



CENTER FOR IMPROVING  
**VALUE** IN HEALTH CARE

950 S. CHERRY ST., SUITE 1515 | DENVER, COLORADO 80246  
PHONE 720.583.2095 | FAX 720.549.9189 | WWW.CIVHC.ORG

## **Data Release Policies and Procedures Data Release Review Committee (DRRC) Colorado All Payer Claims Database (APCD)**

### **Section I: Purpose and Authority**

**Purpose:** The purpose of these policies and procedures is to establish a framework for responding to requests for Specialized Reports and analytic data sets based on the Colorado All Payer Claims Database (APCD).

**Authority:** The authority to create the APCD is based on § 25.5-1-204, C.R.S. pursuant to Chapter 299 of the Acts of 2010 of the Colorado General Assembly.

CRS 25.5-1-204(1)(a) describes the purpose of the APCD as, “facilitating the reporting of health care and health quality data that results in transparent and public reporting of safety, quality, cost, and efficiency information at all levels of health care.”

CRS 25.5-1-204(5) directs the APCD Administrator to:

- (e) determine the reports and data to be made available to the public with recommendations from the advisory committee in order to accomplish the purposes of this section, including conducting studies and reporting the results of the studies; and
- (f) collect, aggregate, distribute, and publicly report performance data on quality, health outcomes, health disparities, cost, utilization, and pricing in a manner accessible for consumers, public and private purchasers, providers, and policymakers.

CRS 25.5-1-204 (7) The all-payer health claims database shall:

- (a) be available to the public when disclosed in a form and manner that ensures the privacy and security of personal health information as required by state and federal law, as a resource to insurers, consumers, employers, providers, purchasers of health care, and state agencies to allow for continuous review of health care utilization, expenditures, and quality and safety performance in Colorado;
- (b) be available to state agencies and private entities in Colorado engaged in efforts to improve health care, subject to rules promulgated by the executive director;
- (c) be presented to allow for comparisons of geographic, demographic, and economic factors and institutional size;
- (d) present data in a consumer-friendly manner.

The release of data from the APCD is authorized under rules issued by the Department of Health Care Policy and Financing (HCPF), effective October 2011, under 1.200.5. Requests for Data and Reports:

I.200.5.A. 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.

I.200.5.B. A data release review committee shall review the request and 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 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.

I.200.5.C. The administrator may charge a reasonable fee to provide the requested data.

## **Section 2: Definitions**

As used in the following policies and procedures, the term:

“Analytic Portal” means the APCD website [www.cohealthdata.org](http://www.cohealthdata.org) and data access and analytical tools provided on behalf of CIVHC in its role as APCD Administrator by the APCD Technology Vendor.

“APCD” means the All Payer Claims Database, a secure database, authorized by statute, that aggregates claims data from public and private payers and serves as a comprehensive source of health claims information for the state of Colorado.

“APCD Administrator” or “Administrator” means the individual or entity who has been appointed by the Executive Director of the Colorado Department of Health Care Policy and Financing (HCPF) to oversee the operation of the APCD pursuant to 25.5-1-204 C.R.S. CIVHC was appointed as APCD Administrator in August of 2010.

“Applicant” means an individual or organization that requests access to a Specialized Report by submitting a written Data Release Application to CIVHC in its role as APCD Administrator.

“APCD Public User” means any person accessing Public Facing Reports and other information generated based on the APCD through the Analytic Portal developed and maintained on CIVHC’s behalf by the APCD Technology Vendor.

“APCD Technology Vendor” means the entity or entities CIVHC, in its role as APCD Administrator, contracts with to provide the computer hardware, software, Analytic Portal and other services necessary to support operations of the APCD.

“Authorized User” means an entity and the specific individuals named by that entity approved by CIVHC to access APCD data under the terms of a signed Data Use Agreement.

“CIVHC” means the Center for Improving Value in Health Care. Pursuant to 25.5-1-204 C.R.S., The Division of Health Care Policy and Financing (HCPF) has appointed CIVHC as the APCD Administrator.

“Claim” or “Health Insurance Claim” means a specific set of information generated when a medical provider or patient submits a request for payment or reimbursement to their health insurer for the cost of health services rendered or provided.

“Claims Data” means structured information submitted by a Data Provider to the APCD according to the specifications established in the APCD Data Submission Guide.

“Data Provider” means a public or private health insurer or health plan that submits Claims Data to the APCD as required by statute, or an employer, Third Party Administrator (TPA), Administrative Services Only (ASO) or any other insurer or health plan that submits Claims Data to the APCD on a voluntary basis.

“Data Release Application” means the application and supporting documentation an Applicant or potential Authorized User submits to CIVHC in its role as APCD Administrator to request access to APCD data for a specified purpose.

“Data Release Policies” means the specific policies and procedures followed by the Data Release Review Committee (DRRC) in evaluating Data Release Applications and in advising the APCD Administrator.

“Data Release Review Committee” (DRRC), as required under HCPF promulgated APCD rules, shall be appointed by the APCD Administrator and is responsible for reviewing and making recommendations to the APCD Administrator regarding the appropriateness of Data Release Applications.

“Data Use Agreement” means a document signed by CIVHC and an Applicant that defines the terms and conditions under which access to and use of APCD data is permitted, as well as how the data will be secured and protected.

“De-Identified Data Set” has the meaning given to it by HIPAA, especially 45 CFR § 164.514(a). De-identification by CIVHC and the APCD will be achieved by removing all 18 identifiers enumerated at 45 CFR § 164.514(b)(2).

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

“HIPAA” means The Health Insurance Portability and Accountability Act of 1996 and the regulations and rules promulgated thereunder, including regulations found at 45 CFR Parts 160, 162, and 164 (“HIPAA Rules”), the regulations specific to privacy found in 45 CFR Part 164, Subpart E (“HIPAA Privacy Rules”), and the regulations specific to security found in 45 CFR 164, Subpart C (“HIPAA Security Rules”).

“HITECH” means The Health Information Technology for Economic and Clinical Health (HITECH) Act passed as a part of the American Recovery and Reinvestment Act (ARRA) of 2009 and the regulations and rules thereunder, including Sections 13401, 13402, 13404, 13405, 13406, 13408, and 13409 and the other regulations promulgated thereunder pertinent to CIVHC (the “HITECH Rules”).

“Law” means any applicable statute, ordinance, rule, legislation, constitution, common law, resolution, interpretation, ordinance, code, treaty, decree, directive, pronouncement or other law of any federal, state, local, or other governmental authority.

“Limited Data Set” has the meaning given to it by HIPAA, especially 45 CFR § 164.514(e).

“NIST Special Publication (SP) 800-88” means The National Institute of Standards and Technologies, Special Publication 800-88, Guidelines for Media Sanitization, available at [csrc.nist.gov](http://csrc.nist.gov), that describes how digital media (e.g., hard drives, disks, CDs, etc.) should be handled or destroyed to protect sensitive information when no longer required, as called for under the HITECH Rules.

“PPACA” means the Patient Protection and Affordable Care Act (PPACA) of 2010 and the regulations and rules promulgated thereunder.

“Specialized Report” means any report or analytic data set generated based on the Colorado APCD that is **not** provided as a Public Facing Report available through the Analytic Portal.

“Provider” means a health care practitioner, health care facility, health care group, medical product vendor, or pharmacy.

“Protected Health Information” or “PHI” has the meaning given to it by HIPAA, especially 45 CFR § 160.103, and shall include written or electronic information relating to the diagnosis, treatment, tests, prognosis, admission, discharge, transfer, prescription, claims, or other data or information implicitly or explicitly identifying a patient.

“Public Facing Reports” means reports and other information products generated based on the APCD database that provide aggregated, de-identified information that is available through the Analytic Portal.

### **Section 3: Roles and Responsibilities for Specialized Report and Analytic Data Set Release**

#### **The APCD Administrator is responsible for the following tasks:**

- Determine whether a request requires DRRC review;
- Receive Data Release Applications and forward to appropriate staff for logging;
- Review Data Release Applications and obtain clarifications, if necessary, prior to referring an Application to the Data Release Review Committee (DRRC);
- Appoint members of the DRRC. Under HCPF promulgated rules (1.200.5.B.) the DRRC “shall include a representative of a physician organization, hospital organization, non-physician provider organization and a payer organization.”
- Prepare and distribute DRRC meeting agendas and other materials through a secure, limited access DRRC website;
- Facilitate DRRC meetings and maintain files documenting meeting process and DRRC decisions;
- Produce letters notifying applicants of DRRC and APCD Administrator determinations, as appropriate;
- Collecting any fees;
- Provide updates and reports as appropriate.

#### **The DRRC is responsible for the following tasks:**

- Review Data Release Applications;
- Advise the APCD Administrator on how Applications align with guidelines regarding:
  - Consistency with the statutory purpose of the APCD,
  - Contribution to efforts to improve health care for Colorado residents,
  - Alignment with the requirements of HIPAA.
- Act as a Privacy Board to “authorize a waiver of disclosure requirements” when a data request includes PHI beyond that allowable under the HIPAA definition of a Limited Data Set. In this capacity, the DRRC functions as a Privacy Board and votes on this aspect of the request only. The outcome of such votes is binding on the APCD Administrator; however, a vote to authorize a waiver of the disclosure requirements does not in itself require the APCD Administrator to approve a Data Release Application.

#### **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 to define PHI, or the Privacy Board might define PHI itself.

### **Data Release Review Committee (DRRC) Policies and Procedures**

1. The APCD Administrator shall appoint members to the DRRC.
2. Data Release Applications (Applications) are expected to contain sensitive information and are to be treated as confidential and proprietary.
3. The DRRC and its members may obtain assistance from outside entities such as dataset design experts, clinicians, insurance experts, privacy experts and regulatory authorities among others as needed.
4. The APCD Administrator will conduct a preliminary review of each Application for completeness. If the Application is incomplete, the APCD Administrator may require supplemental information and will notify the Applicant of its decision within 45 days of receipt of such information.
5. The APCD Administrator will provide access to Applications and related materials at least ten days prior to DRRC meetings via the secure DRRC website.
6. DRRC members are expected to review Applications and related materials prior to meetings.
7. DRRC members are invited to submit questions, requests for clarification and identify deficiencies or other perceived Application weaknesses in advance of meetings via the forum on the secure DRRC website.
8. If the DRRC determines that supplemental information is required to advise the APCD Administrator:
  - a. In the case of a minor deficiency (or deficiencies), the DRRC may issue a conditional recommendation for approval pending submission of supplemental information that resolves the issue(s) to the satisfaction of the APCD Administrator;
  - b. In the case of a major deficiency (or deficiencies), the APCD Administrator will obtain supplemental information and the Application will be reconsidered at the next DRRC meeting;
9. If the APCD Administrator denies an Application for data in whole or in part, an Applicant may resubmit his or her Application to address the concerns raised by the Administrator.

10. A summary of each approved Application will be posted on the Data Release section of the CIVHC website unless a specific embargo period is negotiated with the Administrator. Unless otherwise negotiated or agreed to, Application summary information will be posted within six months of DRRC approval.
11. An abstract of any published reports or other public information generated based on the APCD data that is the subject of an approved Application will be posted to the Data Release section of the CIVHC website. Applicants are encouraged to provide a brief description of the project purpose for public release.
12. DRRC members must be present in-person or through electronic means in real time at meetings.
13. Members may not delegate authority to designees.
14. A member shall be recused from any discussion of an Application if he/she has a self-disclosed or discovered financial or other conflict of interest (as defined in the DRRC Member Agreement) in the outcome.
15. An Application will be:
  - a. Recommended for approval,
  - b. Recommended for conditional approval, or
  - c. Not recommended for approval and returned to the APCD Administrator along with a list of deficiencies that must be corrected before a recommendation for approval can be made.
16. The DRRC will meet according to a schedule posted on the CIVHC website, generally monthly or on an as needed basis.
17. DRRC meetings are not open to the public.
18. Applications must be submitted at least 15 days prior to a regularly scheduled DRRC meeting in order to be considered at that meeting. A DRRC meeting may be cancelled if no new Applications have been received or if a pending Application is not yet complete.

#### **Section 4: Process for the Release of Custom Reports, De-Identified Data, a Limited Data Set or Identifiable Information from the Colorado APCD**

##### **General Provisions**

The Administrator may provide Specialized Reports generated based on the Colorado APCD at different levels of detail to meet various types of stakeholder requests.

All requests for Specialized Reports must be submitted in writing. Requests for Custom Reports and De-Identified Data Sets that meet DRRC established criteria do not require a formal review. The DRRC will be informed of all requests for Custom Reports and De-Identified Data as well as any actions taken with respect to such requests by the APCD Administrator. Requests for a Limited Data Set or Identifiable Information require a full review by the Data Release Review Committee.

- Custom Reports and De-Identified Data contain no Protected Health Information (PHI) and requests may be granted under the terms of a Data Use Agreement executed to establish the terms and conditions of use and to protect APCD interests.

- A Limited Data Set or Identifiable Information contains PHI. Access to such data may be granted under the terms of a HIPAA-compliant Data Use Agreement that is aligned with the requirements for a HIPAA Covered Entity.

## **Data Release Application**

1. All applicants must submit a written Application using the format provided by the APCD Administrator. Each applicant shall, as applicable:
  - a. specify the purpose and intended use of the data requested, including a detailed project description that describes any other data sources to be used for the project;
  - b. specify the qualifications of the requesting entity, and any partner organizations, that specifically address experience and expertise with projects of similar scale and scope;
  - c. specify both the type of data and specific data elements requested along with appropriate justification for any restricted data elements;
  - d. specify security and privacy measures that will be taken in order to safeguard patient privacy and to prevent unauthorized access to or use of such data;
  - e. specify the applicant's methodology for maintaining data integrity and accuracy;
  - f. describe how the results of the applicant's analysis will be published, including level of aggregation of data that will be presented;
  - g. agree to provide the results of all analyses, research, or other product(s) based on the data requested for review by the APCD Administrator prior to publication, release or other dissemination;
  - h. agree to data disclosure restrictions and prohibitions on re-release of the data; and
  - i. obtain prior approval from the APCD Administrator to release any reports that use PHI prior to publication or other release to another person or entity. In such cases, the APCD Administrator will review the report to determine whether the privacy rights of any individual would be violated by the release of the report.
2. In keeping with the minimum necessary standard established under HIPAA, applicants must demonstrate a need for each data element requested. The Administrator will release only those data elements which are determined to be absolutely necessary to accomplish the applicant's intended use as described in the approved Application.
3. Applicants may be required to show written approval from an Institutional Review Board or a Privacy Board as part of the Application.
4. Applicants requesting summary level information based on Medicare claims data will be required to conform to CMS requirements to obtain and use applicable data. CMS rules currently prohibit the release of Medicare claims data at the level of individual records.
5. The APCD will not include any Medicare data provided under the State Agency Request Data Use Agreement in Specialized Reports, including custom reports and analytic data sets or extracts, released to entities other than state agencies or researchers under contract to the state.
6. Medicaid data may not be included in Identifiable Information unless the release of such data conforms to all applicable federal and state laws and regulations, including laws and regulations governing the de-identification of such data, and any data release restrictions in the agency's interagency service agreement.

## **Data Release Criteria**

The Data Release Review Committee will review Applications and advise the APCD Administrator based on the following criteria:

1. The release of data is consistent with the statutory purpose of the APCD;
2. The release of data will contribute to efforts improve health care for Colorado residents;
3. The release of data complies with the requirements of HIPAA.
4. The analysis as described in the Application employs recognized analytic methods.

### **Conflict of Interest**

A member shall be recused from any discussion of an Application if he/she has a self-disclosed or discovered financial or other conflict of interest (as defined in the DRRC Member Agreement) in the outcome.

### **Fees**

The APCD Administrator will charge a reasonable fee to provide data. The fee schedule shall reflect the total cost of systems analysis, program development, computer production costs incurred in producing the requested data, vendors' fees, consulting services, and any other costs related to production of the requested data including a share of overhead costs required to support ongoing operations of the APCD. The fee schedule will be tiered to reflect differences in complexity and work effort required to fulfill different types of data requests at various levels of detail. Colorado APCD fee schedules will be provided as an attachment to the Data Release Application and will be updated from time to time.

If the custom report or analytic dataset contains Medicare data provided under the State Agency Request Data Use Agreement, the APCD may recover the actual cost of extracting the data and transmitting the dataset to a state agency or a researcher recipient under contract to the state.

## **Section 5: Provisions for Data Release**

Required Assurances: The applicant's Data Release Application will be incorporated into the Data Use Agreement. In addition, all applicants shall provide written assurances that:

- a) Data will be used only for the purpose stated in the Application;
- b) No attempt will be made to use any data supplied to ascertain the identity of specific insured individuals or patients or to report data at a level of detail that could permit a reader to ascertain the identify of specific insured individuals or patients, nor will downstream linkages to outside data sources occur without specific authorization from the APCD Administrator;
- c) Restricted data elements will not be released to any other person or entity except as specifically approved in the original Application and Data Use Agreement;

- d) The Applicant will obtain these assurances in writing from any recipient of data or agent that processes data on behalf of the Applicant; and
- e) The data will not be re-released in any format to anyone except personnel identified and approved in the original Application and Data Use Agreement.

## **Section 6: Enforcement**

Violation of the terms of the Data Use Agreement constitutes a breach of contract and may result in any or all of the following:

1. The APCD Administrator may require the immediate surrender and return of all APCD data.
2. Denial of future access to APCD data.
3. Lead to civil action by the APCD Administrator for breach of contract.
4. Result in a complaint filed with the U. S. Department of Health & Human Services, Office for Civil Rights, as well as potential civil and criminal action and penalties.
5. State Attorneys General are also empowered to take civil action against Applicants who violate the terms of the Data Use Agreement.