Iowa Medicaid Drug Rebate Program Policy & Procedure Manual

Version 10.0
March 2022

Revision Log Policy & Procedure (P&P)

Revision History Policy & Procedure Manual		
Version	**Date**	**Modifications**
V 1.0	June 2005	
V 2.0	September 2008	Drug Rebate Report A-07-07-03094 – Added state hearing mechanism after other options under CMS's Best Practices have failed to resolve a rebate dispute with a drug manufacturer XI. Drug Rebate Disputes
V 3.0	June 2010	Revised XI. Drug Rebate Dispute Resolution Policy; Added XII. Nonresponsive Manufacturer; XIII. Dropped-Off NDCs from CMS NDC Tape and XV. Business Rule for Bankrupt Manufacturer
V 4.0	June 2012	Revised VI. Contractor Responsibilities related to CMS Drug Data Reporting (DDR) system
V 5.0	September 2013	Revised VI. Contractor Responsibilities related to MEF; Updated IX. Performance Standards
V 6.0	February 2014	Revised to document Medicare Crossover Claims
V 7.0	April 2015	Updated III. Drug Rebate External Interfaces, VIII. Inputs and XII. Drug Rebate Disputes. Added V. Rebate and Invoice Types and VII. Contractor Responsibilities - Physician Administered Out-patient Drug Rebates
V 8.0	April 2016	Updated V. Rebate and Invoice Types and Unique Invoicing Requirements
V 9.0	March 2018	Name change GHS to CHC
V 10.0	March 2022	Entire manual revised and reformatted; changed DDR Application (Termed 11/02/2021 for states)

Revision Log P&P Attachments

Revision History Attachments			
Att.	**Topic**	**Original Date**	**Revision Date/Modifications**
1	340 Drug Rebate Policy	June 2014	● August 2014 (Added on MEF & meet column A requirements) ● April 2016 (Add 340B contract pharmacy carve out) ● June 2021 (Updated electronic medical billing; Diabetic Supply SRA change)
2	340B Orphan Drug Rebate Policy	August 2014	
3	ESRD & Drug Rebate Policy	June 2014	
4	Manufacturer Late Notice Procedure	April 2015	● July 2021 (Name changes)
5	Payer Compliance Attestation for Drug Rebate	February 2019	● FFS - March 2019; July 2019; August 2019 ● MCO Current - AGP – June 2019; July 2019 - ITC – June 2019 Termed - AmeriHealth – June 2019; August 2019 - UHC – June 2019

Contents

1. Purpose and General Information

The purpose of the Medicaid Drug Rebate Program is to identify drugs dispensed or administered, and request any associated rebate from the manufacturer (also called "labelers") consistent with federal regulations. The Contractor must follow all CMS released rebate Guidance, State/Manufacturer Releases, Medicaid Drug Rebate Program (MDRP) Data Guide for States and Labelers as posted on the Medicaid Drug Programs (MDP) Bulletin page and the Iowa Medicaid Drug Rebate Policy and Procedure Manual.

Using the national drug code (NDC) number and the Drug Rebate Manufacturer Agreement data, the Contractor determines totals, by manufacturer, of the amount of all drugs prescribed for or administered to Iowa Medicaid members covered by the agreement.

Claims for pharmacies or other eligible entities receiving drugs under the 340B program or covered entities who "carve in" Medicaid under the 340B program as identified by the Health Resource Services Administration (HRSA) are not included in the totals based on the rules pursuant to federal requirements and as identified in *Attachments 1 and 2*. Additional policies for rebate invoicing exclusions are included on *P&P Attachment 3*.

In Iowa, Change Healthcare (CHC) is the "Contractor" who performs comprehensive drug rebate functions, as prescribed by state and federal regulations. This Contractor calculates the amount of rebate owed by each manufacturer and generates the respective invoices. As rebates are received, the Contractor updates the rebate management system.

The Contractor also resolves and tracks drug manufacturer disputes, and resulting resolution, as part of their rebate management responsibility. If the Contractor determines that there was an error with units submitted, the pharmacy or other eligible entity are contacted by the appropriate staff (MCO or FFS) and asked to reverse and resubmit the claim for the correct quantity.

The Contractor provides the Medicaid Management Information System (MMIS) with feeds of pharmacy claims three times a week, for adjudication. MMIS provides the Contractor verification of claims adjudication weekly for rebate collection. MMIS also provides a feed of paid medical claims and a feed of medical encounter claims (from Managed Care Organizations-MCOs) monthly.

Updates to the CMS 64 financial tracking are also required to report drug rebate collections. The quarterly Drug Rebate Manufacturer Agreement data from CMS is processed as part of the drug rebate function.

NOTE: This is current as of the date updated. The State/Contractor are required to follow the most current federal/state requirements.

2. Drug Rebate Objectives

Drug rebate objectives are as follows:

a) Identify drug claims eligible for rebates.
b) Invoice drug manufacturer for rebates due.
c) Collect drug rebate funds from manufacturer.
d) Provide a complete accounting of rebates due, corrected, and outstanding, and of Rebate Offset Amounts (ROA).

3. Drug Rebate External Interfaces

The Contractor component interfaces with the following external entities for the drug rebate function:

a) CMS for quarterly rebate update
b) Drug manufacturer to resolve billing problems
c) HRSA Quarterly Medicaid Exclusion File (MEF)

4. Drug Rebate Internal Interfaces

The Contractor component interfaces with the following internal entities for the drug rebate function:

a) IME MMIS

5. Rebate and Invoice Types

The Contractor invoices for federally required (OBRA) and State supplemental drug rebates (SR). There were State supplemental diabetic supply rebates (Durable Medical Equipment - DME) through Agreement end date of December 31, 2018 (Note: the State opted to cover preferred products through March 31, 2019, with Prior Quarter Adjustment Statement - PQAS through 2020Q3). The outpatient prescribed drugs for which rebate must be invoiced includes pharmacy (outpatient pharmacy) and physician (provider) administered drugs (professional and institutional claims including Medicare crossover claims). This includes drugs dispensed and administered to individuals enrolled with a Medicaid MCO.

a) Invoice Types
    1. Invoices for the regular Medicaid population are under the invoice type “FFSU”.
    2. Invoices for the Medicaid MCO population are under the invoice type “MCOU”.
    3. Invoices for the Medicaid eligible expansion population are under the invoice type “FEDERAL” commencing with the 2014Q1 invoice cycle to distinguish the Medicaid expansion eligible population invoicing. The federal population may be under FFSU or MCOU and receive separate invoices for clear identification of expansion rebate collections.

b) Invoice Designations Under “FFSU”
    Each invoice type for “FFSU” are broken into the following designations

and invoice numbers:

1. OBRA - 1000
2. SR - 2000
3. J Code - 3000
4. J Code SR - 3150
5. DME - 6000
6. Federal OBRA - 9000
7. Federal SR - 9200
8. Federal J Code - 9300
9. Federal J Code SR - 9400
10. Federal DME - 9600

c) Invoice Designations Under "MCOU"
Each invoice type for "MCOU" are broken into the following designations and invoice numbers:

1. MCO OBRA - 1500
2. MCO SR - 9800
3. MCO J Code - 3500
4. MCO J Code SR - 3550
5. MCO DME - 6500
6. Federal MCO OBRA - 9150
7. Federal MCO SR - 9250
8. Federal MCO J Code - 9350
9. Federal MCO J Code SR - 9450
10. Federal MCO DME - 9650

d) Unique Invoicing Requirements

1. 340B Claims — 340B Covered entity provider claims submitted in accordance with the Iowa Medicaid FFS & MCO billing policy are removed from rebate utilization prior to processing invoices. See *P&P Attachment 1.*
    i. Physician (Provider) Administered Drugs: Exclude claims from invoicing when the provider NPI matches the NPI listed on the HRSA MEF found on the Office of Pharmacy Affairs website and if FFSU, exclude if there is also a HCPCS modifier on the claim indicating the drug was purchased at 340B discount. Effective beginning July 1, 2014, MCOU is excluded if there is also a HCPCS modifier on the claim indicating the drug was purchased at 340B discount.
    ii. Pharmacy Drug Claims: Exclude claims from invoicing when the provider NPI matches the NPI listed on the HRSA MEF found on the Office of Pharmacy Affairs website and if FFSU, exclude if there is also a SCC=20 on the claim indicating the drug was purchased at 340B discount. Effective beginning April1, 2016, MCOU is excluded if there is also a SCC=20 on the claim indicating the drug was purchased at 340B discount.

2. Federal Supply Schedule (FSS) Drugs
    i. Drugs reimbursed to providers who purchase through the FSS are

included in Iowa Medicaid rebate invoicing [Resource State Release #113; #180]

3. End Stage Renal Disease (ESRD)
    i. See *P&P Attachment 3.*

6. State Responsibilities

DHS is responsible for developing and providing policy to the Contractor on the drug rebate program. DHS also sets performance standards for timeliness, accuracy, and funds recovery under the rebate function in accordance with state and federal requirements.

7. Contractor Responsibilities

The Contractor has the following responsibilities under the drug rebate program:

a) Follow all Medicaid Drug Rebate federal regulations, CMS released Medicaid Drug Rebate Guidance, State/Manufacturer Releases, Medicaid Drug Rebate Program (MDRP) Data Guide for States and Labelers as posted on the Medicaid Drug Programs (MDP) Bulletin page and the Iowa Medicaid Drug Rebate Policy and Procedure Manual.
b) Federally Required (OBRA) Drug Rebates
    1. Maintain a drug manufacturer data set with data necessary for processing drug rebate claims, including the capability of calculating variable Federal Medical Assistance Percentage (FMAP) and billing Interest on past due accounts.
        i. Refer to CMS Interest Calculation for Late Rebate Payments and State Program Releases posted here including #29, #48, #65, #88, #98, #114, #121, #154 and #166.
    2. Maintain the drug rebate system, including programs and data in a configuration that can be easily transferred, to a new Contractor, through a standard procurement process, or to the State.
    3. Store and capture appropriate data for management of the drug rebate program including maintaining a file of participating drug manufacturer, identifying claims subject to rebate collection, calculating the rebate amount and generating rebate invoices and reports.
    4. LOAD CMS DATA - Check the CMS MDP system beginning 35 days after the quarter ends for the Current Rebate File and Current Manufacturer Contact File, download, process and store the files. The Rebate File contains the current drug Unit Rebate Amount (URA)/ Unit Rebate Offset Amount (UROA) data and prior period adjustments (PPA) to the URA for all covered drugs of participating manufacturer.
        i. Dropped-Off NDCs - Managed through the rebate flag determination process.
            1. Automated comparison of new file to prior to capture differences (addition or removal of NDCs and NDC Termination Dates) and reasons.

2. Proposals are loaded into the Rebate/Drug Efficacy Study Implementation (DESI) application for new rebate decisions that do not match that of the current ones, includes reason for the change i.e. “NDC ON TAPE” (“TAPE” synonymous with rebate file), “DROPOFF” (NDC was on the preceding file, not on the new one), or “CMS TERM”.
3. New NDCs are collected from files sent by Medi-Span for prior weeks and made available to load into Rebate/DESI tool. First the NDC is assigned a rebatable status of “true” or “false” from an automated process.
4. Rebatable status may be as follows:
    a. Rx/OTC – False if OTC, unless on MDRP as rebatable and none of the attributes below make it false. True if Rx, unless one or more attributes below make it false.
    b. Labeler Participation in MDRP – False if the labeler does not participate regardless of reason.
    c. NDC Termination Date – False if NDCs termination date has passed or is within one week of the date of load. Termination date may not be prior to the effective date of the current rebate event. If so, delete any events that fall after the termination date.
    d. Rebate Exclusions – False if the NDCs Generic Product Identifier (GPI) matches a GPI listed on the rebate exclusion table, unless the NDC is listed on MDRP as rebatable.
5. This process above impacts the Medicaid Point-of-Sale (POS) system. It is important that this process is accurate so that the Medicaid does not pay for a drug for which the program cannot collect rebate on.

5. CALCULATE INVOICES - Calculate the drug rebate amount based on drug claims paid during the quarter.
    i. Ensure there is an established process (including MCO communication) to identify and load “Off-Cycle Claims”, identified as Pharmacy older than 9 months and Medical older than the current cycle paid date for both FFS and MCO. The MCO must notify, including the File Name,
        1. POS Contractor by email for Pharmacy claims and
        2. MMIS for Medical claims, with MMIS notifying POS Contractor
6. RUN INVOICE AUDITS - Verify the accuracy of utilization data for drugs with data edits including, but not limited to, unit types appropriate for the NDC, units match the amount paid and the amount paid is appropriate for the drug. Those drugs, identified by NDC number, for which the number of units has been rounded, are shown by a rounding indicator for the number of units dispensed.
7. GENERATE AND MAIL/SEND INVOICES - Process billings of all rebate claims subject to rebate collections and prepare and mail invoices to drug manufacturer or send an email notification that the electronic invoice(s) are available on the secure portal. Include on the invoices submitted to manufacturer all the following:

i. State Identification
ii. Rebate period and year for which the data applies
iii. The NDC number
iv. Total units paid for, by NDC, during a rebate period
v. Product name (FDA registration name)
vi. Total amount of rebate that the state claims for each NDC
vii. Total number of prescriptions paid for during the rebate period by NDC number
viii. Rebate amount per unit and the total amount paid during the rebate period by NDC number to verify rebate payment
ix. Record Type "FFSU", "or "MCOU"

Iowa DHS Form 470-4861 Invoice Notification

8. Physician (Provider) Administered Outpatient Drug Rebates
   i. Maintain data set of paid physician administered outpatient drug claims data including Medicare crossover claims with data necessary for processing drug rebate invoices.
   ii. Invoice Physician Administered outpatient drug claims paid during the quarter when there is a valid Healthcare Common Procedure Coding System (HCPCS) Code and rebate eligible NDCs combination (using a crosswalk for HCPCS Level II A, C, J and Q procedure codes and units) to the manufacturer of these drugs.
   iii. When NDCs are provided on the claim form, utilize the HCPCS, quantity billed and NDC number to bill manufacturer for rebates on these drugs, using a crosswalk for the units.
   iv. Contractor maintains a crosswalk of valid NDC/HCPCS records and NDC's that need a unit of measure conversion when HCPCS Description, CMS and Medi-Span packaging data are inconsistent. The HCPCS code crosswalk is a combination of the initial Noridian file downloaded from the Noridian website and ongoing Contractor HCPCS code conversions that are identified using the Crosswalk maintenance process.
9. Provide access to a minimum of 5 years of drug rebate data online; archive data over 5 years and allow retrieval within 24 hours of a request.
10. PAYMENT RECEIPT AND ALLOCATION - Receive and process drug rebate payments from the drug manufacturer, a process that includes the following functions:
    i. Obtain a completed CMS Form 304, Reconciliation of State Invoice (ROSI), from each manufacturer within 37 calendar days of mailing or email notification of the drug utilization information.
    ii. Follow-up by e-mail and/or phone, with each manufacturer who has not submitted payment and/or a completed ROSI form within the 37 day period. See *P&P Attachment 4* regarding communications if a manufacturer is out of compliance with rebate payment requirements.
    iii. Maintain an accounts receivable system to track all paid and unpaid invoices and adjustments. This accounts receivable system must meet all Iowa, DHS, and CMS accounting requirements.
    iv. Maintain a method to also track units paid for the purpose of

calculating rebate offset amount (ROA). The ROA is calculated by applying the Unit Rebate Offset Amount (UROA) to the total number of units for which rebate payments have been received from manufacturer. The UROA pricing file is received in conjunction withthe quarterly rebate data submission from CMS. It contains both current quarter and prior quarter prices; thus, there can be adjustments to prior quarters (PPAs).

v. CASH MANAGEMENT - All payments for Drug Rebate, including any accrued interest belong to the State. Rebate checks are logged into OnBase following deposit into Lockbox #0910195 at Wells Fargo in Minneapolis, MN where manufacturers remit rebate checks to P.O. Box 850195, Minneapolis, MN 55485-0202.

vi. FINANCIAL REPORTING (Sent to Financial Reporting Recipient Groups at State and Rebate Contractor)

1. MONTHLY –
    a. Monthly A/R and Cash Reports – Named IOWA MONTHLY REBATE REPORT: A/R BALANCE, INVOICING, AND CASH RECEIPTS for FFS, FFS Federal Expansion (900), MCO and MCO Federal Expansion (900) = 4 reports
        i. Due the 17th of each month.
        ii. Report of drug rebate funds collected listed by rebate type, A/R Balance, the total amount invoiced, PPAs/adjustments, amounts collected (including interest) and unpaid amounts of drug rebates.
2. QUARTERLY
    a. Quarterly A/R and Cash Reports – Same format as Monthly (1.a.) and included with last monthly report of the quarter.
    b. Quarterly CMS 64.9R FFS and MCO – FFS, FFS Federal Expansion (900), MCO, MCO Federal Expansion (900), Combined FFS and Combined MCO = 6 reports
        i. Due mid-month, the month following the close of the quarter.
        ii. The form CMS-64.9R was created to report the aging of pending Drug Rebate collections for Total Computable. This is authorized under Section1927(c)(1) of the Act.
    c. Medication Assisted Treatment (MAT) Drugs Report – Named IOWA MAT DRUGS REPORTING = 1 report
        i. Due the 5th business day before the end of the month, in the month following the close of the quarter.
        ii. Report of estimates (FFS and MCO – spend, OBRA & SR rebates, and ROA) for SUPPORT Act provision for Opioid Use Disorder MAT services effective for the period beginning

October 1, 2020 (Lines 46 and 46A CMS-64.9 Base).

d. Rebate Offset Amount (ROA) = 1 report
    i. Due the 5th business day before the end of the month, in the month following the close of the quarter.
    ii. Report of Increased ACA offset for FFS and MCO effective January 1, 2010 (Lines 7A5 and 7A6 CMS-64.9 Base).

3. ANNUAL
    a. Generally Accepted Accounting Principles (GAAP) Package – used in the process to close out the fiscal year's financial transactions.

11. STATE UTILIZATION FILE TO CMS - Submit a quarterly file to CMS of state drug utilization data (SDUD) invoiced to drug manufacturer for the quarter. [Resource State Release #177]
12. Perform DISPUTE RESOLUTION on invoices questioned by manufacturer. Attempt to resolve any data inconsistencies identified by manufacturer prior to submission of the Remittance Advice Form from the manufacturer. Perform the following dispute resolution activities:
    i. Contact the manufacturer by email within thirty (30) calendar days of the postmark of a manufacturer's check where a ROSI Form contains disputed amounts to discuss the dispute and to present a preliminary response to the disputed items. A Claim Level Detail (CLD) Report with drug utilization data that supports the quantity for quarter/s disputed is made available on the secure portal. [Resource State Release #173]
    **** Iowa DHS Form 470-4862 State Confirmation Manufacturer Alleged Error***
    ii. Retain supporting documentation of resolved disputes for at least 7 years from the date of the resolution.
    **** Iowa DHS Form 470-4863 Dispute Resolved***
    iii. Complete negotiations within 2 quarters of the original invoice. If disputes remain unresolved longer than this and no progress is shown towards resolution the assigned rebate specialist reports the matter to their Team Lead. If agreement cannot be reached between a manufacturer and Contractor, the matter is elevated to DHS. See Section XIV Non-Responsive Manufacturer and Delinquent Rebate Payments.
    iv. Calculate the interest due, as specified by CMS on late payments including payment due as a result of a PPA or unpaid disputed rebate payments resolved in the State's favor.
    v. See Section XII for additional Drug Dispute Resolution processes.
    vi. Provide Appeal Rights to the manufacturer if resolution is not possible and participate in any Appeal Process.
    **** Iowa DHS Form 470-4864 NOD by State on Open Unresolved Disputes; Iowa DHS Form 470-4865 NOD for Manufacturer to Escalate Open Unresolved Disputes; Iowa DHS Form 470-4866 Final Appeal Decision, with Balance Due***

vii. Maintain a DHS approved MCO/FFS Communication Plan for timely resolution of disputed claims.

13. Process and send quarterly drug rebate reports and bills to manufacturer on rebate details and amounts due, and control reports for the State to track rebate recoveries.

c) Supplemental Drug Rebates

1. Execute SSDC negotiated state supplemental rebate agreements (SRAs) with pharmaceutical manufacturer in a format approved by DHS.
2. Provide DHS with access to all SRAs and related documentation.
3. Ensure that supplemental rebates are as per the SRA and in compliance with federal law.
4. The terms of the SRA with each pharmaceutical manufacturershall be confidential and not be disclosed except to DHS.
5. Provide supplemental rebate calculations including NDC information necessary to invoice pharmaceutical manufacturer for their supplemental rebates (within 30-45 days after receipt of the CMS federal rebate file).
6. Submit the supplemental rebates to DHS in the format and schedule approved by DHS.
7. Provide a Drug Rebate System to manage and support the supplemental drug rebate program.
8. Assist DHS in dispute resolution activities with pharmaceutical manufacturer as they pertain to supplemental rebate calculations.
9. Subject to DHS approval, manage all aspects of processing rebate agreements.
10. On a quarterly basis, invoice participating manufacturer based on their utilization activity and collect all supplemental rebates following procedures established by DHS as agreed to by the parties. Deposit the supplemental rebates into the Department's recoupment account according to procedures established by DHS.
11. Provide to DHS monthly and ad hoc reports in a format approved by DHS on the performance of the PDL and supplemental rebates. Quarterly reports are due by the 10th day of the month following the end of each quarter.
12. Provide a savings report to DHS or its designee indicating the savings associated with the PDL supplemental rebates. Reports are delivered to DHS in a format and schedule approved by DHS.
13. The SRAs are signed 30 days prior to the scheduled P&T Committee meetings. Contractor provides a SRA status report 30 days prior to the P&T meetings. The list reports all partially executed agreements received and those sent but not signed and returned by manufacturer. Partially executed agreements are brought to the P&T meeting by Contractor staff, if in hard copy. At the end of the meeting, the accepted agreements are separated from the non-accepted and are provided to the Department in hard copy or electronic version. Following signature by the DHS Director, copies are returned to the Contractor and DHS staff and copies are returned to the manufacturer within one week of signing.

8. Inputs

The inputs to the Drug Rebate function are:

a) Paid outpatient pharmacy claims from the MMIS system for FFS claims and MCOs for pharmacy encounter claims.
b) Paid physician administered (professional and institutional) outpatient drug claims from the MMIS system including fee for service, managed care, and Medicare crossover claims
c) CMS quarterly updates
d) HRSA quarterly covered entity information of those who “carve-in” Medicaid
e) Rebate payment information
f) Disputed invoices
g) Corrected Claims including Off-Cycle Claims (FFS and MCO)

9. Outputs

The outputs from the Drug Rebate function are:

a) Drug Rebate invoices
b) Drug Rebate reports
c) Drug Rebate control reports

10. Performance Standards

The performance standards for the drug rebate functions are:

a) Update the manufacturer rebate data within 5 business days of receipt of the update from CMS.
b) Generate and mail/send invoices to manufacturer within 60 days of the end of the rebate period for OBRA, J Code, Supplemental and Special DME Rebates.
c) Initiate late notice correspondence to manufacturer for any invoices that are 5 days past due.
d) Collect 95% of the current Quarters’ invoicing by the end of the following quarter.
e) Reconcile with the Department total cash receipts for the month by the 15th day of the following month.
f) Create and update operational procedure manuals within 10 business days of the approval of the implementation procedure or change by the Department.
g) Produce the Department-defined reports within the required timeframe determined by the Department.

11. Reports

The following reports are required:

a) Report to CMS and the State quarterly:
    1. NDCs that have dropped off the quarterly CMS drug rebate file.
    2. URAs that post a zero on the quarterly CMS drug rebate file for 2 or more consecutive quarters.
b) Report to the State any unresolved disputes within 240 calendar days of receipt of a ROSI Form with unresolved disputes or within 30 days from the last contact date with the manufacturer where the Contractor and the

manufacturer have reached an impasse.

c) Detailed dispute resolution logs quarterly to the State.

12. Drug Rebate Disputes and Threshold

a) Iowa Medicaid Dispute Resolution Policy

1. Drug Rebate Team works all disputes, regardless of whether disputed previously or not.
2. If neither party has the CLD the dispute is not worked, the burden of proof falls on the party presenting the dispute. Note: Iowa sent claims to Data Niche Associates (DNA) from 1991 through 2005 and Contractor can provide Claim Details for 2005 forward.
3. If one party has the CLD, it is shared with the other party so the dispute can be worked.
4. Contractor loads historical CMS Rebate Data sent by Iowa Medicaid to assist them in resolving these disputes. Note: This will provide information about the original units invoiced, the price invoiced, and the rebate at the NDC level. It will not have any payment or adjustment information. The manufacturer will be asked to provide copies of Checks, ROSI and PQAS and current balance information, dispute resolution letters, or any other supporting documentation they have to support the dispute/audit. They will need to send their proposed resolution with the documentation and claim detail in order for Contractor to review and come to resolution or counter proposal.
5. CMS Dispute Resolution Program Best Practices -The State and Contractor must follow current Dispute Resolution Program Best Practices as posted on the CMS Medicaid website and as noted below, if applicable.
    i. Dispute Resolution Steps for States
    - Review receivables to identify outstanding balances
    - Aged Disputes when data is unreliable or unavailable
    - Schedule, prioritize, and understand available resources
    - Work with the manufacturer to agree on a resolution process and acquire managerial support
    - Reconcile balances due to accounting/bookkeeping differences
    - Reconcile data disputes; Contractor makes recommendations to the State on POS edits to implement, if possible, to prevent future recurring billing problems
    - Agree to necessary unit adjustments and document appropriately
    - Complete resolution statement
    - Monitor timely receipt of final resolution
    - Post resolution payments and document resolution

    ii. Steps to Take If the Process Is Unsuccessful
    - Encourage the manufacturer to attend a national dispute resolution meeting. Notify the State in writing if issues are not resolved through this process.
    - DHS contacts one of the CMS regional offices in writing.

- DHS contacts CMS central office in writing.
- National Drug Rebate Agreements provide that manufacturer may request a state administrative hearing. [Resource State Release #181] Within 60 days after Iowa receives notice from the CMS Central Office that it has been unable to resolve a dispute, DHS will notify the Contractor of its final position regarding the dispute and the Contractor will issue a written notice of decision to the manufacturer, including notice of the manufacturer's right to use the State's hearing mechanism to resolve any remaining dispute.
- State may pursue action based on breach of drug rebate agreements.

b) Process - Dispute Initiation, Procedure and Outcome

1. Initiation - In order for a dispute to be considered an official dispute, the state/manufacturer needs to have documented the disputed units on the official ROSI CMS Form-304 or PQAS CMS Form-304a.
2. Procedure - Most states and manufacturer prefer to engage in the dispute resolution process. A state hearing option is available to both states and manufacturer when they have reached an impasse or when one of the parties is not being responsive.
3. Dispute Resolution Outcome

i. Resolved

- Settlement Reached -
  - All disputes must be resolved on a unit basis only, and not on any other factor (e.g., monetary amounts, percentages, etc.).
  - Both parties must sign a copy of a resolution letter (if appropriate), template created by the Contractor. A separate letter is prepared for each quarter resolved in the event of a future issue - the entire dispute period is not reopened, only a smaller period.
  - The Contractor must document resolution of disputes involving the NDC number(s) and rebate quarter(s) in correspondence with the manufacturer.
  - Once payment/credit is processed, dispute is closed.
- State Decides to Cease Process: Dispute Threshold Write-Off Guidelines
  - While CMS Drug Rebate Program guidelines indicate the State does not need to pursue further dispute resolution with a manufacturer if the disputed amount in any quarter is less than $10,000 per manufacturer, and less than $1,000 per product code, and further dispute attempts would not be cost-effective, the Contractor should seek guidance from the State on how to proceed in these circumstances. [Resources State Release #19 and #181].

ii. Not Resolved

- Contractor should communicate with the State for next steps. If no resolution can be reached, as a last resort, appeal rights will be provided to the manufacturer.

13. Terminated Manufacturer and Reinstatement; Terminated Products and Reactivation

Termination of a *Manufacturer* from the MDRP Program - A manufacturer may terminate its Rebate Agreement for any reason, and such termination shall not become effective until the first day of the first calendar quarter beginning 60 days after the manufacturer gives written notice to CMS. Rebate is required to be paid and price reporting obligations end as of the manufacturer's termination date quarter.

- *Reinstatement* - Once terminated, labelers may not participate in the program for at least one quarter beyond the termination date quarter. State TCs are contacted to determine any outstanding rebates and/or interest due from the labeler's previous participation. List of drugs is reviewed to determine if eligible for inclusion. Non-rebate eligible drugs, missing data, non-payment, and other known compliance issues identified from previous participation will be resolved prior to the labeler's reinstatement.

Termination of a *Product* from the MDRP Program - Terminated NDCs (dispute code N) are those products where the shelf life for last lot produced has expired or date drug withdrawn. Per CMS guidelines, the affected manufacturer is required to submit pricing data and pay rebates for four (4) quarters past the termination date (but only for claims with a date of service prior to the termination date).

- *Late Submission* of Product Termination Dates *(Retroactive Termination)* - Manufacturers should not request credits and should not dispute state utilization on the basis that a product is terminated when the product's termination date was entered late.
- *Reactivation Date* - Reflects the date on which a previously terminated product is reintroduced to the market (i.e., reactivated).

[Resource State Release #168, MDRP Data Guide and MDP User Manual]

a) Iowa Medicaid Policy for Termination – The policy follows the State Release guidance and MDRP Data Guide for States and Labelers.
b) Process – Iowa Medicaid will invoice and collect rebates from terminated manufacturer and for terminated products in compliance with the resources listed.

14. Non-Responsive Manufacturer and Delinquent Rebate Payments

A manufacturer is required to calculate and pay quarterly rebates to states to offset some of the cost of the covered outpatient drugs that each state paid for during the invoiced quarter/year. The Medicaid National Drug Rebate Agreement (NDRA) states that, within 30 days of receiving a quarterly invoice, manufacturer should provide written notification to states if they are disputing some or all the units included on the invoice. Manufacturer that fail to either pay rebates or appropriately dispute utilization within 60 days of receipt of a state invoice are considered to be in violation of the NDRA. Such violations, if not rectified, may lead to the manufacturer's termination from the Medicaid Drug Rebate Program and/or other penalties. [Resource State

Release #181 and Manufacturer Release #105]

a) Iowa Medicaid Nonresponsive Manufacturer Policy
    1. No Response - If a manufacturer has not responded to requests for payment within one month of the original request, the rebate specialist should first talk to colleagues to see if there is another contact that could be used or if there is any reason (such as bankruptcy or a manufacturer being bought by another company) that explains this.
    2. Reporting
        i. State - If no contact can be established one week after this, the manufacturer should be included in the Iowa reporting documents as being unresponsive.
        ii. CMS - The rebate specialist should also send an email to CMS Operations at mdroperations@cms.hhs.gov of those manufacturers that are in violation of the NDRA, with a cc to DHS Pharmacy Consultant and POS Contract Account Manager alerting them of the situation with information as noted in "iii" below. See *P&P Attachment 4* for additional process detail if a manufacturer is out of compliance with rebate payment requirements.
        iii. Reporting Information And Supporting Documentation
            - Multiple attempts, timeline, and correspondence
            - Documentation of manufacturer responses if any
            - Officially disputed claims. If yes but nonresponsive to efforts work through Dispute Resolution Program (DRP) Team
            - Not disputed, provide specific details regarding all the unpaid federal rebates under the NDRA
            - If outstanding rebate payments from multiple labeler codes, the state should submit a separate request for assistance for each labeler code.

15. Uncollected Rebate Invoicing - Threshold

a) Per State Release #19 do not invoice a manufacturer for rebate amounts that are less than the administrative costs associated with preparing a quarterly invoice (i.e., rebate amounts of $10 or less). This rebate threshold was later increased in State Release #45 to $50 per labeler code per quarter, and also stated that the threshold could be applied to utilization changes for any quarter's invoice. [Resource State Release #181]
    1. Process - The Contractor should provide a report and discuss with DHS any manufacturers who fall in this category.
    2. Reporting - The Contractor/State are encouraged to notify CMS of any active manufacturer with outstanding uncollected rebate amounts (i.e., those that are not in dispute and have never been paid) that have not responded to the State's attempts to collect such rebates and interest. Such notifications can be sent via email to the MDRP Operations team at mdroperations@cms.hhs.gov.

Per CMS Drug Rebate Program guidelines, there are different thresholds depending

upon whether the uncollected rebates were officially disputed, and the disputes were never resolved, or whether the uncollectable rebates were invoiced, never paid, and never disputed by the manufacturer.

16. Bankrupt Manufacturer

In general, when a manufacturer files for bankruptcy, States are expected to protect Medicaid's interest related to any rebate payments owed from the affected labelers. A manufacturer that has filed for bankruptcy may voluntarily terminate from the program or be terminated from the program by CMS if necessary pursuant to section 1927(b)(4)(B). However, filing for bankruptcy does not result in automatic termination from the program. If a manufacturer is terminated from the program following a filing for bankruptcy, as with all terminations, we will notify States of the terminated manufacturer by email. [Resources State Release #61; #66; #159]

a) Business Rule/Process

The following process if followed for bankrupt manufacturer:

1. Notice Received. Notice of bankruptcy is received. The notice is sent to the established group including DHS, the Attorney General's Office representative and the POS Contract Account Manager as soon as possible. The notice is also placed in the IME Universal Bankruptcy folder and logged into the tracking document.
2. Estimate Exposure. Receipt of the notice will automatically trigger the rebate specialist to look at the State of Iowa's estimated exposure. The preliminary estimated exposure will be sent to the group as soon as possible.
3. Communication with Bankrupt Manufacturer. The Contractor will continue to invoice the manufacturer (invoices just relay amounts due) but will manually hold all late notices regarding the balance due related to the PoC filed.
4. Proof of Claim (PoC) Documents. DHS reviews for Governmental Bar Date and provides reminder for the date the Proof of Claim (PoC) documents are needed from rebate staff for claim submission.
    i. Petition Amount - PoC only represents the time period up through the end of the Quarter in which the bankruptcy petition was filed. Amounts owed will be calculated through that Quarter end.
    ii. Post-Petition Amount - A separate claim can be filed for amounts that accrue after the bankruptcy filing date, as the manufacturer may still be accruing new debts. Amounts owed will be calculated beginning with the first Quarter after the petition was filed.
    iii. A full account review will be done by Contractor based on OBRA and/or Supplemental Rebate receivables from 2005Q1 and forward. Contractor sends outstanding invoiced amounts to the group in the agreed upon format (Using the *Proof of Claim Bankruptcy Summary Document Template including all Overdue Invoices*).
5. Additional Bankruptcy Communications. Ongoing notices are shared with the group including the AAG for review of any other necessary actions.
6. Tracking of Documents. Contractor will keep electronic folder by manufacturer of all notices received.

7. File PoC. At near time of Governmental Bar Date, DHS assesses whether to make the claim in bankruptcy. AAG prepares PoC and submits electronically with approval from Medicaid Director, requesting clarification from Policy and Rebate Staff if needed. Submitted PoC will be saved in IME Universal Folder.
8. Post-PoC Invoicing and Collection Process.
    i. The Contractor will continue to invoice the manufacturer but will hold all late notices regarding the balance due related to the PoC petition amount filed.
    ii. The Contractor will continue to invoice the manufacturer on the balance due for claims post-petition submission but hold all late notices unless late notice(s) would exclude amounts owed under PoC filed.
    iii. Twelve calendar months following PoC filing the Contractor should relay to the group:
        a. If manufacturer has been terminated from the program
        b. Unpaid balance issues, if any, and
        c. Last date of payment and/or communication.
9. Monitoring of Bankruptcy Closing. AAG will follow and notify group of bankruptcy outcome and closure.
    i. Bankruptcy plan filed will indicate funds to be received, if any.
    ii. If receiving funds account should be kept open until received (likely not full claim).
    iii. Account file should record the funds received and the rest can be noted as dismissed pursuant to bankruptcy law. File documents:
        a. Bankruptcy notice
        b. Information from the AAG about the bankruptcy outcome including amount collected and amount discharged. If none was collected, then the full amount as discharged by the bankruptcy court.
        c. There should be no further attempt to collect remaining amounts after the bankruptcy plan filed as this would be in violation of bankruptcy law.
    iv. Status of Labeler Account – To determine the status of the labeler Medicaid Drug Rebate account following bankruptcy closing, the IME will consult with the AAG, Medicaid Budget Analyst and CMS. The bankruptcy outcome depends on the type of bankruptcy filed.
10. Unpaid Balances. See #17 for process related to unpaid rebate balances.

17. Reconciliation of Manufacturer Unpaid Drug Rebate Receivable Accounts

a) Unpaid balances may be due to a variety of issues including but not limited to bankruptcy, termination from the program, nonresponsive manufacturer, etc.
b) Periodic reports will be produced related to the “inactive older” accounts and outstanding amounts including review/resolution of disputed items. Also provide recommendations to resolve or collect outstanding balances if applicable.
c) Write-offs are not recommended as terminated manufacturers may be reinstated [See #13] and reporting and payment obligations must be met.
d) Iowa does not have specific state guidance on write-offs or closing inactive

accounts, other than if it is outstanding for a long time the auditors question why it hasn't been written off. Any write-off approved by the state must be in accordance with CMS guidelines.

18. Disaster Recovery

The Contractor will be required to develop and maintain a disaster recovery plan designed to minimize any disruption to the system or to ensure a resumption of the system following a disaster such as fire, flood, or tornado. The plan must provide for the following:

a) Ensure complete, accurate, and up-to-date documentation of all systems and procedures used to support the IME (including revisions on documentation for the Iowa MMIS).
b) Backup of all tapes and files and storage of the backup tapes and files at an off-site location.
c) Backup of software and storage at an off-site location.
d) A detailed schedule for backing up critical files and their rotation to an off-site storage location.
e) Backup for continuous operations in the event of a disaster.