Prescription Drug Rebate Data Submission Manual

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10 CCR 2505-5

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CENTER FOR IMPROVING
VALUE IN HEALTH CARE

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Note: The Center for Improving Value in Health Care (CIVHC) is basing its approach to collecting information about Prescription Drug Rebates on a program established by the Massachusetts Center for Healthcare Information and Analysis (CHIA). The instructions in this document include language from a 2018 Data Specification Manual to payers about requirements for submitting data on drug rebates. We wish to express our thanks to CHIA for their generous assistance in the creation of this document.

1. Introduction

In October 2018 and in accordance with Code of Colorado Regulation 10 CCR 2505-5, the Department of Health Care Policy and Financing (HCPF) changed the rules governing the All Payer Claims Database (APCD) Data Submission Guide (DSG) to require the Center for Improving Value in Health Care (CIVHC) to collect data on alternative payment models and prescription drug rebate information from public and private payers.

Prescription drug rebate is defined as aggregated information regarding the total amount of any prescription drug rebates and other pharmaceutical manufacturer compensation or price concessions paid by pharmaceutical manufacturers to a payer or their pharmacy benefit manager(s).

This Data Submission Manual provides technical details to assist payers in reporting and filing prescription drug rebate data.

2. Why Collect Drug Rebate Data?

The goal for collecting drug rebate data is to measure the effect of prescription drug rebates on pharmacy spending and spending growth.

3. File Submission Instructions and Schedule

Payers can access CIVHC's APM data submission Excel file from the CIVHC website here and should submit APM information according to the following schedule:

Alternative Payment Model and Drug Rebate Data Submission Schedule	
Date	**Files Due**
July 1, 2019	• Test files of data for 2016
September 1, 2019	• Waiver request due (if applicable)
September 30, 2019	• Final files for each of three calendar years, 2016, 2017 and 2018.

Files should be submitted in Excel format (.xlsx, .xls, or .csv) through the SFTP server.

Naming conventions should follow the template:

TESTorPROD_PayerID_SubmissionYearDueFileTypeVersionNumber.xlsx

For example, the following naming conventions will be used for testing and production in 2019:

TEST_0000_2019DRv01. xlsx
PROD_0000_2019DRv02. xlsx

4. Waivers

CIVHC will work collaboratively with payers to ensure that required drug rebate data submissions achieve the intent of the rules. These rules have been put in place to deliver a high quality, reliable source of data for Colorado.

CIVHC will consider requests from data submitters to provide summarized data or file exemptions for their drug rebate files. The purpose of permitting submission of summarized data is to enable a payer to materially comply with the data submission guide requirements while gaining time to develop the capability to overcome their limitations in providing required detailed data. This policy is intended to recognize the limitations of some payers and also maintain the utility of the overall drug rebate data set.

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Please see Appendix A for instructions for filing a waiver and waiver form.

5. Data Submission of Prescription Drug Rebate Details

Unlike Alternative Payment Model submissions, payers are not required to submit prescription drug rebate information at the provider level.

Prescription drug rebate files will contain different record types, including:

- Payer summary information and comments
- Member Months, by Colorado residency
- Pharmacy Expenditures, by insurance category and brand/specialty status
- Prescription Drug Rebates, by insurance category and brand/specialty status

Rebate Data Specifications

The payer is expected to record prescription drug rebate data in the Prescription Drug Rebate Submission DSG 10 Excel template. Below is a description of each field.

Payer Code: The CIVHC-assigned organization ID for the payer or carrier submitting the file.

Payer Name: The name of the payer or carrier submitting the file.

Insurance Category: The insurance category being reported, according to Table B.1.A. Insurance Type of the Data Submission Guide, displayed below. Payers shall submit drug rebate information for all insurance categories for which they have business. Payers reporting under the "99 Other" category will be asked to identify the type of insurance reflected in this category.

Code	Insurance Type Code Description
12	Preferred Provider Organization (PPO)
13	Point of Service (POS)
15	Indemnity Insurance
16	Health Maintenance Organization (HMO) Medicare Advantage
17	Dental Maintenance Organization (DMO)
CI	Commercial Insurance Company
DN	Dental
HM	Health Maintenance Organization
HN	HMO Medicare Risk/ Medicare Part C
MA	Medicare Part A
MB	Medicare Part B
MC	Medicaid
MD	Medicare Part D
MP	Medicare Primary
QM	Qualified Medicare Beneficiary
TV	Title V
99	Other

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Code	Insurance Type Code Description
SP	Medicare Supplemental (Medi-gap) plan
CP	Medicaid CHIP
MS	Medicaid Fee for service
MM	Medicaid Managed care
CS	Commercial Supplemental plan
SF	Self-Funded

Calendar Year (DR004): The payer must report the calendar year for which the drug rebate data will be reported.

Member Population (DR005): Payers must define the population of covered members for all data provided in this data filing as members that are Colorado residents. If the payer cannot report the information requested in this file for Colorado residents only, they should contact CIVHC.

Payers should only include information pertaining to members for which they are the primary payer, and exclude information for members for which they were the secondary or tertiary payer.

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Member Months (DR006): The number of members receiving primary health insurance coverage by a plan over the specified period of time expressed in months of membership. The member months provided in this field should correspond to the patient population identified in Member Population. All members in the defined member population must be counted in the member month value.

Please note that for the Commercial insurance category, payers should only report on those members for whom they have complete pharmacy expenditure and prescription drug rebate information. Any members for which a payer has no pharmacy expenditure or prescription drug rebate data, or partial pharmacy expenditure or prescription drug rebate data, should be excluded from this data reporting. As a result, all member month, pharmacy expenditure, and prescription drug rebate data for excluded members should be excluded from this data filing.

Pharmacy Expenditure Amounts (applicable to Total Pharmacy Expenditure Amount (DR007) and for Specialty and Non-Specialty Brand and Generic Drugs (DR008 – DR010): The sum of all incurred claim allowed payment amounts to pharmacies for prescription drugs, biological products, or vaccines as defined by the payer's prescription drug benefit in a given calendar year. This amount shall include member cost sharing amounts. This shall include all incurred claims for individuals included in the member population regardless of where the prescription drugs are dispensed (i.e., includes claims from in-state and out-of-state providers). Claims should be attributed to a calendar year based on the date of fill.

The allowed paid amount is equal to the total payment amounts to a pharmacy including all payer paid amounts, pharmacy benefit manager (PBM) paid amounts, and member cost sharing. This amount shall include direct drug costs and exclude non-claim costs. Importantly, this amount shall not reflect prescription drug rebates in any way (i.e., the amount must not be reduced by prescription drug rebates).

Pharmacy Expenditure Amount: Specialty Drugs (DR008): A drug defined as a specialty drug by the payer or under the terms of a payer's contract with its PBM. Specialty drug expenditure and rebate amounts should be mutually exclusive from non-specialty brand drug and non-specialty generic drug expenditure and rebate amounts.

Pharmacy Expenditure Amount: Non-Specialty Brand Drugs (DR009): A drug defined as a non-specialty brand drug by the payer or under the terms of a payer's contract with its PBM. Non-specialty brand drug expenditure and rebate amounts should be mutually exclusive from specialty drug and non-specialty generic drug expenditure and rebate amounts.

Pharmacy Expenditure Amount: Non-Specialty Generic Drugs (DR010): A drug defined as a non-specialty generic drug by the payer or under the terms of a payer's contract with its PBM. Non-specialty generic drug expenditure and rebate amounts should be mutually exclusive from specialty drug and non-specialty brand drug expenditure and rebate amounts.

Prescription Drug Rebate Amount (applicable to Total Prescription Drug Rebate Amount (DR0111) and Rebate Amounts for Specialty and Non-Specialty Brand and Generic Drugs (DR012 – DR014): Total rebates, and other price concessions (including concessions from price protection and hold harmless contract clauses) provided by pharmaceutical manufacturers for prescription drugs with specified dates of fill, excluding manufacturer-provided fair market value bona fide service fees. This amount shall include PBM rebate guarantee amounts as well as any additional rebate amounts transferred by the PBM in addition to the rebate guarantee amounts. This amount shall include the total amount of prescription drug rebates and price concessions provided by pharmaceutical manufacturers, regardless of whether they are conferred to the payer directly by the manufacturer, a PBM, or any other entity. In addition, this amount shall include the total amount of prescription drug rebates and price concessions provided by pharmaceutical manufacturers, regardless of whether they are conferred to the payer through regular aggregate payments, on a claim-by-claim basis at the point-of-sale, as part of retrospective financial reconciliations (including reconciliations that also reflect other contractual arrangements), or by any other method.

> Rebates and other price concessions: A reduction in the amount a buyer (i.e., payer or PBM) pays for an item or service based on an arms-length transaction. The terms of the reduction must be fixed and disclosed in writing to the buyer at the time of the initial purchase to which the reduction applies, and the reduction must not be given by the offer or at the time of sale.
>
> For the purposes of this data collection, Medicare Part D coverage gap discounts shall be treated in the same manner as they are treated for pharmacy expenditures. If coverage gap discounts are excluded from pharmacy expenditures, they should be excluded from prescription drug rebates. If coverage gap discounts are included in pharmacy expenditures, they should be included in prescription drug rebates.
>
> Fair market value bona fide service fees: Fees paid by a manufacturer to a third party (e.g., payers, PBMs, payer- or PBM-owned pharmacies), that represent fair market value for a bona fide,

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itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement (e.g., data service fees, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs), etc.).

Prescription Drug Rebate Amount: Specialty Drugs (DR012): Rebates specific to specialty drugs.

Prescription Drug Rebate Amount: Non Specialty Brand Drugs (DR013): Rebates specific to non-specialty drugs brand drugs.

Prescription Drug Rebate Amount: Non-Specialty Generic Drugs (DR014): Rebates specific to non-specialty generic drugs.

Per Member Per Month Pharmacy Expenditure Amount (Insurer & Member Liability) (DR015): The value for this field must be calculated as the Total Pharmacy Expenditure Amount divided by Member Months (DR007÷ DR006)

Per Member Per Month Prescription Drug Rebate Amount (DR016): The value for this field must be calculated as the Total Prescription Drug Rebate Amount divided by Member Months (DR011÷ DR006).

Combined Rebate Identifier (DR017): Some carriers are unable to submit claims data for each individual insurance category and the most granular data they are able to submit is for multiple categories. This Combined Rebate Identifier will allow CIVHC to determine whether the submitted information is for individual or combined insurance categories.

If rebate data is only available to a payer at an aggregated level and cannot be separated to provide unique information for each of the insurance categories, the payer shall report a separate observation with all required data elements for each insurance category except for the following data elements: DR011 - Total Prescription Drug Rebate Amount, DR012 – Prescription Drug Rebate Amount: Specialty Drugs, DR013 – Prescription Drug Rebate Amount: Non-Specialty Brand Drugs, DR014 – Prescription Drug Rebate Amount: Non-Specialty Generic Drugs, and DR016 - Per Member Per Month Prescription Drug Rebate Amount. These data elements should contain the same values for all insurance categories included in the combined rebate data for a given year.

For the data element, DR016 - Per Member Per Month Prescription Drug Rebate Amount, the payer should sum the member months for the insurance categories to which the rebates apply and then divide the total rebate amount, DR011 - Total Prescription Drug Rebate Amount, by sum of member months.

To identify combined rebate data, payers should assign common alphabetic identifiers (e.g., A) in the "Combined Rebate Identifier" to observations for which rebate data is combined and the values in data elements DR011, DR012, DR013, DR014, and DR016 are the same.

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6. Drug Rebate File Content

Data Element #	Data Element Name	Type	Length	Description/Codes/Sources	Required
DR001	Payer Code	varchar	8	Distributed by CIVHC	R
DR002	Payer Name	varchar	30	Distributed by CIVHC	R
DR003	Insurance Type Code/Product	char	2	See Lookup Table B-1.A	R
DR004	Calendar Year	Year	4	4 digit Year for the most recent calendar year time period reported in this submission	R
DR005	Member population	Int	N/A – Excel file	The population of covered members for all data provided in this data filing. Payers should only include information pertaining to members for which they are the primary payer, and exclude information for members for which they were the secondary or tertiary payer. All Colorado resident members for whom a payer provides primary coverage should be included in the member population, regardless of product or funding type.	R
DR006	Member Months	Int	N/A – Excel file	The number of members receiving primary health insurance coverage by a plan over the specified period of time expressed in months of membership. The member months provided in this field should correspond to the patient population identified in Member Population. All members in the defined member population must be counted in the member month value. Sum of member months. No decimal places; round to nearest integer. Example: 12345	R
DR007	Total Pharmacy Expenditure Amount	Numeric	N/A – Excel file	The sum of all incurred claim allowed payment amounts to pharmacies for prescription drugs, biological products, or vaccines as defined by the payer's prescription drug benefit in a given calendar year. This amount shall include member cost sharing amounts. This shall also include all incurred claims for individuals included in the member population regardless of where the prescription drugs are dispensed (i.e., includes claims from in-state and out-of-state providers).	R

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Data Element #	Data Element Name	Type	Length	Description/Codes/Sources	Required
				Claims should be attributed to a calendar year based on the date of fill. (allowed amount should include direct drug costs and exclude non-claim costs. This amount will not reflect prescription drug rebates in any way)	
DR008	Pharmacy Expenditure Amount: Specialty Drugs	Numeric	N/A – Excel file	The total expenditure for a specialty drug. Specialty drug expenditure and rebate amounts should be mutually exclusive from non-specialty brand drug and non-specialty generic drug expenditure and rebate amounts. Drug defined as a specialty drug under the terms of a payer's contract with its PBM.	R
DR009	Pharmacy Expenditure Amount: Non-Specialty Brand Drugs	Numeric	N/A – Excel file	The total expenditure for Non-Specialty Brand Drugs. Non-specialty brand drug expenditure and rebate amounts should be mutually exclusive from specialty drug and non-specialty generic drug expenditure and rebate amounts. A drug defined as a non-specialty brand drug under the terms of a payer's contract with its PBM.	R
DR010	Pharmacy Expenditure Amount: Non-Specialty Generic Drugs	Numeric	N/A – Excel file	The total expenditure for Non-Specialty Generic Drugs. Non-specialty generic drug expenditure and rebate amounts should be mutually exclusive from specialty drug and non-specialty brand drug expenditure and rebate amounts. A drug defined as a non-specialty generic drug under the terms of a payer's contract with its PBM.	R
DR011	Total Prescription Drug Rebate Amount	Numeric	N/A – Excel file	Total rebates, and other price concessions (including concessions from price protection and hold harmless contract clauses) provided by pharmaceutical manufacturers for prescription drugs with specified dates of fill, excluding manufacturer-provided, fair market value, bona fide service fees.	R
DR012	Prescription Drug Rebate Amount: Specialty Drugs	Numeric	N/A – Excel file	The total rebate amount for all specialty drugs. Specialty drug expenditure and rebate amounts should be mutually exclusive from non-specialty brand drug and non-specialty generic drug expenditure and rebate amounts.	R

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Data Element #	Data Element Name	Type	Length	Description/Codes/Sources	Required
				Drug defined as a specialty drug under the terms of a payer's contract with its PBM.	
DR013	Prescription Drug Rebate Amount: Non-Specialty Brand Drugs	Numeric	N/A – Excel file	The total rebate amount for all Non-Specialty Brand Drugs. Non-specialty brand drug expenditure and rebate amounts should be mutually exclusive from specialty drug and non-specialty generic drug expenditure and rebate amounts. A drug defined as a non-specialty brand drug under the terms of a payer's contract with its PBM.	R
DR014	Prescription Drug Rebate Amount: Non-Specialty Generic Drugs	Numeric	N/A – Excel file	The total rebate amount for all Non-Specialty Generic Drugs. Non-specialty generic drug expenditure and rebate amounts should be mutually exclusive from specialty drug and non-specialty brand drug expenditure and rebate amounts. A drug defined as a non-specialty generic drug under the terms of a payer's contract with its PBM.	R
DR015	Per Member Per Month Pharmacy Expenditure Amount	Numeric	N/A – Excel file	Calculated as the Total Pharmacy Expenditure Amount (DR007) divided by Member Months (DR006)	R
DR016	Per Member Per Month Prescription Drug Rebate Amount	Numeric	N/A – Excel file	Calculated as the Total Prescription Drug Rebate Amount (DR011) divided by Member Months (DR006)	R
DR017	Combined Rebate Identifier	Varchar	N/A – Excel file	If rebate data is only available to a payer at an aggregated level and cannot be separated to provide unique information for each of the insurance categories for which the payer has business, the payer shall report data at the most granular level available. In such instances, the payer shall report a separate observation with all required data elements for each insurance category.	R
DR018	Comments	Varchar	N/A – Excel file		R
DR019	Record Type	Char	2	DR	R

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Appendix A: Waiver Instructions and Form

INSTRUCTIONS TO REQUEST A DATA SUBMISSION WAIVER for the COLORADO ALL PAYER CLAIMS DATABASE – APM AND DRUG REBATE FILES

CIVHC will work collaboratively with APCD data submitters to ensure that required submissions achieve the intent of the rules. These rules have been put in place to deliver a high quality, reliable source of health care data for Colorado. The APCD Program will engage in a Continuous Quality Improvement (CQI) process intended to achieve ever higher levels of data quality and completeness as the APCD Program evolves.

Consistent with the CQI process, the APCD will consider requests from data submitters to provide summarized data or file exemptions for their Alternative Payment Model (APM) and Drug Rebate files. The purpose of permitting submission of summarized data is to enable a data submitter to materially comply with the data submission guide requirements while gaining time to develop the capability to overcome their limitations in providing required detailed data. This policy is intended to recognize the limitations of some submitters and also maintain the utility of the overall data set.

Data submitters may request a one year waiver for a file type or a one year relief from submitting required details for a data element. If the latter, the request should include the following information for each data element.

<u>For waivers of a particular data element:</u>

- The year for which the summarized data/file exemption is requested.
- The specific field(s) including number and description for which the submitter is requesting to provide summarized data, if the request involves a specific field.
- The data submitter's proposal for providing summarized data for each field, if applicable.
- An explanation as to why the data submitter is unable to submit the file or provide requested details for those same fields, including the conditions or factors affecting the data submitter's ability to comply.
- A description of the process the data submitter will follow to develop the capability to achieve the established requirements in the future, including milestones for completion.
- An original signed certification by the organization's Chief Information Officer or Regulatory Compliance Office that includes the above information and asserts that the data submitter cannot meet the requirements because the requested information is not available and cannot be derived from the data submitter's information systems.

A template for the request for waiver is attached for your convenience. Please attach additional pages of narrative as needed to provide a full explanation of the reasons that the data submitter cannot comply and the plans for improving compliance over the term of the waiver. Please submit all documentation electronically to **submissions@civhc.org**. Questions may also be directed to **submissions@civhc.org**.

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Colorado APCD Data Variance Submission Request for [Year]:______

Name of Submitter:	Date Submitted:
Contact Name, Email and Phone:	

The following information should be included for each file type. Include data element if applicable; attach additional pages of narrative as needed to explain the request and describe the plan to improve compliance if applicable.

Data File Name	Data Element Number (if applicable	Data Element Name (if applicable)	Detailed description of reason

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Certification: On behalf of ____________________________________, I certify that this data submitter cannot submit the files listed or meet the required threshold because the required information is not available and cannot be derived from the data submitter's information systems.

Submitted by: ____

Name Title Date

Appendix B: Sample of Completed Prescription Drug Data File

DR001	DR002	DR003	DR004	DR005	DR006	DR007	DR008	DR009	DR010	DR011	DR012	DR013	DR014	DR015	DR016	DR017	DR018	DR019
Payer Code	Payer Name	Insurance Type Code/Product	Calendar Year	Member Population	Member Months	Total Pharmacy Expenditure Amount	Pharmacy Expenditure Amount: Specialty Drugs	Pharmacy Expenditure Amount: Non-Specialty Brand Drugs	Pharmacy Expenditure Amount: Non-Specialty Generic	Total Prescription Drug Rebate Amount	Prescription Drug Rebate Amount: Specialty Drugs	Prescription Drug Rebate Amount: Non-Specialty	Prescription Drug Rebate Amount: Non-Specialty Generic	Per Member Per Month Pharmacy Expenditure	Per Member Per Month Prescription Drug Rebate Amount	Combined Rebate Identifier	Comments	Record Type
0000	Example Insurance Co	12	2015	250,082	3,000,000	$ 195,000,000.00	$ 40,511,250.00	$ 121,533,750.00	$32,955,000.00	$ 9,809,800.00	$ 3,235,694.62	$ 33,152,271.12	$ 74,960.32	$ 65.00	$ 34.20	A	Could not differentiate between Insurance Type 12, 13, 15	DR
0000	Example Insurance Co	13	2015	33,359	400,000	$ 60,000,000.00	$ 12,465,000.00	$ 37,395,000.00	$ 10,140,000.00	$ 9,809,800.00	$ 3,235,694.62	$ 33,152,271.12	$ 74,960.32	$ 150.00	$ 34.20	A	Could not differentiate between Insurance Type 12, 13, 15	DR
0000	Example Insurance Co	15	2015	3,423	40,000	$ 8,600,000.00	$ 1,786,650.00	$ 5,359,950.00	$ 1,453,400.00	$ 9,809,800.00	$ 3,235,694.62	$ 33,152,271.12	$ 74,960.32	$ 215.00	$ 34.20	A	Could not differentiate between Insurance Type 12, 13, 15	DR
0000	Example Insurance Co	HN	2015	29,190	350,000	$ 31,500,000.00	$ 6,544,125.00	$ 19,632,375.00	$ 5,323,500.00	$49,555,962.00	$ 16,328,730.55	$ 6,569,440.58	$ 4,664.80	$ 90.00	$ 141.59	B		DR
0000	Example Insurance Co	12	2016	249,198	2,990,000	$ 213,785,000.00	$ 48,613,500.00	$ 130,965,900.00	$34,205,600.00	$ 14,607,960.00	$ 4,529,972.46	$38,620,519.02	$ 102,071.00	$ 71.50	$ 33.96	C	Could not differentiate between Insurance Type 12, 13, 15	DR
0000	Example Insurance Co	13	2016	35,444	425,000	$ 72,675,000.00	$ 14,958,000.00	$ 46,089,000.00	$ 11,628,000.00	$ 14,607,960.00	$ 4,529,972.46	$38,620,519.02	$ 102,071.00	$ 171.00	$ 33.96	C	Could not differentiate between Insurance Type 12, 13, 15	DR
0000	Example Insurance Co	15	2016	4,244	50,000	$ 12,255,000.00	$ 2,143,980.00	$ 8,150,220.00	$ 1,960,800.00	$ 14,607,960.00	$ 4,529,972.46	$38,620,519.02	$ 102,071.00	$ 245.10	$ 33.96		Could not differentiate between Insurance Type 12, 13, 15	DR
0000	Example Insurance Co	HN	2016	37,513	450,000	$ 42,930,000.00	$ 7,852,950.00	$ 28,208,250.00	$ 6,868,800.00	$ 61,582,812.80	$ 22,860,222.77	$10,023,632.34	$ 54,355.20	$ 95.40	$ 136.85	D		DR

Keep the following in mind when reviewing the sample above:

- Payer 0000 provides health insurance coverage to members in the Commercial market and the Medicare Advantage market.
- Payer 0000 is not able to report on prescription drug rebates by unique insurance category within their commercial market. Rebate information is combined for the following: (1) all commercial members and (2) all Medicare Advantage members.
  - Therefore, payer 0000 utilizes Combined Rebate Identifier (DR017) and Comments (DR018) fields
  - Rebate dollar values in DR011, DR012, DR013, and DR014 are equal for lines with the same combined rebate identifier
  - Drug Rebate PMPM (DR016) values use the sum of member months in the rows with the same combined rebate identifier as the denominator to calculate this field.
- Payer 0000 is able to stratify drug rebates by specialty, generic, and brand drugs.

Appendix C: Frequently Asked Questions

1) When is each file due?

Test files for Alternative Payment Models, Drug Rebate and Control Totals are due by July 1, 2019. Test files should include data for calendar year 2016.

Final production files are due by September 30, 2019. Production files must be submitted with data for three previous calendar years – 2016, 2017, 2018.

2) How should the files be submitted and named?

Files should be submitted in Excel format (.xlsx, .xls, or .csv) through the SFTP server. Naming conventions should follow the template:

TESTorPROD_PayerID_SubmissionYearDueFileTypeVersionNumber.xlsx

For example, the following naming conventions will be used for testing and production in 2019:
TEST_0000_2019DRv01. xlsx
PROD_0000_2019DRv02. xlsx

3) What is the objective for collecting Drug Rebate data?

The drug rebate data will allow CIVHC to report the impact of drug rebates on trends in total costs of care and in prescription drug costs in Colorado.

CIVHC does not plan to report this data by payer/submitter.

4) My organization submits under multiple CIVHC-assigned payer codes. How should I handle this in the Drug Rebate file?

You may submit this information in one file. However, be sure to enter each assigned payer code (DR001) and enter requested information for each code separately. Please note that the Alternative Payment Model (APM) files should be submitted separately for each payer code.

5) What is the timeframe of the payments included in the Drug Rebate files?

Fill dates corresponding to each of the three most recent calendar years (2018, 2017 and 2016) should reported in these files.

6) What is the process for requesting waivers and exceptions to the Drug Rebate file submission requirements?

Please complete the form on page two of Appendix A, "Data Submission Waiver Instructions - APM and Drug Rebate Files" and email it to **submissions@civhc.org**. CIVHC will review the document and provide comments, if necessary. CIVHC will then complete the Data Submission Waiver Agreement and combine this with the completed instruction file submitted by your organization. CIVHC will provide this document to you for your records.

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Please submit these waiver documents no later than September 1, 2019.

7) **Will you be joining these files to the other claims files (MC, PC, ME, MP) that we submit to the APCD?**

No, we will not join these files to the data in the APCD. CIVHC understands that the data collected in the drug rebate file are based on different inclusion criteria than the data in the APCD files, so it is not expected that the numbers will be equal. However, we will compare the paid amounts and member months in these files to ensure the numbers are in the same ball park.

8) **In the Drug Rebate file, what date should be used as the basis for reporting pharmacy expenditures?**

Payers should base these records on fill date.

9) **Which members (DR005) should be included when reporting pharmacy expenditures and rebates?**

Members are defined as those individuals covered by the payer and residing in the state of Colorado. This field should reflect the total distinct member population that applies to the given row. If the payer cannot report the information requested in this file for Colorado residents only, they should contact CIVHC.

10) **How are member months (DR006) defined?**

The number of members receiving primary health insurance coverage by a plan over the specified period of time expressed in months of membership. The member months provided in this field should correspond to the patient population identified in Member Population. All members in the defined member population must be counted in the member month value. If your organization covers a person for even one day of the month, even if it's the 1st or the 31st, then this counts as a member month.

Please note that for the Commercial insurance category, payers should only report on those members for whom they have complete pharmacy expenditure and prescription drug rebate information. Any members for which a payer has no pharmacy expenditure or prescription drug rebate data, or partial pharmacy expenditure or prescription drug rebate data, should be excluded from this data reporting. As a result, all member month, pharmacy expenditure, and prescription drug rebate data for excluded members should be excluded from this data filing.

11) **What payment amounts should be included in the payment fields (DR007-DR010)?**

The sum of all incurred claim *allowed payment amounts* to pharmacies for prescription drugs, biological products, or vaccines as defined by the payer's prescription drug benefit in a given calendar year should be included in these fields. This amount shall include member cost sharing amounts. This shall include all incurred claims for individuals included in the member population regardless of where the prescription drugs are dispensed (i.e., includes claims from in-state and out-of-state providers). Please refer to the Data Submission Guide (DSG) or Manual for a complete definition.

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12) How do you define specialty drugs (DR008 and DR012)?

Specialty drugs are defined based on the payer's definition. CIVHC will NOT provide a list of what we consider specialty drugs.

13) My organization is unable to break out the drug rebate amount by specialty, brand, and generic drugs (DR008-DR010, DR012-DR014). How should I populate these fields?

Please contact CIVHC and complete a waiver form with the details of what you are unable to submit. CIVHC will work with you to develop modified data specifications that accommodate your data limitations and allow CIVHC to fulfill its statutory obligations.

14) How is Total Prescription Drug Rebate Amount (DR011) defined? Does it include prior year dollars included from any retro-active payments?

CIVHC intends to use the definition established by the Massachusetts Center for Healthcare Information and Analysis, below. Payers should report only rebate amounts that are associated with payments for prescriptions filled during the reported calendar year. Payers should report retroactive payments in the calendar year when the associated prescriptions were filled.

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Total rebates, and other price concessions (including concessions from price protection and hold harmless contract clauses) provided by pharmaceutical manufacturers for prescription drugs with specified dates of fill, excluding manufacturer-provided fair market value bona fide service fees. This amount shall include PBM rebate guarantee amounts as well as any additional rebate amounts transferred by the PBM in addition to the rebate guarantee amounts. This amount shall include the total amount of prescription drug rebates and price concessions provided by pharmaceutical manufacturers, regardless of whether they are conferred to the payer directly by the manufacturer, a PBM, or any other entity. In addition, this amount shall include the total amount of prescription drug rebates and price concessions provided by pharmaceutical manufacturers, regardless of whether the they are conferred to the payer through regular aggregate payments, on a claim-by-claim basis at the point-of-sale, as part of retrospective financial reconciliations (including reconciliations that also reflect other contractual arrangements), or by any other method.

15) How is Combined Rebate Identifier (DR017) going to be used by CIVHC?

Some carriers are unable to submit claims data for each individual insurance category and the most granular data they are able to submit is for multiple categories. This Combined Rebate Identifier will allow CIVHC to determine whether the submitted information is for individual or combined insurance categories.

16) What should I include in Comments (DR018)?

This cell should be used if a payer cannot fully complete the Drug Rebate file to the specifications outlined in the DSG. The payer should enter an explanation of how their submission differs from the specifications.

17) What should be included in Record Type (DR019)?

Please populate each record in the Drug Rebate file with “DR”. This is for administrative purposes.

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