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Introduction

In the 2021-2022 Colorado State Legislative Session, Colorado passed SB21-175. This piece of legislation, known as the Prescription Drug Affordability Review Board, "creates the Colorado prescription drug affordability review board (board) in the division of insurance (division) in the department of regulatory agencies as an independent unit of state government, requires the board to perform affordability reviews of prescription drugs, and authorizes the board to establish upper payment limits for prescription drugs the board determines are unaffordable for Colorado consumers. The board is also required to promulgate rules as necessary for its purposes."

A portion of this legislation requires the administrator of the CO APCD to collect information from submitters related to the affordability of prescription drugs across the state.

This Data Submission Manual provides technical details to assist payers in reporting and filing the Prescription Drug Affordability Board file (PDAB). CIVHC recommends that payers coordinate efforts to complete the PDAB 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 are accurate.

Why Collect Data Related to the Prescription Drug Affordability Board?

The PDAB legislation (SB21-175) requires the following:

BEGINNING IN THE 2022 CALENDAR YEAR, FOR ALL PRESCRIPTION DRUGS (Excluding DME/Supplies; Only reporting Prescription drugs) DISPENSED AT A PHARMACY IN THIS STATE AND PAID FOR BY A CARRIER PURSUANT TO A HEALTH BENEFIT PLAN ISSUED UNDER PART 2, 3, OR 4 OF THIS ARTICLE 16 DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR, INCLUDING BRAND-NAME DRUGS, AUTHORIZED GENERIC DRUGS, BIOLOGICAL PRODUCTS, AND BIOSIMILAR DRUGS:

- a. EACH CARRIER AND EACH PHARMACY BENEFIT MANAGEMENT FIRM ACTING ON BEHALF OF A CARRIER SHALL REPORT TO THE ALL-PAYER HEALTH CLAIMS DATABASE THE FOLLOWING INFORMATION:
 - I. THE TOP FIFTEEN PRESCRIPTION DRUGS BY VOLUME, CALCULATED BY UNIT, FOR WHICH THE CARRIER PAID.
 - II. THE FIFTEEN COSTLIEST PRESCRIPTION DRUGS FOR WHICH THE CARRIER PAID, AS DETERMINED BY TOTAL ANNUAL PLAN SPENDING.
 - III. THE FIFTEEN PRESCRIPTION DRUGS PAID FOR BY THE CARRIER THAT ACCOUNTED FOR THE HIGHEST INCREASE IN TOTAL ANNUAL PLAN SPENDING WHEN COMPARED WITH THE TOTAL ANNUAL PLAN SPENDING FOR THE SAME PRESCRIPTION DRUGS IN THE YEAR IMMEDIATELY PRECEDING THE YEAR FOR WHICH THE INFORMATION IS REPORTED.
 - IV. THE FIFTEEN PRESCRIPTION DRUGS THAT CAUSED THE GREATEST INCREASES IN THE CARRIER'S PREMIUMS.

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- V. THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER PAID MOST FREQUENTLY AND FOR WHICH THE CARRIER RECEIVED A REBATE FROM MANUFACTURERS.
- VI. THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER RECEIVED THE HIGHEST REBATES, AS DETERMINED BY PERCENTAGES OF THE PRICE OF THE PRESCRIPTION DRUG.
- VII. THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER RECEIVED THE LARGEST REBATES.
- VIII. THE TOTAL SPENDING FOR EACH OF THE FOLLOWING CATEGORIES OF PRESCRIPTION DRUGS:
 - A. BRAND-NAME DRUGS PURCHASED FROM RETAIL PHARMACIES.
 - B. AUTHORIZED GENERIC DRUGS PURCHASED FROM RETAIL PHARMACIES.
 - C. BRAND-NAME DRUGS PURCHASED FROM MAIL-ORDER PHARMACIES.
 - D. AUTHORIZED GENERIC DRUGS PURCHASED FROM MAIL-ORDER PHARMACIES.
 - E. PRESCRIPTION DRUGS DISPENSED BY A PRACTITIONER IN ACCORDANCE WITH SECTION 12-280-120 (6);
 - F. PRESCRIPTION DRUGS ADMINISTERED IN AN INPATIENT HOSPITAL SETTING; AND
 - G. PRESCRIPTION DRUGS ADMINISTERED IN AN OUTPATIENT HOSPITAL SETTING; AND
- IX. THE TOTAL SPENDING FOR THE PRESCRIPTION DRUGS DESCRIBED IN SUBSECTION
 (1)(a)(VIII) OF THIS SECTION PAID FOR BY A CARRIER PURSUANT TO A HEALTH BENEFIT PLAN
 ISSUED UNDER PART 2, 3, OR 4 OF THIS ARTICLE 16 DURING THE IMMEDIATELY PRECEDING
 CALENDAR YEAR FOR EACH OF THE FOLLOWING MARKET SECTORS:
 - A. INDIVIDUAL.
 - B. SMALL EMPLOYER; AND
 - C. LARGE EMPLOYER
- b. IF THE ALL-PAYER HEALTH CLAIMS DATABASE DOES NOT COLLECT AND MAINTAIN THE DATA THAT IS REQUIRED TO BE REPORTED TO THE DATABASE PURSUANT TO SUBSECTION (1)(a) OF THIS SECTION, THE ADMINISTRATOR OF THE ALL-PAYER HEALTH CLAIMS DATABASE SHALL AMEND THE REQUIREMENTS REGARDING THE DATA TO BE SUBMITTED TO THE DATABASE PURSUANT TO SECTION 25.5-1-204 (5) TO INCLUDE THE DATA REQUIRED BY SUBSECTION (1)(a) OF THIS SECTION DURING THE NEXT UPDATE OF SUCH REQUIREMENTS, BUT NO LATER THAN JUNE 1, 2022.

While a majority of the requirements in this section can be sourced from data already submitted to the CO APCD, items IV-VII, designated in green font above, must be collected via the annual PDAB submission.

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File Submission Instructions and Schedule

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

Alternative Payment Model and Drug Rebate Data Submission Schedule			
Date	Files Due		
April 1, 2025	Waiver request due (if applicable)		
July 1, 2025	Test files of data for 2024 due		
August 1, 2025	Deadline to update contact list in Portal for each file type		
September 1, 2025	Final files due for calendar year: 2024		
November 1, 2025	Deadline for all PDAB files to pass CIVHC QC validation		
November 15, 2025	Deadline for attestation form to be signed for PDAB files		

For the 2025 submission year, PDAB files will be submitted via Excel (.xlsx, .xls, or .csv). Please see the chart below for specific instructions for each file type and links to Excel templates, if applicable. The **PDAB** file type associated with this manual is highlighted in **orange** below for your convenience.

Annual File Submission Format by File Type				
File Type	Format	Link to Template		
AM: Alternative Payment Model	.txt	AM File Template		
CT: APM Control Total	.txt	CT File Template		
AC: APM Contract (formerly 2 nd tab in CT file)	Excel	AC File Template		
CF: Member Capitation	.txt	CF File Template		
DR: Drug Rebate	.txt	DR File Template		
PB: PBM Contract (formerly 2 nd tab in DR file)	Excel	PB File Template		
PD: Prescription Drug Affordability Board	Excel	PD File Template		
VB: Value-Based Pharmacy Contract	Excel	VB File Template		

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Naming conventions should follow the template: TESTorPROD_PayerID_SubmissionYearDueFileTypeVersionNumber.txt

For example, the following naming conventions will be used for testing and production in 2025: TEST_0000_2025PDv01.xlsx PROD_0000_2025PDv02.xlsx

Waivers

CIVHC will work collaboratively with payers to ensure that required 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 **Prescription Drug Affordability Board** 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 does not receive rebates for clinician/medically administered drugs.

*It is REQUIRED for all payers that provide prescription drug benefits to submit PDAB data to the CO APCD and they cannot waive out of this requirement.

Please see Appendix A for instructions for filing a waiver and waiver form. Please see Appendix B for updated criteria around what is considered a Health Benefit Plan and who must submit PDAB data.

Changes to the PDAB Submission Manual

The following are changes to this Prescription Drug Affordability Submission Manual, which were adopted following the Data Submission Guide v16 Rule Hearing on October 30, 2024.

PD003 – Additional clarification added for Immediately Preceding Year (Paid_Date_Year)

Data Submission of PDAB - Details

The submission of PDAB data involves the completion of one file labeled "PD." Below is a description of each field.

Payer Code (PD001): The CIVHC-assigned organization ID for the payer or carrier submitting the file.

Payer Name (PD002): The name of the payer or carrier submitting the file.

Year (PD003): Four-digit year immediately preceding submission. This data should be pulled using Paid Date Year.

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Legislative Reference (PD004): The legislative reference code that a drug falls under according to Table B.1.P PDAB Legislative Reference of the Data Submission Guide, displayed below.

Code	Legislative Reference Description
IV	The fifteen prescription drugs that caused the greatest increases in the carrier's premiums
V	The fifteen prescription drugs for which the carrier paid most frequently and for which the carrier received a rebate from manufacturers.
VI	The fifteen prescription drugs for which the carrier received the highest rebates, as determined by percentages of the price of the prescription drug
VII	The fifteen prescription drugs for which the carrier received the largest rebates

Rank (PD005): Drug rank of 1-15 for the drugs listed for each Legislative Reference in PD004.

NDC (National Drug Code) (PD006): 11-digit NDC of associated drug associated with PD004. NDCs should not repeat within a Legislative Reference.

Drug Name (PD007): Name of drug associated with NDC in PD006.

Note that CIVHC is <u>not</u> prescribing a detailed methodology for each legislative requirement. Instead, CIVHC requests a detailed methodological description to be submitted as an additional tab in the PDAB submission. CIVHC will utilize the submitted methodological information to develop specifications into the future.

Member Population Included

Per Colorado regulation 10 CCR 2505-5 1.200, Payers are required to submit data to the CO APCD under the following conditions:

- 1. The Payer has 1,000 or more Colorado residents covered under a fully insured health plan **OR**
- 2. The Payer has 100 or more Colorado residents covered under a self-insured employer-sponsored plan not subjected to ERISA.

Once either of the above thresholds has been met, Payers should submit data for all Colorado residents covered under these plans.

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Payers should only include information for members for which they are the primary payer and exclude any paid claims for which they are the secondary or tertiary payer.

PDAB File Content

Submitted to CIVHC via SFTP in Excel file format. Please populate the template for submission.

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Data Element #	Data Element Name	Туре	Length	Description/Codes/Sources	Required
PD001	Payer Code	varchar	N/A – Excel file	Distributed by CIVHC	R
PD002	Payer Name	varchar	N/A – Excel file	Distributed by CIVHC	R
PD003	Year	varchar	N/A – Excel file	Immediately preceding year (Paid_Date_Year)	R
PD004	Legislative Reference	varchar	N/A – Excel file	See table B.1.P	R
PD005	Rank	varchar	N/A – Excel file	Populate field with rank of 1-15	R
PD006	NDC	varchar	N/A – Excel file	11-digit NDC of associated drug (Do not repeat NDC within a single legislative reference)	R
PD007	Drug Name	varchar	N/A – Excel file	Name of associated NDC	R

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Appendix A: Waiver Instructions and Form

Data Submitter Request Form

Waiver of Annual File Submissions



↔			
	Waiver Submission Tracking		
	Annual File Submission Year:	YYYY	
	Data Submitter Code/Name (<u>one</u> per form):	0000 Entity Name	
	Submitter Contact Name:		
	Submitter Contact Email:		
	Date of Form Submission to CIVHC:		
	Date of CIVHC Decision:	Compliance Decision on	

The Center for Improving Value in Health Care (CIVHC), in its role as the Colorado All Payer Claims Database (CO APCD) Administrator, will work collaboratively with CO APCD Data Submitters to support their compliance with regulatory submission requirements.

In addition to monthly file submissions, Data Submitters must submit eight (8) more files on an annual basis related to drug rebates and Alternative Payment Models (APMs). These submission requirements are defined in <u>C.R.S. 10-16-1405</u> and CO APCD governing statute <u>10 CCR 2505-5-1.200</u>. Details about annual files' structure and content can be found in the <u>Data Submission Guide</u> and related <u>Data Submission Manuals</u>.

To be considered for <u>waiver</u> from the annual file submission requirement for one year, Data Submitters must complete the following:

- Indicate on pages 2 and 3 of this form which files are requested waived from the annual submission requirement and provide the reason for waiver request.
- 2. Read the Agreement to Waiver Conditions included in this document.
- 3. Certify this form with a signature from the organization's authorized signatory (e.g., Chief Information Officer, Regulatory Compliance Officer, etc.) asserting that the Data Submitter cannot meet the submission requirements because the requested information is not available and cannot be derived from the Data Submitter's information systems.
- Submit this form to <u>Submissions@CIVHC.org</u> no later than April 1 to be considered for production files due September 1 of the same calendar year.

This form will be returned with CIVHC's decision to the Data <u>Submitter</u> by June 1 of the calendar year in which it is submitted. An approved waiver applies only to the submission year in which it is approved (i.e., a new waiver request must be submitted every calendar year).

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Data Submitter Request Form

Waiver of Annual File Submissions



Waiver Request Details

See the CIVHC's <u>Submitter Resources</u> web page for the below files' respective Data Submission Manuals.

The Data Submitter named in this document requests waiver of the annual submission requirement for the following file(s):

Alternative Payment Model (APM) Files					
File Abbreviation and Name	Reason for Waiver Request				
☐ AM − APM File¹	Choose an item.				
	CIVHC Decision:	☐ Approved	☐ Denied		
☐ CT — APM Control Total ¹	Choose an item.				
	CIVHC Decision:	☐ Approved	☐ Denied		
☐ AC – APM Contract Information¹	Choose an item.				
	CIVHC Decision:	☐ Approved	☐ Denied		
Drug Rebate (DR) Files					
	Drug Rebate (DR)	Files			
File Abbreviation and Name	Drug Rebate (DR) Reason for Waiver				
File Abbreviation and Name DR – Drug Rebate Data ¹					
	Reason for Waiver		☐ Denied		
	Reason for Waiver Choose an item.	Request	☐ Denied		
☐ DR — Drug Rebate Data ¹	Reason for Waiver Choose an item. CIVHC Decision:	Request	☐ Denied		
☐ DR — Drug Rebate Data ¹	Reason for Waiver Choose an item. CIVHC Decision: Choose an item.	Request			

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 $^{^{1}}$ Annual submission requires the three (3) calendar years preceding the reporting year (e.g, the 2025 submission will include files for 2022, 2023, and 2024 reporting years).

² Submission is required under <u>C.R.S. 10-16-1405</u>: "Each carrier and each pharmacy benefit management firm acting on behalf of a carrier shall report to the all-payer health claims database."

 $^{^{3}}$ Annual submission requires one (1) calendar year preceding the submission year (e.g., the 2025 submission will include the 2024 reporting year).

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□ VB – VBPC Collection	Choose an item.		
Information ⁴	CIVHC Decision:	☐ Approved	☐ Denied
	Other Files		
File Abbreviation and Name	Reason for Waiver	Request	
Collection Information ¹	Profession Facility Ca Behaviora Global Cap Payment t Comprehe	Health Capitation itation o Integrated nsive Payment and I capitation	Delivery Systems
	CIVHC Decision:	☐ Approved	☐ Denied
Additional Co	omments from Data	Submitter (Optional)	
	nal Comments from C	IVHC (Optional)	
Additior			

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Data Submitter Request Form

Waiver of Annual File Submissions



Agreement to Waiver Conditions

- This Agreement to Waiver Conditions ("Agreement") is made and entered as of the date of the last signature obtained below (the "Effective Date") by and between CIVHC, in its capacity as the CO APCD Administrator, and the submitting entity named in this document ("Data Submitter").
- The Data Submitter requests, and CIVHC hereby grants, waiver from the annual submission requirement of the file(s) selected by the Data Submitter under Waiver Request Details ("Waiver") and marked with CIVHC Decision "Approved."
- The Data Submitter acknowledges and agrees that the Waiver granted under this Agreement will
 remain in effect only through SELECT DATE, or until such time as the Data Submitter is reasonably
 able to submit the required annual files in accordance with the Data Submission Guide ("DSG"),
 whichever is earlier.
- 4. The Data Submitter acknowledges and agrees that the Waiver granted under this Agreement is temporary in nature, effective only for the term described in the previous provision and granted based on current systematic issues or limitations that, according to CIVHC's understanding and under CIVHC's sole discretion, prevent the Data Submitter from complying with the DSG.
- 5. The granting of any Waiver, under this Agreement or otherwise, provides no guarantee of the approval or granting by CIVHC of any future request for Waiver from the Data Submitter.
- As a condition of being granted this Waiver, the Data Submitter agrees that it will act in a reasonable
 and diligent manner to correct the systematic issues or limitations that prevent it from complying
 with the DSG as soon <u>as reasonably</u> possible.
- 7. By signing this Agreement, the Data Submitter certifies that it cannot currently meet the DSG's requirements because (a) the required data is not reasonably available within Data Submitter's systems, and/or (b) the required data cannot be reasonably derived from data that is available within Data Submitter's systems.

Data	a Submitter Acknowledgement	CIVHC Acknowledgement	
Signature:		Signature:	
Name:		Name:	
Title:		Title:	
Date:		Date:	

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replacement of the PDAB requirement



Appendix B: Additional Information Regarding Criteria for Submission of PDAB Data

DOI defines a health benefit plan as "any hospital or medical expense policy or certificate, hospital or medical service corporation contract, or health maintenance organization subscriber contract or any other similar health contract subject to the jurisdiction of the commissioner available for use, offered, or sold in Colorado." as stated under 10-16-102(32)(a)-(b), C.R.S. Additionally, under (32)(b) it defines what a "health benefit plan" does not include as:

*Submitters that fall under one of the categories above are able to submit an exemption wa	aiver in
(XII) Specified disease, hospital confinement indemnity, or limited benefit health insurance if coverage	the types of
(XI) Automobile medical payment insurance; or	
(X) Coverage issued as a supplement to liability insurance, workers' compensation, or similar	insurance;
(IX) Coverage for on-site medical clinics;	
(VIII) Liability insurance including general liability insurance and automobile liability insurance	e;
(VII) Disability income insurance;	
(VI) Benefits for long-term care, home health care, community-based care, or any combination	on thereof;
(V) Medicare supplement;	
(IV) Vision;	
(III) Dental;	
(II) Credit;	
(I) Accident only;	

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Appendix C: Sample File

Data Tab:

PD001	PD002	PD003	PD004	PD005	PD006	PD007
Payer Code	Payer Name	Year	Legislative Reference	Rank	NDC	Drug Name
0000	Example Payer	2024	IV	1	23333333333	Drug TT
0000	Example Payer	2024	IV	2	34444444444	Drug UU
0000	Example Payer	2024	IV	3	4555555555	Drug VV
0000	Example Payer	2024	IV	4	56666666666	Drug WW
0000	Example Payer	2024	IV	5	6777777777	Drug XX
0000	Example Payer	2024	IV	6	78888888888	Drug YY
0000	Example Payer	2024	IV	7	89999999999	Drug ZZ
0000	Example Payer	2024	IV	8	90000000000	Drug AAA
0000	Example Payer	2024	IV	9	10000000000	Drug BBB
0000	Example Payer	2024	IV	10	20000000000	Drug CCC
0000	Example Payer	2024	IV	11	30000000000	Drug DDD
0000	Example Payer	2024	IV	12	40000000000	Drug EEE
0000	Example Payer	2024	IV	13	50000000000	Drug FFF
0000	Example Payer	2024	IV	14	60000000000	Drug GGG
0000	Example Payer	2024	IV	15	70000000000	Drug HHH
0000	Example Payer	2024	V	1	80000000000	Drug III

Methods Tab:

Legislative Reference	Methodology Description		
n.	Provide methodological detail on legislative reference IV (Top 15 drugs		
IV	that caused greatest increases in carrier's premiums). Provide methodological detail on legislative reference V (Top 15 drugs for		
V	which the carrier paid most frequently and for which the carrier received a rebate from manufacturers).		
	Provide methodological detail on legislative reference VI (Top 15 drugs for which the carrier received the highest rebates, as determined by		
VI	percentages of the price of the prescription drug).		
VII	Provide methodological detail on legislative reference VII (Top 15 drugs for which the carrier received the largest rebates).		
	lethods (+)		

Link: PDAB (PD) Scenario File

Appendix D: Frequently Asked Questions

1) When is each file due?

Test files for PDAB submissions are due by July 1, 2025. Test files should include data for calendar year 2024.

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Final production files are due by September 01, 2025. Production files must be submitted with data for the previous calendar year (2024).

Please use 'Paid Date Year' when submitting 'Calendar Year' data.

2) How should the PDAB files be submitted and named?

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

TESTorPROD_PayerID_SubmissionYearDueFileTypeVersionNumber.FileExtension

Naming conventions should follow the template:

 $TESTor PROD_Payer ID_Submission Year Due File Type Version Number. File Extension$

For example, the following naming conventions will be used for testing and production in 2025:

TEST_0000_2025PDv01.xlsx PROD 0000 2025PDv02.xlsx

3) What is the objective for collecting PDAB data?

The objective for collecting PDAB data is to satisfy legislative requirements identified in SB21-175 and allow the Prescription Drug Affordability Board to make informed decisions on matters related to prescription drugs in Colorado.

4) What is the process for requesting waivers to the PDAB file submission requirements?

Please complete the form shown in Appendix A, "Data Submission Waiver Instructions - APM and Drug Rebate Files" and email it to submissions@civhc.org. CIVHC will review the document return to the submitter with the waiver decision. If approved, CIVHC will complete the Data Submission Waiver Agreement and Acknowledgement section. CIVHC will then provide this document to you for your records. If the waiver is not approved, CIVHC will send back form with comments to the submitter.

Please submit these waiver documents no later than April 1, 2025.

5) 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 perform a series of checks to ensure the submitted data passes various validation criteria. These checks may involve aggregation of CO APCD data sourced from the ME or PC files.

6) What methodology should my organization use to produce the required information?

CIVHC is not providing detailed methodological instructions for the PDAB submission. Instead, CIVHC requests that carriers provide their organization's specific methods used to produce the reported information in the PDAB file as a separate Methodology tab. Please refrain from using filler language.

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CIVHC will continue to analyze and collate the methodologies across carriers to provide detailed instruction for future collection efforts.

7) Can my organization submit Durable Medical Equipment (DME) in our PD data?

No. DME, or Durable Medical Equipment are **NOT** to be included in the PD data file submission. The PD file submission should only contain prescription drugs.

This can be a bit confusing in reference to diabetes supplies. Anything that contains a pre-filled prescription medication embedded within the device, such as Cosentyx Sensoready Pens, or the Lantus Solostar Insulin Pens, are allowed in the PD file. This is because their NDC code corresponds to a prescription drug.

Durable Medical Equipment that aids in testing, monitoring, etc., but does NOT have a prescription medication embedded within it are NOT allowed.

Below are examples of non-allowable Durable Medical Equipment that we have received in past submissions. Submission of any DME will result in failure of the file, and a request for resubmission.

NDC	Drug Name
08627001601	DEXCOM G6 TRANSMITTER
08627005303	Dexcom G6 Sensor
08627007801	Dexcom G7 Receiver
08627009111	DEXCOM G6 MIS RECEIVER
53885004401	ONETOUCH VERIO FLEX METER
53885004601	ONETOUCH ULTRA2
53885024450	OneTouch Ultra Test
53885024510	ONETOUCH ULTRA
53885027025	OneTouch Verio
53885027210	OneTouch Verio
53885044801	ONETOUCH ULTRA2
53885065701	ONETOUCH VERIO METER
53885092701	ONETOUCH VERIO REFLECT METER
53885099425	ONETOUCH ULTRA TEST STRIP
56151146001	TRUE METRIX GLUCOSE TEST STRIP
56151147002	TRUE METRIX BLOOD GLUCOSE MTR
57599000101	FreeStyle Libre 14 Day Sensor
57599081800	FreeStyle Libre 3 Sensor
57599881401	Precision Xtra
65702040810	ACCU-CHEK AVIVA PLUS
65702061710	ACCU-CHEK GUIDE MONITOR SYSTEM
65702071210	ACCU-CHEK GUIDE TEST STRIPS
65702072910	ACCU-CHEK GUIDE MONITOR SYSTEM
65702073110	ACCU-CHEK GUIDE ME GLUCOSE MTR
99073070805	FREESTYLE LITE METER
99073070827	FreeStyle Lite Test
99073070914	FreeStyle Freedom Lite

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Appendix E: 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
- Annual Test files in .xlsx format (PD)
- [root]/incoming/AnnExcelProdPortal
- Annual Prod files in .xlsx format (PD)
- [root]/incoming/AnnExcelProdPortal

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 your organization to obtain this information. PGP encryption will not be supported for these file types.

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Appendix F: CO APCD Data Submission Guide Version 16 Testing Instructions

Last Updated: June 23, 2025

Introduction

This document contains your instructions to begin testing APM File (AM), Control Total (CT), APM Contract Supplement (AC), Drug Rebate (DR), PBM Contract Supplement (PB), Value Based Purchasing Contract (VB), and Member Capitation (CF) files in the Data Submission Guide Version 16 format for the Colorado APCD.

Data Submission Guide Version 16 Overall Implementation Timeline

DSG 16 Timeline			
Task	Due Date	Complete	
Payer Connect Calls	Bimonthly	Ongoing	
Request for DSG feedback (monthly and annual files)	Ongoing	✓	
Initial Payer feedback due	8/1/2024	✓	
CIVHC distribute updated DSG 16 draft based on stakeholder feedback	9/1/2024	✓	
CIVHC File Rule Packet with HCPF	10/4/2024	✓	
Public Review Meeting	10/30/2024	✓	
Executive Director Hearing	11/22/2024	✓	
Rule Effective	3/1/2025	✓	
Annual Override Reset	2/28/2025	✓	
Monthly Data Files (ME, MC, PC, MP) Testing and Impler	mentation		
Submitter testing of DSG v16 in Test Portal (ME, MP, MC, PC)	6/2 – 6/20	√	
April 2025 due in DSG v15 in Production Portal	6/1/2025	✓	
April 2025 Submissions Must be in a Status of Validation Passed	6/15/2025	✓	
Production Portal closed for upgrades. DSGv15 format no longer accepted. Files submitted in DSGv16 format between 6/24 and 6/25 will be processed on 6/26/2025	6/23/2025	✓	
DSG v16 Production Portal Go Live	6/26/2025		
May 2025 Submissions Due in DSG v16 – no less than 120 days after Rule Effective Date	7/1/2025		
May 2025 Submissions Must be in a Status of Validation Passed	7/15/2025		
Annual Data File (AM, CT, DR, AC, VB, PD, PB) Testing and Im	plementation		
Annual File Submission Waivers Due	4/1/2025	✓	
Test files with 2022, 2023, 2024 data due (AM, CT, AC, DR, PB)	7/1/2025		
Test files with 2021, 2022, 2023, 2024 data due (VB)			
Test files with 2024 data due (PD, CF)			
Production files with above reporting data by file type due	9/1/2025		
PLEASE NOTE: If you are onboarding to the CO APCD follow the timeline discu	ssed with CIVHC and HSRI.		

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Testing Requirements

7/1/2025 - 7/15/2025

- Transmit properly named, compressed, and encrypted files via SFTP to the appropriate directory (see details below).
- During this testing period you will test annual file submissions, with test files to be submitted and passing all intake validations by July 15th.
- Review all validation results and resolve all structural and failure-level validation issues by resubmission

Please note we have made updates to the Test SFTP folder directories:

- Annual Files in .txt format (AM, CT, CF, DR) should be transmitted to: [root]/incoming/AnnTxtProdPortal
- Annual Files in .xlsx format (VB, AC, PB, PD) should be transmitted to: root]/incoming/AnnExcelProdPortal

Overview of Testing Steps

- 1. **Prepare Annual files in DSG v16 Format:** Properly name files "TEST" according to the file naming convention outlined in DSG v16. Submit each file type typically required to submit.
- 2. **Compression and Encryption of File(s):** Compress and encrypt your data files using the same method as used in production (256-bit AES or PGP).
- 3. **Transfer of Compressed and Encrypted File(s) via SFTP:** Transfer the compressed and encrypted files via the SFTP server transfer.norc.org. **See above details for new test folder directories**.
- 4. **Portal Login:** Login to the CO APCD Test Portal: https://coapcd.norc.org. All production portal (https://coapcd.norc.org) user account credentials have been copied to the test portal for use. If you do not have an account or have issues logging into the Test Portal, please contact the Help Desk (civhchelp@hsri.org).
- 5. **Review and Resolve Validation Issues:** After receiving a notification email, login and review validation issues. Resolve structural and failure-level validation issues.

Step 1: Prepare Annual files in DSG v16 Format.

Name **annual files** according to the file naming convention outlined in DSG v16: TEST_PayerID_SubmissionYearDueFileTypeVersionNumber.txt

- TEST: "TEST" for test files
- Payer ID: This is the four-digit payer ID assigned to each submitter
- Submission year due, expressed as CCYY (four-digit calendar year).

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- File Type APM File (AM), Control Total (CT), APM Contract Supplement (AC), Member Capitation (CF), Drug Rebate (DR), PBM Contract Supplement (PB), PDAB (PD), Value Based Purchasing Contract (VB), Member Capitation (CF).
- Version number: Used to differentiate multiple submissions of the same file. This is important when a file must be resubmitted to resolve an issue, such as a validation failure. The letter v should be used, followed by two digits, starting with v01. Please include the leading zero. Original submissions of all files should be labeled v01. The Portal will not accept files that have the same name as an existing file.
- File extension (.xlsx for PD, PB, AC and VB files, .txt for AM, CT, DR and CF files)
- Example: TEST_0000_2025AMv01.txt

Step 2: Compression and Encryption of File(s)

Data Preparation

To ensure the security of personally identifiable information and personal health information, and to reduce file transmission times, we require submitters to compress and encrypt all files before submission. Compress and encrypt your data files using the same method as used in production (256-bit AES or PGP).

Step 3: Transfer of Compressed and Encrypted File(s) via SFTP

Data submissions will be made via SFTP.

All files transferred via SFTP will be automatically associated with the submitter account based on the file name. It is important that the files be named per the standard naming convention outlined in CIVHC's Data Submission Guide Version 16 to ensure that the file type and submission periods can properly be discerned.

- Annual Files in .txt format (AM, CT, DR, CF) should be transmitted to: [root]/incoming/AnnTxtProdPortal
- Annual Files in .xlsx format (VB, AC, PB, PD) should be transmitted to: [root]/incoming/AnnExcelProdPortal

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

• Folder Name: see above

• User: Production username

Password: Production password

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Step 4: Portal Login

You will receive an email notifying you of the file status once the validation is complete. At that time, login to the CO APCD Production Portal to track the progress of your file. If you have any issues logging in, contact the CIVHC Help Desk.

Step 5: Submission Notification, Review and Resolve Validation Issues

As part of this testing period, we expect you to review the validation results and resolve structural and failure level validation issues by resubmitting a corrected file. The override functionality will be disabled for profile, ad hoc, and exemption level validation issues. Continue reading for details.

Once a file has been submitted via SFTP you will receive a notification that it has been received and is being processed. Files will then be evaluated against a set of data validations before they can proceed for further quality assurance checks. You will receive an email notifying you of the file status once the validation is complete. The validations and validation issues will all be viewable within the Production Portal. Login to the Production Portal and navigate to the Submissions menu to track the progress of your file. When files complete processing, they will display a Status of "Error", "Failed", or "Validation Passed".

Processing typically takes under an hour, but we guarantee it will happen within 24 hours. If your submission does not reach one of these statuses within 24 hours and/or you do not receive an email, please contact the Help Desk so that we can investigate. If the validation failed, you would then log in to the Production Portal to view details of the validation results.

Files with a "Validation Failed" status mean your file has failed one or more data intake validations. When this is the case, you will need to click on "Details" to see what the specific issues are. This will take you to a list of issues in the file.

- Structural Level Validation Issues: If there are issues with an Issue Type of "Structural", you will need to resolve these before moving on to other issues. Most structural issues cannot be overridden. Structural issues tend to involve file structure and formatting of fields such as too many characters or are in direct conflict with the specification in the Data Submission Guide. You can see additional information about a validation by clicking on "Details". For most structural validations, you will see a message indicating that the error needs correction in the file and will thus need resubmission.
- **Failure Level Validation Issues:** Issues of type "Failure" cannot be overridden. They typically involve an intrinsic issue with the format of the data and will need to be fixed and resubmitted.
- **Profile Level Validation Issues:** Issues of type "Profile" represent validations that vary by book of business and can be overridden with a clear explanation of why you consider the data of sufficient quality. Subsequent failures on the same validation rule will be automatically overridden for the remainder of the calendar year once a Profile override has been established.

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- Exemption Level Validation Issues: Issues of type "Exemption" can be overridden but require approval from CIVHC. Requesting an override for these issues will require you to supply a time for which you believe you will need the exemption. All overrides are reset yearly, so if you need an exemption past December of a given year, you will need to submit a new request the following year, if your data continues to fail the validation.
- Ad Hoc Level Validation Issues: Issues of type "Ad Hoc" may be overridden without the need for CIVHC approval. However, unlike Profile overrides, Ad Hoc overrides will not persist for subsequent failures on the same validation rule such that submitters will need to provide an explanation whenever criteria for such a rule are not met.

Files with a "Validation Passed" status have passed our data intake validations and will move on to the level II data quality validation process.

Feedback and Questions

If you encounter any issues during testing, please contact the CIVHC Help Desk at civhchelp@hsri.org.

Resources

CO APCD User Manual: https://coapcd-test.norc.org/Home/UserManual

CO APCD Frequently Asked Questions: https://coapcd-test.norc.org/Home/FAQ