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 21-12-02-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 fall of 2021. 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 Drug Rebate (DR), Alternative Payment Models (APM), and APM Control Total 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 August 18, 2021. CIVHC hosted a webinar that same day and presented the proposed changes to DSG v 13. More than 100 representatives from over 20 data submitters attended the webinar and had opportunity to ask questions and discuss the proposed changes with CIVHC. Submitters did not raise questions regarding the substance of the proposed changes during the webinar.

   After the webinar, CIVHC proactively coordinated with stakeholders to continue updating the submission guide to incorporate appropriate changes. CIVHC produced two more drafts and distributed the first one on September 29th, 2021. The next draft was produced and distributed on December 1st, 2021. CIVHC hosted various calls with stakeholders to learn about relevant topics related to the proposed changes and updated the DSG as appropriate.

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:

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 21-12-02-A
Division / Contact / Phone: Health Care Policy and Financing/Health Information Office / HCPF- Chris Underwood, 303-866-4766 / CIVHC - Kristin Paulson 720-583-2095

3. Federal authority for the Rule, if any:

4. State Authority for the Rule:

   Section 25.5-1-108, C.R.S. (2021);
   § 25.5-1-204(9), C.R.S.

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 21-12-02-A
Division / Contact / Phone: Health Care Policy and Financing/Health Information Office / HCPF- Chris Underwood, 303-866-4766 / CIVHC - Kristin Paulson 720-583-2095

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 13 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.

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.

1.200 ALL-PAYERS CLAIMS DATABASE

1.200.1 Definitions

"administrator" means the administrator of the APCD appointed by the director of the department.

"APCD" means the Colorado All-Payer Claims Database.

"Alternative Payment Model (APM) file" means a detailed file that captures payments made to providers outside of the traditional fee-for-service model. This includes: Foundation Payments for Infrastructure and Operations, Pay for Reporting, Pay for Performance, Shared Savings, Shared Savings and Downside Risk, Risk Based Payments NOT Linked to Quality, Condition-Specific Population-Based Payment, Comprehensive Population-Based Payment, Integrated Finance and Delivery Systems, and Capitated Payments NOT Linked to Quality. APM files are submitted according to the requirements contained in the submission guide.~~Pay for Performance Payment/Penalty, Shared Savings/Shared Risk, Global Budget, Limited Budget, Capitation – Unspecified, Bundled/Episode-Based, Integrated Delivery System, Patient-Centered Medical Home, Accountable Care Organizations and Other Non-FFS payments.~~

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

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

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

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

"department" means the Colorado Department of Health Care Policy and Financing.

"director" means the Executive Director of the department.

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

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

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

"historic data" means eligibility data file(s), medical claims data file(s), pharmacy file(s) and provider file(s) for the period commencing January 1, 2009 through December 31, 2014 (except in the case of a self-insured employer-sponsored health plan, in which case, "historic data" shall mean, at minimum, such data file(s) for the period commencing January 1, 2015 through December 31, 2015).

"medical claims data file" means a file that includes data about medical claims and other encounter information, according to the requirements contained in the submission guide.

"payer" means a private health care payer and a public health care payer.

"pharmacy benefit manager contract information file" means a file that includes information related to contracts between carriers and pharmacy benefit managers; and is submitted according to the requirements contained in the submission guide.

"pharmacy file" means a file that includes data about prescription medications and claims filed by pharmacies, according to the requirements contained in the submission guide.

"prescription drug affordability board file" means a file that includes required information about prescription drugs as outlined in SB21-175; and is submitted according to the requirements contained in the submission guide.

"Prescription Drug Rebate" means 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).

"private health care payer" means an insurance carrier as defined in C.R.S. § 10-16-102(8) covering an aggregate of 1,000 or more enrolled lives in health coverage plans as defined in C.R.S. § 10-16-102(34). For purposes, of this regulation, "private health care payer" includes carriers, third-party administrators, administrative services only organizations, and pharmacy benefit managers offering health benefits plans under C.R.S. § 10-16-102(32)(a), dental, vision, pharmacy, Medicare Advantage, Medicare supplemental plans, limited benefit health insurance, or short-term limited-duration health insurance. For the purposes of this regulation, a "private health care payer" also means a self-insured employer-sponsored health or pharmacy plan covering an aggregate of 100 or more enrolled lives in Colorado if the employer is not subject to ERISA. It does not include a self-insured employer-sponsored health or pharmacy plan if the employer is subject to ERISA~~, if such health or pharmacy plan is administered by a third-party administrator, or administrative services only organization, or pharmacy benefit manager ("TPA/ASO/PBM") that services less than an aggregate of 1,000 enrolled lives in Colorado~~; carriers offering accident only; credit; benefits for long term care, home health care, community-based care, or any combination thereof under Article 19 of Title 10; disability income insurance; liability insurance including general liability insurance and automobile liability insurance; coverage issued as a supplement to liability insurance; worker's compensation or similar insurance; or automobile medical payment insurance, specified disease, or hospital indemnity and other fixed indemnity insurance.

"protected health information" shall have the same meaning as in the HIPAA Privacy Rule in 45 C.F.R. § 160.103.

"provider file" means a file that includes additional information about the individuals and entities that submitted claims that are included in the medical claims file; and is submitted according to the requirements contained in the submission guide.

"public health care payer" means the Colorado Medicaid program established under articles 4, 5 and 6 of title 25.5, C.R.S., the children's basic health plan established under article 8 of title 25.5, C.R.S. and Cover Colorado established under part 5 article 8 of title 10, C.R.S.

"self-funded employee health plans" means health plans where the financial risk associated with medical claims is held by the organization sponsoring the health coverage.

"submission guide" means the document entitled "Colorado All-Payer Claims Database Data Submission Guide" developed by the administrator that sets forth the required schedules, data file format, record specifications, data elements, definitions, code tables and edit specifications for payer submission of eligibility data files, medical, dental and pharmacy claims data files and provider data files to the APCD dated Version 131.5 ~~April~~ January 2022~~2020~~, which document is hereby incorporated by reference.

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

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

1.200.2 Reporting Requirements

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

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

1.200.2.B. For payers already submitting mandatory data submissions to the CO APCD, effective January 1, 2023, each payer providing claim administration services for an ERISA-covered employer who maintains a self-funded employee plan shall provide the employer a copy of the APCD Self-funded Employee Health Plan Opt-In form for purposes of determining whether an employer agrees to opt-in to submission of its self-funded employee plan's health care claims data as described in this rule.

1.200.2.B.I Each payer shall provide the APCD Self-funded Employee Health Plan Opt-In form to self-funded clients:

(a) by January 1, 2023 for existing clients; or

(b) within 30 days after claims administration services are retained and it is determined the employer meets the requirements of this section.

1.200.2.B.II An opt-in signed by an employer and received by a payer before March 1, 2023 shall be effective for the claims adjudicated in January 2023 and later. An opt-in signed by an employer

and received by a payer on or after March 1, 2023 shall be effective for the claims adjudicated in the reporting period in which the form was signed. An employer may not opt-in for a partial reporting period. An employer that has opted-in may opt-out for subsequent reporting periods by notifying the payer in writing at least 30 days before the beginning of the next reporting period.

1.200.2.B.III For a self-funded employee plan whose employer has made an affirmative election for the submission of health care claims data, the payer shall:

(a) include the self-funded employee plan data as part of the payer's data submission otherwise required by this rule starting with the reporting period covering the date of the affirmative election as defined in 1.200.2.B.II; and

(b) not charge or assess any costs or fees associated with the submission of the self-funded employee health plan data to the CO APCD.

1.200.2.B.IV Each payer shall file the following with the CO APCD Administrator, annually by January 31 of each year for the prior calendar year:

(a) a list of the self-funded employee plans whose employer made an affirmative election for the submission of their health care claim data and the date election was submitted;

(b) a list of the self-funded employee plans whose employer did not elect to submit their health care claim data;

(c) a list of employers who previously filed an opt-in request and have elected to opt-out for future reporting periods as provided under Subsection (2)(c) and the date opt-out was submitted; and

(d) a certification from an officer of the payer that the payer has taken reasonable efforts to provide the form to all known required employers; and

(e) a list identifying the employers to whom the form was provided and their contact information.

1.200.2.B.V The APCD Self-funded Employee Health Plan Opt-In form is for use only with ERISA-covered self-funded employee plans and does not affect the mandatory reporting otherwise required by this rule. Nothing in this section requires a payer to submit claims processed before the payer was contracted to provide services.

Nothing in this section requires a payer who has no current obligation to report health plan data to the CO APCD to begin submitting data. ERISA-covered employers with self-funded health plans opting into submission cannot be used as a basis to require a payer to begin submitting to the CO APCD if they are not otherwise mandated to submit.

1.200.3 Schedule for Mandatory Data Reporting

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

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

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

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

1.200.4 APCD Reports

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

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

1.200.5 Requests for Data and Reports

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

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

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

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

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

1.200.6 Penalties

1.200.6.A. If any payer fails to submit required data to the APCD in a timely basis, or fails to correct submissions rejected because of errors, the administrator shall provide written notice to the payer. The administrator may grant an extension of time for just cause. If the payer fails to provide the required information within thirty days following receipt of said written notice, the administrator shall provide the payer with notice of the failure to report and will notify the director of the payer's failure to report. The director shall assess a penalty of up to $100~~2,5~~1,~~0~~00 per day per issue for the first thirty days that a payer fails to provide the required data to the APCD and $1,000 for each day thereafter. In determining whether to impose a penalty, the director may consider mitigating factors such as the size and sophistication of a payer, the reasons for the failure to report and the detrimental impact upon the public purpose served by the APCD.

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

1.200.7 Interagency Agreement

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

1.200.8 Privacy and Confidentiality

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

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

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

1.200.9 Incorporation by Reference

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

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

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