Prescription Drug Rebate Data Submission Manual

10 CCR 2505-5

September 8, 2020

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. With the adoption of the Data Submission Guide v11.5, passed in April 2020, the collection of drug rebate data was expanded to include high-level information about each payer's Pharmacy Benefit Manager (PBM) contract.

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). PBM Contract Information is a supplement to the drug rebate file and describes the contractual arrangement a payer has with its PBM.

This Data Submission Manual provides technical details to assist payers in reporting and filing prescription drug rebate data and PBM contract information. **CIVHC recommends that payers coordinate efforts to complete the drug rebate file between the department responsible for managing agreements with pharmacy benefit managers or drug manufacturers and the department responsible submitting monthly files to the APCD** to ensure that details, such as Insurance Product Type and prescription drug expenditures, are accurate.

2. Why Collect Drug Rebate Data?

The goal for collecting drug rebate data is to measure the effect of prescription drug rebates and other compensation on pharmacy spending and spending growth. The purpose of collecting PBM contract information is to understand the role of the PBM in managing the pharmacy benefit and negotiating drug manufacturer rebates and other compensation, which are important when analyzing the total impact of rebates and other compensation in offsetting expenditures for prescription drugs.

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, 2020	• Waiver request due (if applicable)
July 15, 2020	• Test files of data for 2017 due
September 30, 2020	• Final files for three calendar years, 2017, 2018 and 2019

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 2020:

TEST_0000_2020DRv01. xlsx
PROD_0000_2020DRv02. xlsx

The Drug Rebate file consists of two separate tabs: the first tab, labeled 'DR' captures the number of members and member months, pharmacy expenditures, and drug rebates. The second tab, labeled 'PBM', captures summary information about a payer's contract with its PBM.

4. Waivers

CIVHC will work collaboratively with payers to ensure that required drug rebate data are submitted in a manner that satisfies the intent of the Data Submission Guide 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 for file exemptions under certain circumstances. Data submitters should submit a waiver request for the Drug Rebate filing if the organization meets one of the following criteria:

1) Payer does not provide prescription drug benefits (e.g. payer only provides medical benefits, payer only provides dental benefits, etc.)
2) Payer only provides supplemental insurance (e.g. Medicare Supplemental policies only)
3) Payer does not receive any rebates or other compensation from drug manufacturers/PBMs

If you believe your organization is not obligated to submit a Drug Rebate file, but your circumstances do not fall under items 1, 2, or 3 above, please contact CIVHC.

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

5. Changes to the Drug Rebate Submission Manual

The following are changes to this Drug Rebate Data Submission Manual, which were adopted following the Data Submission Guide v11.5 Rule Hearing on April 15, 2020.

- Data fields previously labeled "drug rebate" are now labeled "drug rebate/other compensation" to remind submitters that the fields are intended to capture manufacturer drug rebates and all other compensation conferred to the payer.
- Add a requirement that payers submit a supplement to the drug rebate file that describes the contractual arrangement they have with their pharmacy benefit manager (PBM). The supplement will be used to collect information about the:
    - PBM role in drug formulary management
    - PBM role in negotiating rebates with drug manufacturers
    - Percentage of drug manufacturer rebates and other compensation the PBM conferred to the payer

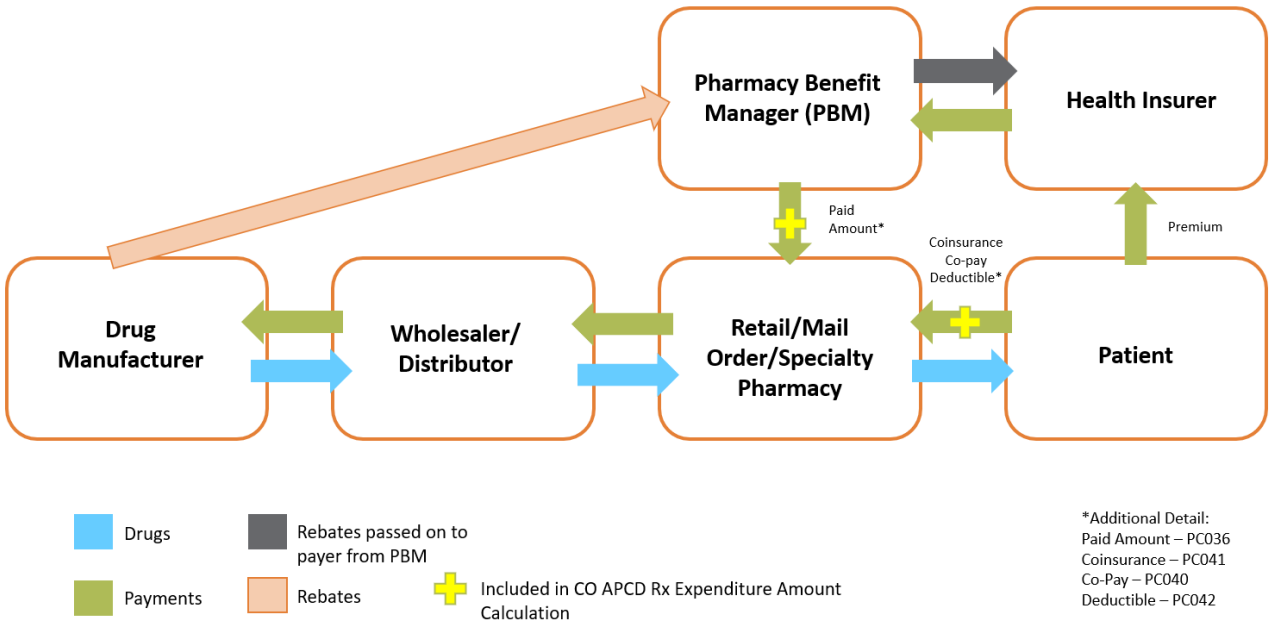
6. Data Submission of Prescription Drug Rebate Details

Prescription drug rebate files capture several types of data, including:

- Payer summary information and comments
- Member Months, for members residing in Colorado
    - A Colorado resident is defined as any eligible member whose residence is within the State of Colorado, and all covered dependents. An exception to this is subscribers covered under a student plan. In this case, any student enrolled in a student plan for a Colorado college/university would be considered a Colorado resident regardless of their address of record.
- Pharmacy Expenditures, by insurance category and generic/brand/specialty status
- Prescription Drug Rebates, by insurance category and generic/brand/specialty status
- Pharmacy Benefit Manager contract information

When reporting rebates, payers should report the total rebates and other compensation **received from the PBM**. If a payer does not utilize a PBM, then the carrier should report the total rebates and other compensation received directly from drug manufacturers.

This diagram provides a simplified illustration of the prescription drug supply chain and the flow of drugs, payments and rebates. It is a useful guide for describing drug rebate file reporting requirements. Payers with PBMs should report the total amount represented by the ***gray*** line. If the submitter is a PBM, then it should report the total amount represented by the ***orange*** line.



Rebate Data Specifications (DR Tab)

The payer is expected to record prescription drug rebate data in the Prescription Drug Rebate Submission DSG 11.5 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

Code	Insurance Type Code Description
17	Dental Maintenance Organization (DMO)
DN	Dental
HM	Health Maintenance Organization
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
SP	Medicare Supplemental (Medi-gap) plan
CP	Medicaid CHIP
MS	Medicaid Fee for service
MM	Medicaid Managed care
CS	Commercial Supplemental plan

Calendar Year (DR004): The payer must enter the calendar year for which the drug rebate data will be reported. Prescription drug rebate data should be reported based on drug fill date.

Member Population (DR005): The population for which prescription drug rebate data must be reported are covered members who are residents of Colorado. A Colorado resident is defined as any eligible member whose residence is within the State of Colorado, and all covered dependents. An exception to this is subscribers covered under a student plan. In this case, any student enrolled in a student plan for a Colorado college/university would be considered a Colorado resident regardless of their address of record. If the payer cannot report the information requested for Colorado residents only, they should contact CIVHC. This field should contain a numeric value.

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.

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. (Members for whom payers have complete expenditure and drug rebate information but whose expenditures were $0 during the calendar year because the members did not fill a prescription should be included). 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.

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.

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/Other Compensation Amount (applicable to Total Prescription Drug Rebate/Other Compensation Amount (DR011) and Rebate/Other Compensation 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, 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.).
>
> Compensation: Compensation includes, but is not limited to, discounts; credits; rebates, regardless of how categorized; fees; educational grants received from manufacturers in relation to the provision of utilization data to manufacturers for rebating, marketing and related purposes; market share incentives; commissions; manufacturer administrative fees; and administrative management fees.

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

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

Prescription Drug Rebate/Other Compensation 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.

If you expect that your organization will need to utilize the Combined Rebate Identifier field, please reach out to CIVHC.

7. Data Submission of PBM Contract Information

The PBM Contract Information tab in the Drug Rebate file captures information about the contractual arrangement a payer has with its PBM. If your organization is a PBM, then it is not necessary for you to complete this tab.

PBM Contract Information (PBM Tab)

The payer is expected to record prescription drug rebate data in the Prescription Drug Rebate Submission DSG 11.5 Excel template. Below is a description of each field.

Payer Code (PB001): The CIVHC-assigned organization ID for the payer or carrier submitting the file.

Payer Name (PB002): The name of the payer or carrier submitting the file.

Pharmacy Benefit Manager Name (PB003): The name of a pharmacy benefit manager (PBM) that provided any of the following services in a given insurance category and calendar year: claims processing, drug formulary management, or manufacturer drug rebate contracting.

Insurance Product Type Code (PB004): The insurance category being reported, according to Table B.1.A. Insurance Type of the Data Submission Guide, displayed below. Payers shall submit PBM Contract 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)
DN	Dental
HM	Health Maintenance Organization
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
SP	Medicare Supplemental (Medi-gap) plan
CP	Medicaid CHIP
MS	Medicaid Fee for service
MM	Medicaid Managed care
CS	Commercial Supplemental plan

Calendar Year (PB005): The payer must report the calendar year for which the PBM Contract information is reported. On or after January 1 and on or before December 31 for a given year.

Drug Formulary Management (PB006): Payers should identify whether an individual PBM organization performed all, some, or none of the drug formulary management for its pharmacy benefit within a given insurance category and calendar year. Payers should input one of three possible entries: All, Some, or None. If multiple PBMs provided a drug formulary management services within a given insurance category and calendar year, payers should include a separate observation for each PBM and enter "Some" for drug formulary management in each observation.

Manufacturer Drug Rebate Contracting (PB007): Payers should identify whether an individual PBM organization performed all, some, or none of the manufacturer drug rebate contracting for its pharmacy

benefit within a given insurance category and calendar year. Payers should input one of three possible entries: All, Some, or None. If multiple PBMs provided contracting services within a given insurance product type code and calendar year, payers should include a separate observation for each PBM and enter "Some" for manufacturer drug rebate contracting in each observation.

Percent Rebate Passed to Carrier (PB008): Payers should identify the percentage of total rebates and other compensation the PBM passed on to the carrier from the Drug Manufacturer. This element should be expressed in decimal form. For example, if a PBM passed on 80% of the rebates to the carrier, **0.80** should be reported in this field.

Comments (PB009): Payers may use this field to provide additional information or describe any caveats pertaining to the PBM Contract Information.

8a. Drug Rebate File Content

Drug Rebate File Header Record

Data Element #	Data Element Name	Type	Max Length	Description/valid values
HD001	Record Type	char	N/A – Excel file	DR
HD002	Payer Code	varchar	N/A – Excel file	Distributed by CIVHC
HD003	Payer Name	varchar	N/A – Excel file	Distributed by CIVHC
HD004	Beginning Month	date	N/A – Excel file	CCYYMM (Example: 200801)
HD005	Ending Month	date	N/A – Excel file	CCYYMM (Example: 200812)
HD006	Record count	int	N/A – Excel file	Total number of records submitted in the Drug Rebate file, excluding header and trailer records

Drug Rebate File Trailer Record

Data Element #	Data Element Name	Type	Max Length	Description/valid values
TR001	Record Type	char	N/A – Excel file	DR
TR002	Payer Code	varchar	N/A – Excel file	Distributed by CIVHC
TR003	Payer Name	varchar	N/A – Excel file	Distributed by CIVHC
TR004	Beginning Month	date	N/A – Excel file	CCYYMM (Example: 200801)
TR005	Ending Month	date	N/A – Excel file	CCYYMM (Example: 200812)
TR006	Extraction Date	date	N/A – Excel file	CCYYMMDD

Drug Rebate File Contents

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	R

Data Element #	Data Element Name	Type	Length	Description/Codes/Sources	Required
				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.	
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). 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)	R

Data Element #	Data Element Name	Type	Length	Description/Codes/Sources	Required
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/Other Compensation 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/Other Compensation	Numeric	N/A – Excel file	Total drug rebates, discounts and other pharmaceutical manufacturer compensation or price concession amounts for all specialty drugs. Specialty	R

Data Element #	Data Element Name	Type	Length	Description/Codes/Sources	Required
	Amount: Specialty Drugs			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.	
DR013	Prescription Drug Rebate/Other Compensation Amount: Non-Specialty Brand Drugs	Numeric	N/A – Excel file	Total drug rebates, discounts and other pharmaceutical manufacturer compensation or price concession amounts 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/Other Compensation Amount: Non-Specialty Generic Drugs	Numeric	N/A – Excel file	Total drug rebates, discounts and other pharmaceutical manufacturer compensation or price concession amounts 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

Data Element #	Data Element Name	Type	Length	Description/Codes/Sources	Required
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	Use this field to provide additional information or describe any caveats regarding data in the Drug Rebate submission.	O
DR019	Record Type	Char	2	DR	R

8b. PBM Contract Information Content

Data Element #	Data Element Name	Type	Length	Description/Codes/Sources	Required
PB001	Payer Code	varchar	N/A – Excel file	Distributed by CIVHC	R
PB002	Payer Name	varchar	N/A – Excel file	Distributed by CIVHC	R
PB003	Pharmacy Benefit Manager Name	char	N/A – Excel file	The name of a pharmacy benefit manager (PBM) that provided any of the following services in a given insurance category and calendar year: claims processing, drug formulary management, or manufacturer drug rebate contracting.	R
PB004	Insurance Product Type code	varchar	N/A – Excel file	See lookup table B.1.A Payers shall report for all insurance categories for which they have business.	R

Data Element #	Data Element Name	Type	Length	Description/Codes/Sources	Required
PB005	Calendar Year	int	N/A – Excel file	4 digit year for the calendar year time period reported in this submission	R
PB006	Drug Formulary Management?	varchar	N/A – Excel file	Identify whether an individual PBM organization performed all, some, or none of the drug formulary management for its pharmacy benefit within a given insurance category and year. Three possible responses: All, Some, None	R
PB007	Manufacturer Drug Rebate Contracting?	varchar	N/A – Excel file	Identify whether an individual PBM organization performed all, some, or none of the manufacturer drug rebate contracting for its pharmacy benefit within a given insurance category and year. Three possible responses: All, Some, None	R
PB008	Percent Rebate Passed to Carrier	decimal	N/A – Excel file	Identify the percentage of total rebates and other compensation that is passed through to the carrier from the PBM. This field should be in decimal format.	R
PB009	Comments	varchar	N/A – Excel file	Use this field to provide additional information or describe any caveats regarding data in the PBM Contract submission	O

CIVHC
CENTER FOR IMPROVING VALUE IN HEALTH CARE

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 file exemptions for their Alternative Payment Model (APM) and Drug Rebate files. This policy is intended to recognize the special circumstances for each payer (see section 4 of the Data Submission Manuals) and document their exempt status for APM or Drug Rebate submissions.

Data submitters may request a one-year waiver from submitting required file types.

For waivers of a particular file type:

- The year for which the file exemption is requested.
- The file type for which the file exemption is requested.
- An explanation as to why the data submitter is unable to submit the file.
- 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. Please submit all documentation electronically to **submissions@civhc.org**. Questions may also be directed to **submissions@civhc.org**.

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

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

Data File Name (AM, CT, DR, etc)	Detailed description of reason

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

Submitted by: _____

Name Title Date

_____

Signature

Appendix B: Sample Files

Prescription Drug Rebate Tab

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 Drugs	Total Prescription Drug Rebate Amount	Prescription Drug Rebate/Other Compensation Amount: Specialty Drugs	Prescription Drug Rebate/Other Compensation Amount: Non-Specialty Brand Drugs	Prescription Drug Rebate/Other Compensation Amount: Non-Specialty Generic Drug	Per Member Per Month Pharmacy Expenditure Amount	Per Member Per Month Prescription Drug Rebate/Other Compensation Amount	Combined Rebate Identifier	Comments	Record Type
0000	Example Insurance Company	12	2017	250,082	3,000,617	$ 309,063,551.00	$ 40,511,250.00	$ 121,533,750.00	$ 147,018,551.00	$ 37,087,626.12	$ 20,769,070.63	$ 14,093,297.93	$ 2,225,257.57	$ 103.00	$ 129.29			DR
0000	Example Insurance Company	13	2017	33,359	399,887	$ 46,786,779.00	$ 12,465,000.00	$ 25,395,000.00	$ 8,926,779.00	$ 8,421,620.22	$ 4,716,107.32	$ 3,200,215.68	$ 505,297.21	$ 117.00	$ 29.36			DR
0000	Example Insurance Company	15	2017	3,423	40,646	$ 3,983,308.00	$ 1,786,650.00	$ 1,959,950.00	$ 236,708.00	$ 1,314,491.64	$ 736,115.32	$ 499,506.82	$ 78,869.50	$ 98.00	$ 4.58			DR
0000	Example Insurance Company	HN	2017	29,190	349,974	$ 38,847,114.00	$ 6,544,125.00	$ 19,632,375.00	$ 12,670,614.00	$ 4,273,182.54	$ 2,392,982.22	$ 1,623,809.37	$ 256,390.95	$ 111.00	$ 12.21			DR
0000	Example Insurance Company	12	2018	249,198	2,990,011	$ 284,051,045.00	$ 48,613,500.00	$ 130,965,900.00	$ 104,471,645.00	$ 48,288,677.65	$ 27,041,659.48	$ 18,349,697.51	$ 2,897,320.66	$ 95.00	$ 128.38			DR
0000	Example Insurance Company	13	2018	35,444	424,929	$ 34,844,178.00	$ 14,958,000.00	$ 19,089,000.00	$ 797,178.00	$ 3,484,417.80	$ 1,951,273.97	$ 1,324,078.76	$ 209,065.07	$ 82.00	$ 29.15			DR
0000	Example Insurance Company	15	2018	4,244	50,608	$ 4,959,584.00	$ 2,143,980.00	$ 2,150,220.00	$ 665,384.00	$ 843,129.28	$ 472,152.40	$ 320,389.13	$ 50,587.76	$ 98.00	$ 4.55			DR
0000	Example Insurance Company	HN	2018	37,513	449,867	$ 48,585,636.00	$ 7,852,950.00	$ 28,208,250.00	$ 12,524,436.00	$ 5,830,276.32	$ 3,264,954.74	$ 2,215,505.00	$ 349,816.58	$ 108.00	$ 12.96			DR
0000	Example Insurance Company	12	2019	245,848	2,949,847	$ 277,285,618.00	$ 58,336,200.00	$ 125,269,794.00	$ 93,679,624.00	$ 69,321,404.50	$ 38,819,986.52	$ 26,342,133.71	$ 4,159,284.27	$ 94.00	$ 23.50			DR
0000	Example Insurance Company	13	2019	36,116	433,068	$ 42,007,596.00	$ 17,949,600.00	$ 22,263,870.82	$ 1,794,125.18	$ 11,762,126.88	$ 6,586,791.05	$ 4,469,608.21	$ 705,727.61	$ 97.00	$ 27.16			DR
0000	Example Insurance Company	15	2019	5,060	60,364	$ 5,251,668.00	$ 2,572,776.00	$ 1,982,324.44	$ 696,567.56	$ 1,628,017.08	$ 911,689.56	$ 618,646.49	$ 97,681.02	$ 87.00	$ 26.97			DR
0000	Example Insurance Company	HN	2019	43,790	525,086	$ 56,184,202.00	$ 9,423,540.00	$ 34,593,662.25	$ 12,166,999.75	$ 8,989,472.32	$ 5,034,104.50	$ 3,415,999.48	$ 539,368.34	$ 107.00	$ 17.12			DR

DR PBM

PBM Contract Information Tab

PM001	PM002	PM003	PM004	PM005	PM006	PM007	PM008	PM009
Payer Code	Payer Name	Pharmacy Benefit Manager Name	Insurance Product Type Code	Calendar Year	Drug Formulary Management?	Manufacturer Drug Rebate Contracting?	Percent Rebate Passed to Carrier	Comments
0000	Example Insurance Company	Drugs R Us	12	2017	All	Some	0.80	
0000	Example Insurance Company	Drugs R Us	13	2017	All	Some	0.80	
0000	Example Insurance Company	Drugs R Us	15	2017	All	Some	0.80	
0000	Example Insurance Company	Best Rx	MM	2017	None	Some	1.00	
0000	Example Insurance Company	Drugs R Us	12	2018	All	Some	0.85	
0000	Example Insurance Company	Drugs R Us	13	2018	All	Some	0.85	
0000	Example Insurance Company	Drugs R Us	15	2018	All	Some	0.85	
0000	Example Insurance Company	Best Rx	MM	2018	None	Some	1.00	
0000	Example Insurance Company	Drugs R Us	12	2019	All	Some	0.87	
0000	Example Insurance Company	Drugs R Us	13	2019	All	Some	0.87	
0000	Example Insurance Company	Drugs R Us	15	2019	All	Some	0.87	
0000	Example Insurance Company	Best Rx	MM	2019	None	Some	1.00	

DR PBM

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 15, 2020. Test files should include data for calendar year 2017.

Final production files are due by September 30, 2020. Production files must be submitted with data for three previous calendar years – 2017, 2018, 2019.

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 2020:
TEST_0000_2020DRv01. xlsx
PROD_0000_2020DRv02. 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 (2017, 2018 and 2019) should reported in these files.

6) What is the process for requesting waivers 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.

Please submit these waiver documents no later than July 1, 2020.

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. 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.

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 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.

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. If your organization must use this field, please contact CIVHC.

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.

18) My organization is a PBM, but the PBM Contract tab asks about a payer's relationship with a PBM. How should I approach this section of the Drug Rebate filing?

As a PBM, you are not required to complete the contract information tab. After you complete the Drug Rebate template tab, you can leave the PBM tab blank.

Appendix D: SFTP Submission Instructions

CO APCD New File Types

Submitter Instructions

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

1. File Transmission

Data submissions will be made via SFTP. Each submitting entity should have an existing SFTP connection with NORC at the University of Chicago to submit other data types to the Colorado APCD. Payers should coordinate internally to share the existing connection information. All files transferred via SFTP will be automatically linked to the payer's account based on the file name. It is important that the files be named per a standard naming convention outlined in CIVHC's Data Submission Guide to ensure that the file type and submission periods can properly be discerned.

Many tools exist for Secure File Transfer Protocol. FileZilla and WinSCP are two examples. Please refer to your program's documentation for help with setup, if needed.

Connection Information for the SFTP Server:

- Server Name: transfer.norc.org
- User: the account name issued via secure download
- Password: the SFTP password issued via secure download
- Directory: [root]/incoming/APM_CT_DR

You will NOT receive an automated email notification once the file has been received. If you have questions about whether your file has been received please contact the Help Desk (civhchelp@hsri.org).

2. File Format

Files should be submitted in Excel format (.xlsx, .xls, or .csv) through the SFTP server. These files do not contain sensitive data and therefore are not required to be compressed and encrypted. If your organization requires the encryption of files before transmission you can do so with a commercially available, payer-approved file compression and encryption software such as WinZip or 7-Zip. Files should be compressed and encrypted in 256-bit AES. The password can be obtained through the CO APCD Portal. If you do not have access to the portal please coordinate internally at you organization to obtain this information. PGP encryption will not be supported for these file types.