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Release of Data from the Colorado APCD: Overview of Legal and Regulatory Issues

The APCD will provide (or “release”) data at varying levels of detail and specificity. Certain reports containing no detail about individuals or specific claims will be provided to the public through the APCD website, www.cohealthdata.org. Those seeking a greater level of detail must submit a written application to the APCD Administrator. Applications must be reviewed by a Data Release Review Committee (DRRC) for consistency with the APCD’s use guidelines and data management policies.

Purpose: This document is intended to provide an overview of Colorado APCD data release policies from a legal and regulatory perspective.

Publicly Available Information

Note: The Data Release Review Committee (DRRC) is neither required nor expected to play a role in the release of Publicly Available Information generated based on the APCD.

By statute, information from the APCD is to be made publicly available. More specifically, CRS 25.5-1-204(5)(f) stipulates that the APCD “publicly report performance data on quality, health outcomes, health disparities, cost, utilization, and pricing in a manner accessible” for a variety of stakeholder groups.

HCPF promulgated rules (1.200.4. APCD Reports) also provide guidance regarding the public reporting of APCD data.

- 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.

I. Public Facing Reports

The APCD Advisory Committee (established under CRS 25.5-1-204) endorsed a tiered approach for the release of Public Facing Reports derived from APCD Claims Data. Individuals or entities that access such reports via the APCD website are considered Public Users. A Public Facing Report contains a summary or analysis of data derived from the APCD database. Examples of data summaries or analyses include counts; totals; rates per thousand; index values;

standardized metrics; etc. A Public Facing Report never displays claims line or member level detail.

- In the fall of 2012, CIVHC released the initial round of Tier 1 reports providing population-level views of variation in utilization of services and average amounts paid for those services. These reports illustrate variation by geography, gender and age groups, and are available through the Colorado APCD website at www.cohealthdata.org. The initial Tier 1 report releases can be grouped into two broad categories:
 - Interactive reports that demonstrate variation in Total Cost of Care, Utilization of Services Inpatient Utilization by major Service Line, and Provider Access and Readmission Comparisons;
 - Static, or snapshot, reports that demonstrate geographic variation in paid amounts and utilization rates for common medical procedures.
- In late 2013, the APCD will release Tier 2 reports that provide risk adjusted cost, quality and value data of interest to consumers, providers, purchasers and researchers, such as:
 - Variation in risk adjusted median paid amounts for various procedures;
 - Chronic Disease incidence/prevalence and total costs to treat;
 - Incorporate quality of care information obtained from both claims data and non-claims sources; and
 - Generate employer-focused information and analysis to support value-based purchasing decisions.
- In late 2014, the third year of operation, the APCD will deliver advanced analytics in Tier 3 reports. The APCD will be able to add value by employing advanced analytical techniques to compare and contrast service utilization and median paid amounts based on comparable, risk adjusted populations. In addition, we will align these advanced analytics with outside data sources including disease registries and vital statistics, to maximize analytic outputs.

Public Users are able to download the interactive and static report results in pdf format, and the complete aggregated data underlying these reports as an excel spreadsheet.

Every downloaded report automatically includes a report definition describing essential features of the report including methodology and the underlying data, along with a report guide to facilitate interpretation of the results.

Public Users accessing the Colorado APCD website are required to acknowledge, by clicking on a pop-up box, that they agree to abide by associated Privacy Policies and Terms of Use. A link to the full text of the www.cohealthdata.org Privacy Policies and Terms of Use is provided in the pop-up box.

Non-Public Information

Note: Other than Public Facing Reports, all APCD data releases must be reviewed by the Data Release Review Committee (DRRC) with appropriate Data Release Protocols applied according to the category or level of detail of the data requested.

Under HCPF rules (1.200.5. Requests for Data and Reports), “A state agency or private entity engaged in efforts to improve health care or public health outcomes for Colorado residents may request a specialized report 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.”

Colorado APCD Data Releases that require a Written Application

I. Custom Reports

A Custom Report means any report generated based on the APCD that is not provided as a Public Facing Report available through www.cohealthdata.org. Custom Reports are requested by submitting a Data Release Application to the APCD Administrator. Similar to the Public Facing Reports, Custom Reports contain a summary or analysis of data derived from the Colorado APCD database. Examples of data summaries or analyses include counts; totals; rates per thousand; index values; and other standardized metrics. A Custom Report will never display claims line or member level detail. A Custom Report may provide summary level statistics or analysis for subpopulations not otherwise available or identified in Public Facing Reports.

The DRRC has established criteria for the release of a Custom Report. When an Application meets these criteria, the DRRC has determined that the Report may be released by the APCD Administrator. The DRRC will receive regular informational updates about these releases. Because these releases will not provide claims line or member level detail and contain no PHI, they fall outside the scope of HIPAA. A Data Use Agreement will be executed to define the terms and conditions under which the information was released and to protect APCD interests.

2. De-Identified Data Sets

De-Identification of Protected Health Information (PHI): Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information (45 CFR § 164.514(a)).

The following identifiers of the individual or of relatives, employers, or household members of the individual must be removed to meet the HIPAA standard for de-identification at (45 C.F.R. 164.514(b)(2)):

- a) Names;
- b) Geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes except for the initial three digits of a zip code if, according to the currently publicly available data from the Bureau of the Census:
 - i. The geographic unit formed by combining all zip codes with the same three initial digits containing more than 20,000 people; and

- ii. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- c) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- d) Telephone numbers *(not collected by the CO APCD)*;
- e) Fax numbers *(not collected by the CO APCD)*;
- f) Electronic mail addresses *(not collected by the CO APCD)*;
- g) Social security numbers;
- h) Medical record numbers;
- i) Health plan beneficiary numbers;
- j) Account numbers;
- k) Certificate/license numbers;
- l) Vehicle identifiers and serial numbers, including license plate numbers *(not collected by the CO APCD)*;
- m) Device identifiers and serial numbers *(not collected by the CO APCD)*;
- n) Web Universal Resource Locators (URLs) *(not collected by the CO APCD)*;
- o) Internet Protocol (IP) address numbers *(not collected by the CO APCD)*;
- p) Biometric identifiers, including finger and voice prints *(not collected by the CO APCD)*;
- q) Full face photographic images and any comparable images *(not collected by the CO APCD)*; and
- r) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of 45 CFR § 164.514 *(not collected by the CO APCD)*.

A De-Identified Data Set may be requested by submitting a written Data Release Application to the APCD Administrator. The APCD Administrator may elect to select records or grant access to or create a summary data set based on the applicant's selection criteria.

The DRRC has established criteria for release of a De-Identified Data Set. When an Application meets these criteria, the DRRC has determined that the De-Identified Data Set may be released by the APCD Administrator. The DRRC will receive regular informational updates about these releases. Because these releases will not provide claims line or member level detail and contain no PHI, they fall outside the scope of HIPAA. A Data Use Agreement will be executed to define the terms and conditions under which the information was released and to protect APCD interests.

3. Limited Data Sets

Limited Data Set: A limited data set contains some protected health information data elements but must exclude the following direct identifiers of the individual or of relatives, employers, or household members of the individual (45 C.F.R. 164.514(e)(2)):

- a. Names;
- b. Postal address information, other than town or city, State, and zip code;

- c. Telephone numbers *(not collected by the CO APCD)*;
- d. Fax numbers *(not collected by the CO APCD)*;
- e. Electronic mail addresses *(not collected by the CO APCD)*;
- f. Social security numbers;
- g. Medical record numbers;
- h. Health plan beneficiary numbers;
- i. Account numbers;
- j. Certificate/license numbers *(not collected by the CO APCD)*;
- k. Vehicle identifiers and serial numbers, including license plate numbers *(not collected by the CO APCD)*;
- l. Device identifiers and serial numbers; *(not collected by the CO APCD)*;
- m. Web Universal Resource Locators (URLs) *(not collected by the CO APCD)*;
- n. Internet Protocol (IP) address numbers *(not collected by the CO APCD)*; and
- o. Biometric identifiers, including finger and voice prints *(not collected by the CO APCD)*; and
- p. Full face photographic images and any comparable images *(not collected by the CO APCD)*;

A Limited Data Set may be requested by submitting a written Data Release Application to the APCD Administrator.

Releases of Limited Data Sets require DRRC review. Because a Limited Data Set contains PHI, a HIPAA-compliant Data Use Agreement (DUA) must be executed between CIVHC, acting in its role as APCD Administrator, and the Data Requestor. The terms of the Data Use Agreement will be aligned with the requirements for a HIPAA-defined Covered Entity to release a Limited Data Set.

4. Identifiable Information

Identifiable Information refers to analytical datasets generated based on the APCD that include Protected Health Information (PHI) such that they do not meet the HIPAA definition of either De-Identified Data or a Limited Data Set.

Identifiable Information can be requested by submitting a written Data Release Application to the APCD Administrator.

Releases of Identifiable Information require DRRC review. Because Identifiable Information contains multiple PHI data elements, there is a greater risk that the data could be used along with other information to identify a specific individual. Such releases require an extended Data Use Agreement to be executed between CIVHC in its role as APCD Administrator and the Applicant. The terms of this extended DUA will prohibit the Applicant from using or disclosing the APCD data in any manner other than HIPAA allows for a Covered Entity.

Due to the sensitivity of health care claims and related data, requests for Identifiable Information must include either: (i) an Institutional Review Board (IRB) or Privacy Board waiver approval, as required by 45 CFR 164.512(i); or (ii) proof of patient authorization.

This type of request is expected to come from:

1. Researchers seeking to use the data for comparative effectiveness research; or
2. Health Care Providers seeking to use the data for comparative effectiveness research or health care operations purposes. Additional requirements will apply in the case of a request for Identifiable Information from providers for health care operations purposes.

A request for Identifiable Information may require approval of the DRRC acting in the capacity of a Privacy Board.

Note: A Privacy Board votes (and the outcome of the vote is binding), the DRRC advises.

Key points regarding the DRRC Privacy Board function:

- The purpose of the Privacy Board is to approve a waiver of the individual authorization required by § 164.508 for purposes of a research study;
- Procedure [CFR 164.512(i)(2)(iv)]:
 - The Privacy Board must review the proposed research at a convened meeting at which a majority of members are present;
 - The waiver of authorization must be approved by a majority of members present at the meeting, unless the Privacy Board elects to use an expedited review procedure;
 - An expedited review procedure may be used if the research involves no more than minimal risk to the privacy of affected individuals;
 - Under an expedited review, approval of the waiver of authorization may be carried out by the chair or one or more members designated by the chair;
- Composition [CFR 164.512(i)(1)(i)(B)]:
 - Members must have varying backgrounds and appropriate professional competencies as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;
 - Must include at least one member who is not affiliated with the covered entity, is not affiliated with any entity conducting or sponsoring the research, and is not related to any person who is affiliated with any of such entities;
 - No members can be participating in a review of any project in which the member has a conflict of interest;
- Additional documentation requirements (the required information is already reflected in the Data Release Application and Data Use Agreement); and
- The Privacy Board may rely on the researcher or provider to define PHI, or the Privacy Board might define PHI itself.