary, including package NDCs (outer package NDCs and inner package

NDCs).

(d) Beginning with the effective date quarter and in accordance with the specifications pursuant to OMB-approved CMS-367a form, report quarterly pricing data to the Secretary for all covered outpatient drugs in accordance with 42 CFR 447.510. This includes reporting for any package size which may be dispensed to the beneficiary. The manufacturer agrees to provide such information within 30 days of the last day of each rebate period beginning with the effective date quarter. Adjustments to all quarterly pricing data shall be reported on at least a quarterly basis.

(e) In accordance with the OMB-approved CMS-367b form, report information including monthly AMPs and monthly AMP units for all covered outpatient drugs in accordance with 42 CFR 447.510. The manufacturer agrees to provide such information within 30 days of the end of the month of the effective date, and within 30 days of each month thereafter.

(f) Except as provided under V(b), to make rebate payments within 30 days after receiving the state rebate invoice. The manufacturer is responsible for timely payment of the rebate within 30 days so long as the state invoice contains, at a minimum, the number of units paid by NDC in accordance with 1927(b)(1) of the Act. To the extent that changes in product, pricing, or related data cause increases to previously submitted total rebate amounts, the manufacturer will be responsible for timely payment of those increases in the same 30 day time frame as the current rebate invoice.

(g) To comply with the conditions of 42 U.S.C. section 1396r-8, changes thereto, implementing regulations, agency guidance and this Agreement.

(h) In accordance with 1927(a)(1) of the Act, rebate agreements between the Secretary and

the manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall have a mandatory effective date equal to the first day of the rebate period that begins more than 60 days after the date the agreement is entered into. Rebate agreements entered into on or after November 29, 1999 will also have an effective date equal to the date the rebate agreement is entered into that will permit optional state coverage of the manufacturer's NDCs as of that date.

(i) To obtain and maintain access to the system used by the Medicaid Drug Rebate program, use that system to report required data to CMS, and ensure that their contact information is kept updated as required in the OMB-approved CMS-367d form.

(j) To continue to make a rebate payment on all of its covered outpatient drugs for as long as an agreement with the Secretary is in force and state utilization data reports that payment was made for that drug, regardless of whether the manufacturer continues to market that drug. If there are no sales by the manufacturer during a rebate period, the AMP and best price reported in the prior rebate period should be used in calculating rebates.

(k) To keep records (written or electronic) of the data and any other material from which the calculations of AMP and best price were derived in accordance with 42 CFR 447.510, and make such records available to the Secretary upon request. In the absence of specific guidance in section 1927 of the Act, federal regulations and the terms of this agreement, the manufacturer may make reasonable assumptions in its calculations of AMP and best price, consistent with the purpose of section 1927 of the Act, federal regulations and the terms of this agreement. A record (written or electronic) explaining these assumptions must also be maintained by the manufacturer in accordance with the recordkeeping requirements in 42 CFR 447.534, and such records must be

made available to the Secretary upon request.

(l) To notify CMS of any filing of bankruptcy, and to transmit such filing to CMS within seven days of the date of filing.

### **III. Secretary's Responsibilities**

(a) The Secretary will employ best efforts to ensure the State Medicaid Agency shall report to the manufacturer, within 60 days of the last day of each rebate period, the rebate invoice (CMS-R-144) or the minimum utilization information as described in section II(f) of this agreement, that is, information about Medicaid utilization of covered outpatient drugs that were paid for during the rebate period. Additionally, the Secretary will expect any changes to prior quarterly state drug utilization data to be reported at the same time.

(b) The Secretary may survey those wholesalers and manufacturers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as set forth in section 1927(b)(3)(B) of the Act and section IV of this agreement.

(c) The Secretary may audit manufacturer information reported under section 1927(b)(3)(A) of the Act.

### **IV. Penalty Provisions**

(a) The Secretary may impose a civil monetary penalty under section III(b), as set forth in 1927(b)(3)(B) of the Act and applicable regulations, on a wholesaler, manufacturer, or direct seller of a covered outpatient drug, if a wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request by the Secretary, or the Secretary's designee, for information about covered outpatient drug charges or prices or knowingly provides false information, including in any of its quarterly reports to the Secretary. The provisions of section 1128A of the

Act (other than subsection (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B) of the Act and applicable regulations.

(b) The Secretary may impose a civil monetary penalty, for each item of false information as set forth in 1927(b)(3)(C)(ii) of the Act and applicable regulations.

(c) The Secretary may impose a civil monetary penalty for failure to provide timely information on AMP, best price or base date AMP. The amount of the penalty shall be determined as set forth in 1927(b)(3)(C)(i) of the Act and applicable regulations.

(d) Nothing in this Agreement shall be construed to limit the remedies available to the United States or the states for a violation of this Agreement or any other provision of law.

## **V. DISPUTE RESOLUTION**

(a) In the event a manufacturer discovers a potential discrepancy with state drug utilization data on the rebate invoice, which the manufacturer and state in good faith are unable to resolve prior to the payment due date, the manufacturer will submit a Reconciliation of State Invoice (ROSI) form, the CMS-304, to the state. If such a discrepancy is discovered for a prior rebate period's invoice, the manufacturer will submit a Prior Quarter Adjustment Statement (PQAS) form, CMS-304a, to the state.

(b) If the manufacturer disputes in good faith any part of the state drug utilization data on the rebate invoice, the manufacturer shall pay the state for the rebate units not in dispute within the required due date in II (f). Upon resolution of the dispute, the manufacturer will either pay the balance due, if any, plus interest as set forth in section 1903(d)(5) of the Act, or be issued a credit by the state by the due date of the next quarterly payment in II(f).

(c) The state and the manufacturer will use their best efforts to resolve a dispute arising

under (a) or (b) above within 60 days of the state's receipt of the manufacturer's ROSI/PQAS. In the event that the state and manufacturer are not able to resolve the dispute within 60 days, CMS shall require the state to make available to the manufacturer the same state hearing mechanism available to providers for Medicaid payment disputes.

(d) Nothing in this section shall preclude the right of the manufacturer to audit the state drug utilization data reported (or required to be reported) by the state. The Secretary encourages the manufacturer and the state to develop mutually beneficial audit procedures.

(e) The state hearing mechanism is not binding on the Secretary for purposes of the Secretary's authority to implement the civil money penalty provisions of the statute or this agreement.

## **VI. CONFIDENTIALITY PROVISIONS**

(a) Pursuant to section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the manufacturer in connection with this agreement is confidential and, notwithstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the manufacturer, or prices charged by the manufacturer, except as authorized under section 1927(b)(3)(D).

(b) The manufacturer will hold state drug utilization data confidential. If the manufacturer audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or agreement, the manufacturer will observe confidentiality statutes, regulations, and other properly promulgated policy concerning such data.

(c) Notwithstanding the nonrenewal or termination of this agreement for any reason, these

confidentiality provisions will remain in full force and effect.

## VII. NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this agreement, the agreement shall be effective beginning on the date specified in section II(h) of this agreement and shall be automatically renewed for additional successive terms of one year unless the manufacturer gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.

(b) In accordance with section VII (a) of this agreement, the manufacturer may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first rebate period beginning 60 days after the manufacturer gives written notice requesting termination, or CMS initiates termination via written notice to the manufacturer.

The Secretary may terminate the agreement for failure of a manufacturer to make rebate payments to the state(s), failure to report required data, for other violations of this agreement, or other good cause upon 60 days prior written notice to the manufacturer of the existence of such violation or other good cause. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(c) Manufacturers on the Office of Inspector General's (OIG's) List of Excluded Individuals/Entities (Exclusion List) will be subject to immediate termination from the Medicaid drug rebate program unless and until the manufacturer is reinstated by the OIG. Appeals of exclusion and any reinstatement will be handled in accordance with section 1128 of the Act and applicable regulations. Manufacturers that are on the OIG Exclusion List and are reinstated by

the OIG under certain circumstances may be evaluated for reinstatement to the Medicaid drug rebate program by CMS. Reinstatement to the Medicaid drug rebate program would be for the next rebate period that begins more than 60 days from the date of the OIG's reinstatement of the manufacturer after exclusion.

(d) If this rebate agreement is terminated, the manufacturer is prohibited from entering into another rebate agreement as set forth in section 1927(b)(4)(C) of the Act for at least one rebate period from the effective date of the termination, and the manufacturer addresses to the satisfaction of CMS any outstanding violations from any previous rebate agreement(s), including, but not limited to, payment of any outstanding rebates and good faith efforts to appeal or resolve matters pending with the OIG, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

### **VIII. GENERAL PROVISIONS**

(a) This agreement is subject to any changes in the Medicaid statute or regulations that affect the rebate program.

(b) Any notice required to be given pursuant to the terms and provisions of this agreement will be permitted in writing or electronically.

Notice to the Secretary will be sent to:

Centers for Medicaid and CHIP Services

Disabled & Elderly Health Programs Group

Division of Pharmacy

Mail Stop S2-14-26  
7500 Security Blvd  
Baltimore, MD 21244

The CMS address may be updated upon notice to the manufacturer.

Notice to the manufacturer will be sent to the email and/or physical mailing address as provided under section X of this agreement and updated upon manufacturer notification to CMS at the email and/or address in this agreement.

(c) In the event of a transfer in ownership of the manufacturer, this agreement and any outstanding rebate liability are automatically assigned to the new owner subject to the conditions as set forth in section 1927 of the Act.

(d) Nothing in this agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this agreement is found to be invalid by a court of law, this agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.

(e) Nothing in this agreement shall be construed as a waiver or relinquishment of any legal rights of the manufacturer or the Secretary under the Constitution, the Act, other federal laws, or state laws.

(f) The rebate agreement shall be construed in accordance with Federal law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(g) The terms "State Medicaid Agency" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the agreement unless specifically provided for in the rebate agreement or specifically agreed to by an appropriate CMS official.

(h) Except for the conditions specified in II(g) and VIII(a), 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 way of a written amendment, signed by duly appointed representatives of the Secretary and the manufacturer.

(i) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

**IX. CMS-367**

CMS-367 attached hereto is part of this agreement.

**X. SIGNATURES**

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: \_\_\_\_\_ Date: \_\_\_\_\_  
(signature)

Title: Director  
Disabled and Elderly Health Programs Group  
Center for Medicaid and CHIP Services  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments or other changes to this rebate agreement.

By: \_\_\_\_\_ (signature) \_\_\_\_\_ (please print name)

Title: \_\_\_\_\_  
Name of Manufacturer: \_\_\_\_\_  
Manufacturer Address \_\_\_\_\_  
\_\_\_\_\_

Manufacturer Labeler Code(s): \_\_\_\_\_  
Date: \_\_\_\_\_



## CMS-367a

**CMS RECORD SPECIFICATION  
 DDR QUARTERLY PRICING DATA  
 TEXT FILE FOR TRANSFER TO CMS**

Source: Drug Manufacturers

Target: CMS

<b>Field</b>	<b>Size</b>	<b>Position</b>	<b>Remarks</b>
<i>Record ID</i>	1	1 - 1	Constant of "Q"
Labeler Code	5	2 - 6	NDC #1
Product Code	4	7 - 10	NDC #2
Package Size	2	11 - 12	NDC #3
Period Covered	5	13 - 17	QYYYY (Qtr/Yr)
Average Mfr Price	12	18 - 29	99999.999999
Best Price	12	30 - 41	99999.999999
Nominal Price	9	42 - 50	<b>999999999</b>
Customary Prompt Pay Disc.	9	51 - 59	<b>999999999</b>
Initial Drug Available for LE	1	60-60	<i>Y, N, X or Z</i>
Initial Drug	9	61-69	<i>9 digits alpha-numeric</i>

CMS-367a (Exp. 03/31/2019), OMB No. 0938-0578 According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578. The time required to complete this information collection is estimated to average 34.8 hours per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have

comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

### **QUARTERLY PRICING DATA FIELDS – CMS-367a**

**Labeler Code:** First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled.

**Product Code:** Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right justified, zero-filled.

**Package Size Code:** Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right justified, zero-filled.

**Period Covered:** Calendar quarter and year covered by data submission. Numeric 5-digit field, QYYYY.

Valid values for Q:

- 1 = January 1 - March 31
- 2 = April 1 - June 30
- 3 = July 1 - September 30
- 4 = October 1 - December 31

Valid values for YYYY: 4-digit calendar year.

**Average Manufacturer's Price (AMP):** The AMP per unit per product code for the period covered. If a drug is distributed in multiple package sizes, there will be one "weighted" AMP for the product, which is the same for all package sizes. Compute to 7 decimal places, and round to 6 decimal places. Numeric values, 12-digit field: 5 whole numbers, the decimal place ('.') and 6 decimal places; right-justified, zero-filled.

**Best Price:** Per the statute and rebate agreement, the lowest price available per product code, regardless of package size. Compute to 7 decimal places and round to 6 decimal places. Zero-fill for Non-Innovator Multiple Source drugs. Numeric values, 12-digit field: 5 whole numbers, the decimal ('.') and 6 decimal places; right-justified, zero-filled.

**Nominal Price (NP):** Sales that meet the statutory/regulatory definition of NP. Total dollar figure per 11-digit NDC, rounded to nearest dollar. 9-digit field; 9 whole numbers;

right-justified, 0-filled. If no sales for a package size, fill with all zeroes.

**Customary Prompt Pay Discount (CPP):** Labelers may 1) allocate an individual CPP discount dollar amount per 11-digit NDC in each package size's record, or 2) report an aggregate discount dollar amount, by adding up all package sizes, and report this aggregate CPP discount dollar amount in one package size record and zero-fill the remaining package sizes. 9-digit field; 9 whole numbers; right-justified, 0-filled.

**Initial Drug Available for LE:** Identifies whether a line extension drug has an Initial Drug available for the quarter/year being reported.

Valid Values:

Y = Yes

N = No

X = X-Not an LE Drug

Z = Not Applicable (for quarters prior to 2Q2016, or for quarters in which the NDC or labeler was not active).

**Initial Drug:** Identifies the drug (from which a line extension drug is derived) with the highest additional rebate ratio (calculated as a percentage of AMP) for the quarter/year being reported. The Initial Drug's additional rebate ratio is then used in the alternative URA calculation for the line extension drug. The Initial Drug should fall under the same corporation as the corresponding line extension drug, and must be active within the MDR Program at the time it is reported as an Initial Drug. Numeric values only, 9-digit field, right-justified and zero-filled.

## CMS-367b

**CMS RECORD SPECIFICATION  
DDR MONTHLY PRICING DATA  
TEXT FILE FOR TRANSFER TO CMS**

Source: Drug Manufacturers  
Target: CMS

<b>Field</b>	<b>Size</b>	<b>Position</b>	<b>Remarks</b>
<i>Record ID</i>	1	1 – 1	Constant of “M”
Labeler Code	5	2 – 6	NDC #1
Product Code	4	7 – 10	NDC #2
Package Size	2	11 – 12	NDC #3
<i>Month</i>	2	13 – 14	MM
Year	4	15 – 18	YYYY
Average Mfr Price	12	19 – 30	99999.999999
AMP Units	14	31 – 44	99999999999.99
5i Threshold	1	45 - 45	Y, N, X, or Z

CMS-367b (Exp. 03/31/2019), OMB No. 0938-0578 According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578. The time required to complete this information collection is estimated to average 44.8 hours per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this

form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance  
Officer, Baltimore, Maryland 21244-1850.

**CMS-367c**

**CMS RECORD SPECIFICATION  
DDR DRUG PRODUCT DATA  
TEXT FILE FOR TRANFER TO CMS**

**Source: Drug Manufacturers**

Target: CMS

Field	Size	Position	Remarks
Record ID	1	1 – 1	Constant of “P”
Labeler Code	5	2 – 6	NDC #1
Product Code	4	7 – 10	NDC #2
Package Size Code	2	11 - 12	NDC #3
Drug Category	1	13 - 13	See Data Element Definitions
Unit Type	3	14 - 16	See Data Element Definitions
FDA Approval Date	8	17 - 24	MMDDYYYY
FDA Thera. Eq. Code	2	25 - 26	See Data Element Definitions
Market Date	8	27 - 34	MMDDYYYY
Termination Date	8	35 - 42	MMDDYYYY
Drug Type Indicator	1	43 – 43	See Data Element Definitions
OBRA '90 Baseline AMP	12	44 – 55	99999.999999
Units Per Pkg Size	11	56 – 66	9999999.999
FDA Product Name	63	67 – 129	FDA Product Name
DRA Baseline AMP	12	130 – 141	99999.999999
Package Size Intro Date	8	142 – 149	MMDDYYYY
Purchased Product Date	8	150 – 157	MMDDYYYY

5i Drug Indicator	1	158 – 158	See Data Element Definitions
5i Route of Administration	3	159 – 161	See Data Element Definitions
ACA Baseline AMP	12	162 - 173	99999.999999
COD Status	2	174 – 175	See Data Element Definitions
FDA Appl. No./OTC Mono. No.	7	176 – 182	See Data Element Definitions
Line Extension Drug Indicator	1	183 – 183	See Data Element Definitions
*Reactivation Date	*n/a	*n/a	*This field may only be submitted online via DDR. See Data Element Definitions

CMS-367c (Exp. 03/31/2019), OMB No. 0938-0578 According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578. The time required to complete this information collection is estimated to average 43.5 hours per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

### **DRUG PRODUCT DATA FIELDS – CMS-367c**

**Labeler Code:** First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled.

**Product Code:** Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right justified, zero-filled.

**Package Size Code:** Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right justified, zero-filled.

**Drug Category:** Alpha-numeric values, 1 character.

Valid values:

S = Single source

I = Innovator multiple source

N = Non-innovator multiple source

**Unit Type:** One of the 8 unit types by which the drug is dispensed. Alpha-numeric values, 3-character field, left justified.

Valid values:

AHF = Injectable Anti-Hemophilic Factor

CAP = Capsule

SUP = Suppository

GM = Gram

ML = Milliliter

TAB = Tablet

TDP = Transdermal Patch

EA = EACH

**FDA Approval Date:** NDA or monograph approval date. Numeric values, 8-digit field, format: MMDDYYYY.

**FDA TEC:** FDA-assigned Therapeutic Equivalence Codes. Alpha-numeric values, 2 character field.

Valid values:

AA BC BS

AB BD BT

AN BE BX

AO BN NR - Not rated

AP BP A1 thru A9 = AB value

AT BR

**Market Date:** For S and I drugs, the date the drug was first marketed by the original labeler (i.e., NDA holder). For N drugs, the date the drug was first marketed under the labeler's rebate agreement. If a Market Date falls on a date that is earlier than 9/30/1990, CMS will change it to 9/30/1990 in both the Medicaid Drug Rebate (MDR) system and the Drug Data Reporting for Medicaid (DDR) system since dates earlier than the start of

the Drug Rebate Program have no bearing on the program. Numeric values, 8-digit field, format: MMDDYYYY.

**Termination Date:** The date a drug is withdrawn from the market or the drug's last lot expiration date. (Note: Initial termination date submissions may be provided via file transfer; however, subsequent changes to this field may only be submitted online via DDR.) Zero or blank fill if not present. Numeric values, 8-digit field, format: MMDDYYYY.

**Drug Type Indicator:** Identifies a drug as prescription (Rx) or over-the-counter (OTC).

Valid Values:

1 = Rx

2 = OTC

**OBRA'90 Baseline AMP:** The AMP per unit for the period that establishes the OBRA'90 Baseline AMP for innovator drugs. There will be one weighted baseline AMP for the product, which will be the same for all package sizes. Compute to 7 decimal places and round to 6 decimal places. Numeric values, 12-digit field: 5 whole numbers, the decimal ('.') and 6 decimal places; right-justified, zero-filled.

**Units Per Package Size:** Total number of units in the smallest dispensable amount for the 11-digit NDC. Numeric values, 11-digit field: 7 whole numbers, the decimal ('.') and 3 decimal places; right-justified, zero-filled.

**FDA Product Name:** Drug name as it appears on FDA listing form. Alpha-numeric values, 63 characters, left justified, blank-fill unused positions.

**DRA Baseline AMP (optional):** For active innovator drugs with a Market Date less than July 1, 2007, the OBRA'90 or OBRA'93 Baseline AMP revised in accordance with relevant regulations and program guidance. There will be one weighted DRA Baseline AMP for the product, which will be the same for all package sizes. Per CMS-2238-FC, labelers had 4 quarters (i.e., January 2, 2008 – October 30, 2008) to report this optional field. Numeric values, 12-digit field; 5 whole numbers, the decimal ('.') and 6 decimal places, right-justified, zero-filled. Compute to 7 decimal places and round to 6 decimal places.

**Package Size Introduction Date:** The date the package size is first available on the market. Numeric values, 8-digit field, format: MMDDYYYY

**Purchased Product Date:** The date the company currently holding legal title to the NDC first markets the drug under this NDC (this date can result, for example, from the purchase of an NDC from one company by another company, the re-designation of an

NDC from one of a company's labeler codes to another of that same company's labeler codes, cross-licensing arrangements, etc.). Zero or blank fill if not applicable. Numeric values, 8-digit field, format: MMDDYYYY

**5i Drug Indicator:** Identifies whether a product is a 5i Drug. Alpha-numeric values; 1-digit field.

Valid Values:

Y = Yes

N = No

**5i Route of Administration:** Identifies the method by which the 5i drug is administered to a patient. If a product is not a 5i drug, a value of "000" (Not Applicable) should be entered. Numeric values; 3-digit field.

Valid Values:

000 = Not Applicable

001 = Implanted

002 = Infused

003 = Inhaled

004 = Injected

005 = Instilled

**ACA Baseline AMP (Optional):** For active innovator drugs, the OBRA'90, OBRA'93 or DRA Baseline AMP revised in accordance with the statute and relevant program guidance. There will be one weighted ACA Baseline AMP for the product, which will be the same for all package sizes. Numeric values, 12-digit field; 5 whole numbers, the decimal ('.') and 6 decimal places; right-justified; zero-filled. Compute to 7 decimal places and round to 6 decimal places.

**Covered Outpatient Drug (COD) Status:** A category that identifies whether or not a product meets the statutory definition of a covered outpatient drug in accordance with sections 1927(k)(2) to 1927(k)(4) of the Social Security Act. Numeric values, 2-character field.

Valid Values:

01 = Abbreviated New Drug Application (ANDA)

02 = Biologics License Application (BLA)

03 = New Drug Application (NDA)

04 = NDA Authorized Generic

05 = DESI 5\* – LTE/IRS drug for all indications

06 = DESI 6\* – LTE/IRS drug withdrawn from market

07 = Prescription Pre-Natal Vitamin or Fluoride

08 = Prescription Dietary Supplement/Vitamin/Mineral (Other than Prescription

Pre-Natal Vitamin or Fluoride)  
09 = OTC Monograph Tentative  
10 = OTC Monograph Final  
11 = Unapproved Drug – Drug Shortage  
12 = Unapproved Drug – Per 1927(k)(2)(A)(ii)  
13 = Unapproved Drug – Per 1927(k)(2)(A)(iii)

\*NDCs with a COD Status of DESI 5/6 are not eligible for coverage or rebates under the Medicaid Drug Rebate Program.

**FDA Application Number/OTC Monograph Number:** For drugs with a COD status of ANDA, BLA, NDA, or NDA Authorized Generic, this is the seven-digit application number that is assigned by the FDA for approval to market a generic drug or new drug in the United States. Numeric field; 7 characters, fill with leading zeros as needed.

For drugs with a COD status of OTC Monograph Tentative or Final, this is the FDA’s regulatory citation for the OTC. 7 alpha-numeric characters. For drugs with a COD Status of OTC Monograph Final, the first four characters are a constant of “PART”; the last three characters are the numeric values for the appropriate regulatory citation for the product (for example, “225”). For drugs with a COD Status of OTC Monograph Tentative, the first four characters are a constant of “PART”; the last three characters are the numeric values for the appropriate regulatory citation for the product, or 3 zeros if a Monograph Number is not available.

For drugs with a COD Status other than ANDA, BLA, NDA, NDA Authorized Generic, OTC Monograph Final, or OTC Monograph Tentative, the FDA Application No./OTC Monograph No. field should be zero-filled.

**Reactivation Date:** The date on which a terminated product is re-introduced to the market. (Note: This field may only be submitted online via DDR and is **NOT** part of the actual File Transfer Layout.)

**Line Extension Drug Indicator:** Identifies whether a product is a line extension drug as defined in Section 1927 (c)(2)(C) of the Social Security Act.

Valid Values:

Y = Yes

N = No

CMS-367d

MEDICAID DRUG REBATE AGREEMENT

ENCLOSURE B (PAGE 1 OF 2)

SUPPLEMENTAL DATA

LABELER CODE (as assigned by FDA)

LABELER NAME (Corporate name associated with labeler code)

LEGAL CONTACT – Person to contact for legal issues concerning the rebate agreement

NAME OF CONTACT

EMAIL ADDRESS: AREA PHONE NUMBER EXTENSION

NAME OF CORPORATION

STREET ADDRESS

CITY STATE ZIP CODE

INVOICE CONTACT – Person responsible for processing invoice utilization data

NAME OF CONTACT

EMAIL ADDRESS: AREA PHONE NUMBER EXTENSION

NAME OF CORPORATION

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STREET ADDRESS

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CITY

STATE

ZIP CODE

Note: This sheet is to be returned with the signed rebate agreement. If more than one labeler code, attach one sheet for each code.

CMS-367d (Exp. 03/31/2019), OMB No. 0938-0578 According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578. The time required to complete this information collection is estimated to average 1 hour per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.



collection is 0938-0578. The time required to complete this information collection is estimated to average 1 hour per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

**CMS-2397-PN**

Dated: August 11, 2016.

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**Andrew M. Slavitt,**

Acting Administrator,

Centers for Medicare & Medicaid Services.

Approved: October 18, 2016.

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**Sylvia Burwell,**

Secretary,

Department of Health and Human Services.

**BILLING CODE 4120-01-P**

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