

Title of Rule: Revision to the Executive Director of the Department of Health Care Policy and Financing Rule Concerning All-Payers Claims Database, Section 1.200

Rule Number: ED 22-09-16-A

Division / Contact / Phone: Health Care Policy and Financing/Health Information Office / HCPF- Chris Underwood, 303-866-4766 / CIVHC - Kristin Paulson 720-583-2095

STATEMENT OF BASIS AND PURPOSE

1. Summary of the basis and purpose for the rule or rule change. (State what the rule says or does and explain why the rule or rule change is necessary).

As the Colorado All Payer Claims Database (CO APCD) administrator, CIVHC began conversations with the submitters regarding the rule change in the Spring of 2022. The goals of the proposed updates to the Data Submissions Guide (DSG) are to:

- Improve the quality and completeness of submitted data in order to effectively affirm the integrity and credibility of the Colorado All Payer Claim Database (CO APCD);
- Allow for the collection of the member eligibility, medical claims (includes dental), pharmacy claims and provider files to be collected through the submission portal feed; and
- Collect additional information to advance the Triple Aim of health care to lower costs, improve outcomes, and improve care across Colorado.

CIVHC sent the proposed Rule language and revised DSG to all data submitters on 7/15/2022. CIVHC hosted a webinar 8/17/2022 and presented the proposed changes to DSG v 14. More than 40 representatives from over 20 data submitters attended the webinar and had opportunity to ask questions and discuss the proposed changes with CIVHC. Submitters raised questions around collecting vision data and alignment of the DSG to the APCD Common Data Layout, asking if either had been reflected in the initial DSG v14 draft distributed on 7/15/2022.

After the webinar, CIVHC proactively coordinated with stakeholders to continue updating the submission guide to incorporate appropriate changes. CIVHC produced 3 more drafts on 8/31/2022, 9/22/2022, and 9/27/2022.

2. An emergency rule-making is imperatively necessary

- to comply with state or federal law or federal regulation and/or
- for the preservation of public health, safety and welfare.

Explain:

n/a

3. Federal authority for the Rule, if any:

Initial Review

Proposed Effective Date

01/30/22

Final Adoption

Emergency Adoption

11/29/22

DOCUMENT #01

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n/a

4. State Authority for the Rule:

Section 25.5-1-108, C.R.S. (2022);
§ 25.5-1-204(9), C.R.S.

Initial Review
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REGULATORY ANALYSIS

1. Describe the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

Private and public payers who submit data to the CO APCD using Data Submission Guide Version 14 will need to modify their current file formats to accommodate the proposed changes. CIVHC and stakeholders requesting data from the CO APCD will benefit from more comprehensive data that supports the Triple Aim: better health, better care, lower costs.

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

Over 40 payers will need to commit time and resources to amend their file submissions. However, the state would benefit from this rule change because the additional information would improve analysis and contribute to a better understanding of health costs and population health.

3. Discuss the probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

This amendment will have no impact on state appropriations.

4. Compare the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

The state will not incur any costs due to action or inaction. The state would benefit from this rule change because the additional information would improve analysis and contribute to a better understanding of health costs and population health. The rule change will allow CIVHC and the state to collect and investigate spending data, measure utilization to help identify strategies to curb healthcare spending growth.

5. Determine whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

There are no less costly or intrusive strategies to achieve the purpose of the proposed rule.

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6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

None.

1 **1.200 ALL-PAYERS CLAIMS DATABASE**

2 **1.200.1 Definitions**

3 “administrator” means the administrator of the APCD appointed by the director of the department.

4 “APCD” means the Colorado All-Payer Claims Database.

5 “Alternative Payment Model (APM) file” means a detailed file that captures payments made to providers
6 outside of the traditional fee-for-service model. This includes: Foundation Payments for Infrastructure and
7 Operations, Pay for Reporting, Pay for Performance, Shared Savings, Shared Savings and Downside
8 Risk, Risk Based Payments NOT Linked to Quality, Condition-Specific Population-Based Payment,
9 Comprehensive Population-Based Payment, Integrated Finance and Delivery Systems, and Capitated
10 Payments NOT Linked to Quality. APM files are submitted according to the requirements contained in the
11 submission guide.

12 “APM Contract Supplement file” means a file that captures qualitative information related to alternative
13 arrangements between carriers and providers; submitted according to the requirements contained in the
14 submission guide.

15 “Anti-trust safety zone” means the exchange of information that antitrust agencies have identified as
16 unlikely to raise substantial concerns if: 1) the exchange is managed by a third-party, like a trade
17 association; 2) the information provided by participants is more than three months old; *and* 3) at least five
18 participants provide the data underlying each statistic shared, no single provider’s data contributes more
19 than 25% of the “weight” of any statistic shared, and the shared statistics are sufficiently aggregated that
20 no participant can discern the data of any other participant.

21 “control total file” means a file that captures aggregated data related to payments made to providers
22 outside of the traditional fee-for-service model. This includes: Foundation Payments for Infrastructure and
23 Operations, Pay for Reporting, Pay for Performance, Shared Savings, Shared Savings and Downside
24 Risk, Risk Based Payments NOT Linked to Quality, Condition-Specific Population-Based Payment,
25 Comprehensive Population-Based Payment, Integrated Finance and Delivery Systems, and Capitated
26 Payments NOT Linked to Quality. APM files are submitted according to the requirements contained in the
27 submission guide.

28 “dental claims data file” means a file that includes data about dental claims and other encounter
29 information, according to the requirements contained in the submission guide.

30 “department” means the Colorado Department of Health Care Policy and Financing.

31 “director” means the Executive Director of the department.

32 “eligibility data file” means a file that includes data about a person who receives health care coverage
33 from a payer, according to the requirements contained in the submission guide.

34 “ERISA” means the Employee Retirement Income Security Act of 1974, as codified at 29 U.S.C. ch. 18.

35 “HIPAA” means the Health Insurance Portability and Accountability Act, U.S.C. § 1320d – 1320d-8, and
36 its implementing regulations, 45 C.F.R. Parts 160, 162 and 164, as may be amended.

37 “historic data” means eligibility data file(s), medical claims data file(s), pharmacy file(s) and provider file(s)
38 for the period commencing January 1, 2009 through December 31, 2014 (except in the case of a self-

- 1 insured employer-sponsored health plan, in which case, “historic data” shall mean, at minimum, such data
2 file(s) for the period commencing January 1, 2015 through December 31, 2015).
- 3 “medical claims data file” means a file that includes data about medical claims and other encounter
4 information, according to the requirements contained in the submission guide.
- 5 “payer” means a private health care payer and a public health care payer.
- 6 “pharmacy benefit manager contract information file” means a file that includes information related to
7 contracts between carriers and pharmacy benefit managers; and is submitted according to the
8 requirements contained in the submission guide.
- 9 “pharmacy file” means a file that includes data about prescription medications and claims filed by
10 pharmacies, according to the requirements contained in the submission guide.
- 11 “prescription drug affordability board file” means a file that includes required information about
12 prescription drugs as outlined in SB21-175; and is submitted according to the requirements contained in
13 the submission guide.
- 14 “Prescription Drug Rebate” means aggregated information regarding the total amount of any prescription
15 drug rebates and other pharmaceutical manufacturer compensation or price concessions paid by
16 pharmaceutical manufacturers to a payer or their pharmacy benefit manager(s).
- 17 “private health care payer” means an insurance carrier as defined in C.R.S. § 10-16-102(8) covering an
18 aggregate of 1,000 or more enrolled lives in health coverage plans as defined in C.R.S. § 10-16-102(34).
19 For purposes, of this regulation, “private health care payer” includes carriers, third-party administrators,
20 administrative services only organizations, and pharmacy benefit managers offering health benefits plans
21 under C.R.S. § 10-16-102(32)(a), dental, vision, pharmacy, Medicare Advantage, Medicare supplemental
22 plans, limited benefit health insurance, or short-term limited-duration health insurance. For the purposes
23 of this regulation, a “private health care payer” also means a self-insured employer-sponsored health or
24 pharmacy plan covering an aggregate of 100 or more enrolled lives in Colorado if the employer is not
25 subject to ERISA. It does not include a self-insured employer-sponsored health or pharmacy plan if the
26 employer is subject to ERISA; carriers offering accident only; credit; benefits for long term care, home
27 health care, community-based care, or any combination thereof under Article 19 of Title 10; disability
28 income insurance; liability insurance including general liability insurance and automobile liability
29 insurance; coverage issued as a supplement to liability insurance; worker’s compensation or similar
30 insurance; or automobile medical payment insurance, specified disease, or hospital indemnity and other
31 fixed indemnity insurance.
- 32 “protected health information” shall have the same meaning as in the HIPAA Privacy Rule in 45 C.F.R. §
33 160.103.
- 34 “provider file” means a file that includes additional information about the individuals and entities that
35 submitted claims that are included in the medical claims file; and is submitted according to the
36 requirements contained in the submission guide.
- 37 “public health care payer” means the Colorado Medicaid program established under articles 4, 5 and 6 of
38 title 25.5, C.R.S., the children’s basic health plan established under article 8 of title 25.5, C.R.S. and
39 Cover Colorado established under part 5 article 8 of title 10, C.R.S.
- 40 “self-funded employee health plans” means health plans where the financial risk associated with medical
41 claims is held by the organization sponsoring the health coverage.

1 “submission guide” means the document entitled “Colorado All-Payer Claims Database Data Submission
2 Guide” developed by the administrator that sets forth the required schedules, data file format, record
3 specifications, data elements, definitions, code tables and edit specifications for payer submission of
4 eligibility data files, medical, dental and pharmacy claims data files and provider data files to the APCD
5 dated Version ~~1.4.3 January~~ October 2022, which document is hereby incorporated by reference.

6 “third party administrator (TPA)” or “administrative services only (APO)” means a business organization
7 that performs administrative services for a health plan such as billing, plan design, claims processing,
8 record keeping, and regulatory compliance activities.

9 “value-based purchasing contract file” means a file that includes information about pharmacy value based
10 purchasing contracts between carriers/PBMs and drug manufacturers; and is submitted according to the
11 requirements contained in the submission guide.

12 **1.200.2 Reporting Requirements**

13 1.200.2.A Payers shall submit complete and accurate eligibility data files, medical claims data files,
14 pharmacy claims data files, dental claims data files, alternative payment model data files, control
15 total files, APM contract supplement files, prescription drug rebate data files, PBM contract files,
16 prescription drug affordability board information files, pharmacy value based purchasing contract
17 files and provider files to the APCD pursuant to the submission guide. The administrator may
18 amend the submission guide and shall provide notice of the revisions to payers. Any revision to
19 the submission guide will be effective only when incorporated into this rule and issued in
20 compliance with the requirements of C.R.S. § 24-4-103 (12.5). Reports submitted 120 days
21 following the effective date of the revision of this rule and the submission guide shall follow the
22 revised submission guide.

23 1.200.2.B. A private health care payer subject to the provisions of ERISA is not required under this
24 rule to submit claims data to the APCD but may continue to submit claims data or elect to submit
25 claims data at any time in accordance with the procedures described in Sections 1.200.2.A and
26 1.200.3.

27 **1.200.3 Schedule for Mandatory Data Reporting**

28 1.200.3.A. Payers shall submit a test file of its eligibility data, medical and pharmacy claims data and
29 provider files for a consecutive twelve-month period to the administrator by no later than March
30 31, 2012 or no later than 160 calendar days after the effective date of this rule, whichever is later.

31 1.200.3.B. Payers shall submit complete and accurate historic data to the administrator that
32 conforms to submission guide requirements by no later than June 30, 2012, or no later than 250
33 calendar days after the effective date of this rule, whichever is later.

34 1.200.3.C. Payers will transmit complete and accurate eligibility data, medical claims data, pharmacy
35 claims data, dental claims data and provider files covering the period from January 1, 2012 and
36 ending June 30, 2012 to the administrator by no later than August 15, 2012, or for the period as
37 specified by the administrator no later than 305 days after the effective date of this rule,
38 whichever is later.

39 1.200.3.D. On a monthly basis thereafter, payers will transmit complete and accurate monthly
40 eligibility data, medical claims data, pharmacy claims data, dental claims data and provider files
41 to the administrator. These data files for the period ending July 31, 2012, shall be submitted no
42 later than September 15, 2012, or for the period as specified by the administrator, no later than
43 305 days after the effective date of this rule, whichever is later. For each month thereafter, files
44 shall be submitted no later than 30 days after the end of the reporting month. Any time extension

1 shall be provided to payers in writing by administrator at least 30 days prior to established
2 deadlines.

3 **1.200.4 APCD Reports**

4 1.200.4.A. The administrator shall, at a minimum, issue reports from the APCD data at an aggregate
5 level to describe patterns of incidence and variation of targeted medical conditions, state and
6 regional cost patterns and utilization of services.

7 1.200.4.B. The APCD reports shall be available to the public on consumer facing websites and shall
8 provide aggregate and summary reports to achieve the purposes of the APCD. Any such reports
9 shall protect patient identity in accordance with HIPAA's standard for the de-identification of
10 protected health information.

11 **1.200.5 Requests for Data and Reports**

12 1.200.5.A. A state agency or private entity engaged in efforts to improve health care quality, value or
13 public health outcomes for Colorado residents may request a specialized report or data set from
14 the APCD by submitting to the administrator a written request detailing the purpose of the project,
15 the methodology, the qualifications of the research entity, and by executing a data use
16 agreement, to comply with the requirements of HIPAA.

17 1.200.5.B. A data release review committee shall review those requests for reports or data sets
18 containing protected health information and shall advise the administrator on whether release of
19 the data is consistent with the statutory purpose of the APCD, will contribute to efforts to improve
20 health care quality, value or public health outcomes for Colorado residents, complies with the
21 requirements of HIPAA, and does not violate antitrust law, using the Anti-trust Safety Zone as
22 guidance. The administrator shall include a representative of a physician organization, hospital
23 organization, non-physician provider organization and a payer organization on the data release
24 review committee.

25 1.200.5.C. The administrator may charge a reasonable fee to provide the requested data.

26 1.200.5.D The administrator may not release data from the Alternative Payment Model, Control
27 Total, APM Contract Supplement, Drug Rebate, PBM Contract Supplement, or Pharmacy Value
28 Based Purchasing Contract files to external requestors. These data are only to be used for
29 aggregated reporting by the administrator and direct reporting to the State of Colorado.

30 1.200.5.E The administrator may not release data from the premium payment or deductible fields to
31 any external requestors or use the data for aggregate public reporting. Premium and deductible
32 field data may only be released to the Colorado Division of insurance for 2022 and 2023.

33 **1.200.6 Penalties**

34 1.200.6.A. If any payer fails to submit required data to the APCD in a timely basis, or fails to correct
35 submissions rejected because of errors, the administrator shall provide written notice to the
36 payer. The administrator may grant an extension of time for just cause. If the payer fails to
37 provide the required information within thirty days following receipt of said written notice, the
38 administrator shall provide the payer with notice of the failure to report and will notify the director
39 of the payer's failure to report. The director shall assess a penalty of up to \$100 per day per issue
40 for the first thirty days that a payer fails to provide the required data to the APCD and \$1,000 for
41 each day thereafter. In determining whether to impose a penalty, the director may consider
42 mitigating factors such as the size and sophistication of a payer, the reasons for the failure to
43 report and the detrimental impact upon the public purpose served by the APCD.

1 1.200.6.B The penalties specified in Section 1.200.6.A shall not apply to a private health care payer
2 that is subject to the provisions of ERISA, since those payers are not required under this rule to
3 submit claims data to the APCD.

4 **1.200.7 Interagency Agreement**

5 1.200.7.A. The director may enter into an Interagency Agreement on behalf of the APCD and the
6 administrator with the Division of Insurance in the Colorado Department of Regulatory Agencies
7 to assist in the enforcement of these regulations and under the Divisions' authority in Title 10 of
8 the Colorado Revised Statutes.

9 **1.200.8 Privacy and Confidentiality**

10 1.200.8.A. Pursuant to C.R.S. § 24-72-204(3)(a)(I) medical and other health care data on individual
11 persons is not an open record and the department shall deny any open records request for such
12 information.

13 1.200.8.B. Certain aggregate and de-identified data reports from the APCD shall be available to the
14 public pursuant to C.R.S. § 25.5-1-204(7) when disclosed in a form and manner that ensures the
15 privacy and security of protected health information in compliance with HIPAA.

16 1.200.8.C. The administrator shall institute appropriate administrative, physical and technical
17 safeguards to ensure that the APCD, its operations, data collection and storage, and reporting
18 disclosures are in compliance with the requirements of HIPAA, and does not violate antitrust law,
19 using the Anti-trust Safety Zone as guidance. All eligibility claims data, medical, dental, and
20 pharmacy claims data shall be transmitted to the APCD and stored by the APCD in a secure
21 manner compliant with HIPAA.

22 **1.200.9 Incorporation by Reference**

23 1.200.9A The rules incorporate by reference (as indicated within) material originally published
24 elsewhere. Such incorporation, however, excludes later amendments to or editions of the
25 referenced material. Pursuant to C.R.S. § 24-4-103(12.5), the Department of Health Care Policy
26 and Financing maintains copies of the incorporated texts in their entirety which shall be available
27 for public inspection during regular business hours at:

28 Colorado Department of Health Care Policy and Financing
29 Medical Services Board Coordinator
30 1570 Grant Street
31 Denver, CO 80203

32 Copies of material shall be provided by the department, at cost, upon request