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Title of Rule: Revision to the Executive Director of the Department of Health Care Policy and Financing Rule Concerning All-Payers Claims Database. 10 CCR 2505-5,

Rule Number: ED 20-01-13-A

Division / Contact / Phone: HCPF- Chris Underwood, 303-866-4766 / CIVHC Vinita Bahl 720-583-2095

SECRETARY OF STATE

RULES ACTION SUMMARY AND FILING INSTRUCTIONS

SUMMARY OF ACTION ON RULE(S)

1. Department/Agency Name: Health Care Policy and Financing / Executive Director of Health Care Policy and Financing
2. Title of Rule: ED 20-01-13-A,
3. This action is an adoption an amendment of:
4. Rule sections affected in this action (if existing rule, also give Code of Regulations number and page numbers affected):
Sections(s) 1.200.1, 1.200.2 A, 2505 Colorado Department of Health Care Policy and Financing, Executive Director of Health Care Policy and Financing (10 CCR 2505-5).
5. Does this action involve any temporary or emergency rule(s)? No
If yes, state effective date:
Is rule to be made permanent? (If yes, please attach notice of Yes hearing).

PUBLICATION INSTRUCTIONS*

Replace the current text at 1.200.1 with the proposed text beginning at unnumbered paragraph 19 through the end of unnumbered paragraph 19. This rule is effective May 15, 2020.

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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 2019. The goals of the proposed updates to the data submissions guide are outlined below:

- Improve the quality and completeness of the submitted alternative payment model (APM) data to overcome current obstacles for reporting progress toward adoption of APMs and investment in primary care in Colorado.
- Improve the quality and completeness of submitted data about manufacturer drug rebates and other compensation conferred to payers. And, obtain data regarding the contractual arrangement between the payer and its pharmacy benefit manager, including the percentage of rebates and other compensation that are passed through from the pharmacy benefit manager to the payer.

CIVHC sent the proposed Rule language and revised Data Submission Guide (DSG) to all data submitters on January 22, 2020. CIVHC hosted a webinar that same day and presented a the proposed changes to DSG v11.5. 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. The only topic raised by one representative was a question about the timeline and when CIVHC expects feedback on the proposed changes.

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:

3. Federal authority for the Rule, if any:

4. State Authority for the Rule:

Section 25.5-1-108, C.R.S. (2019);

Initial Review
Proposed Effective Date

Final Adoption
Emergency Adoption

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§ 25.5-1-204(9), C.R.S.

Initial Review
Proposed Effective Date

Final Adoption
Emergency Adoption

DOCUMENT #01

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 11.5 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.

43 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.

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.

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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)” means payments made to providers outside of the traditional fee-for-service model. This includes: 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.

“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 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 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 offering health benefits plans under C.R.S. § 10-16-102(32)(a) and dental, vision, limited benefit health insurance, and 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 plan covering an aggregate of 100 or more enrolled lives in Colorado. It does not include a self-insured employer-sponsored health plan, if such health plan is administered by a third-party administrator or administrative services only organization (“TPA/ASO”) that

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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.

"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 11.5 ~~November 2019~~ April 2020, which document is hereby incorporated by reference.

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, prescription drug rebate data 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.

1.200.3 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.

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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 and complies with the requirements of HIPAA. 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.

1.200.6 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 \$1,000 per week for each week that a payer fails to provide the required data to the APCD up to a maximum penalty of \$50,000. 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.

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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 Statutes.

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. 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.