

Colorado All Payer Claims Database Data Release Application

Thank you for your interest in obtaining data from the CO APCD. As you fill out this application, please let us know if you have any questions or concerns by reaching out to ColoradoAPCD@civhc.org. We are here to help!

Also, please be aware that if you are requesting Protected Health Information (PHI), your request requires a recommendation for approval by the Data Release Review Committee (DRRC). Data elements that are considered PHI under HIPAA are indicated below. If PHI is requested, a CIVHC Account Executive will help you successfully complete an application and navigate the DRRC process.

Please use this application to submit information regarding your request for data from the Colorado All Payer Claims Database (CO APCD). This information will help the Center for Improving Value in Health Care (CIVHC), the Administrator of the CO APCD, answer any questions you have regarding your data request and assist us in helping you complete the data application form.

Note: Please reference the CO APCD Data Elements Request Form found at <http://www.civhc.org/get-data/data-release/> when completing this form.

Introduction: Section 10 CCR 2505-5-1.200.5 describes how the CO APCD Administrator addresses Requests for Data and Reports:

1.200.5.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 CO 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 (DUA), to comply with the requirements of HIPAA.

1.200.5. 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 CO 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.

This Data Release Application serves as the written request for information noted in section 1.200.5.A.

PART ONE

Project Information	
Project Title:	22.52 The cost and treatment of epilepsy
Date:	1/11/2022
Organization Requesting Data:	Emory University (Department of Health Policy and Management, Rollins School of Public Health)
Contact Person:	David Howard
Title:	Professor
E-mail:	david.howard@emory.edu
Phone Number:	404-727-3907
Person Responsible for the Project (if different than above):	
Title:	
E-mail:	
Phone Number:	

Project Purpose:

Project questions to be discussed with client representative:

- Please describe your project and project goals/objectives.

Epidemiological data suggests that 10% of Americans will suffer a seizure at some point in their lifetime (i.e., more than 33 million people). Epilepsy, a condition generally characterized by recurrent, unpredictable, spontaneous seizures, is the fourth most common neurological condition in the US (Zack & Kobau, 2017). Nearly 3 million adults in the US currently live with active epilepsy, a heterogeneous group of chronic disorders with multiple etiologies (e.g., generic, acquired), each presenting with a variety of seizure types (e.g., focal vs generalized onset), and subcategorizations (e.g., motor, impaired awareness) (Scheffer et al., 2017).

The advent of newer generation antiepileptic medications such as ezogabine, clobazam, perampanel, eslicarbazepine, brivaracetam, and cannabidiol (Rudzinski et al., 2016) has expanded treatment options. The shift away from older generation anticonvulsants to newer, better-tolerated drugs and their more economical generic formulations has substantially modified patients' access and adherence to treatment.

The overarching goal of our project is to estimate the costs incurred and treatments received by patients with epilepsy and/or seizure. (We include seizure because epilepsy is underdiagnosed, and patients with epilepsy may only have "seizure" recoded on claims for emergency department or hospital encounters.)

References

Rudzinski, L. A., Vélez-Ruiz, N. J., Gedzelman, E. R., Mauricio, E. A., Shih, J. J., & Karakis, I. (2016). New antiepileptic drugs: focus on ezogabine, clobazam, and perampanel. *Journal of Investigative Medicine*, 64(6), 1087-1101.

Scheffer, I. E., Berkovic, S., Capovilla, G., Connolly, M. B., French, J., Guilhoto, L., . . . Moshé, S. L. (2017). ILAE classification of the epilepsies: position paper of the ILAE Commission for Classification and Terminology. *Epilepsia*, 58(4), 512-521.

Zack, M. M., & Kobau, R. (2017). National and state estimates of the numbers of adults and children with active epilepsy—United States, 2015. *MMWR. Morbidity and mortality weekly report*, 66(31), 821.

- What specific research question(s) are you trying to answer or problem(s) are you trying to solve with this data request? (Please list and number the individual questions.)
 1. What are the costs incurred by patients with epilepsy and/or seizure?
 2. To determine how provider characteristics (age, specialty, gender, practice location) influence the treatments patients receive and whether they visit the emergency department.
 3. What are the relationships between insurance type (Medicaid/Medicare vs private) and costs and drugs received.
- How will this project benefit Colorado or Colorado residents? (this is a statutory requirement for all non-public releases of CO APCD data)

Estimates of the burden and cost of epilepsy are useful for prioritizing resources for the treatment and prevention of epilepsy and seizure. Estimates of hospital and emergency-department spending are useful for calling attention to opportunities to improve the diagnosis and outpatient management of epilepsy to prevent acute exacerbations. Descriptions of treatment patterns can identify opportunities to improve quality and reduce costs by increasing access to antiseizure medications and switching patients to less costly drugs.

- Please answer all applicable questions below (Note that your project must meet one or more of the Triple Aim criteria below to generate a benefit for Colorado):
 - If applicable, how will your project support lowering health care costs?

By understanding the costs to treat epilepsy and seizures we can identify and provide evidence on opportunities to 1) reduce spending on emergency department and inpatient care through improved outpatient management and 2) switch patients to less costly but equally effective drugs.

- If applicable, how will you project help improve the health of Coloradans?

While our project won't directly compare alternative approaches for treating epilepsy and/or seizure, studies like the one we are proposing can help to motivate quality improvement projects by quantifying emergency department and inpatient care use among patients who do not receive routine outpatient care or antiseizure medications.

- If applicable, how will your project improve the quality of care or patient experience?
- Do you need a claims data set or would you like a custom report generated by CIVHC that addresses the specific questions/problems your project seeks to address?

We would like to receive individual claims, either for the entire Colorado database or, if that is not possible, for 1) individuals with a claim listing a diagnosis code for epilepsy and/or seizure and 2) a group of individuals without claims for epilepsy or seizure to serve as a control group.

Primary Diagnosis Code (ICD-9) = 34550, 34550, 34551, 34551, 34550, 34570, 34580, 34550, 34570, 34580, 34551, 34571, 34581, 34551, 34571, 34581, 34540, 34540, 34541, 34541, 3452, 3453, 34500, 34510, 34501, 34511, 3452, 3453, 34501, 34511, 3452, 3453, 34560, 34560, 34561, 34561, 34580, 34580, 34580, 34580, 34581, 34581, 34581, 34580, 34581, 34581, 34580, 34580, 34581, 34581, 34580, 34581, 34590, 34590, 34591, 34591, 34580, 34580, 34581, 34581, 34580, 34580, 34581, 34581, 78031, 78032, 78033, 78039

Primary Diagnosis Code (ICD-10) = G40, G400, G40001, G40009, G4001, G40011, G40019, G4009, G401, G4010, G40101, G40109, G4011, G40111, G401111, G40119, G4019, G402, G4020, G40201, G40209, G4021, G40211, G40219, G4022, G40290, G403, G4030, G40301, G40309, G4031, G40311, G40319, G4039, G404, G4040, G40401, G40406, G40409, G4041, G40411, G40419, G405, G40501, G40509, G406, G408, G4080, G40801, G40802, G40803, G40804, G4081, G40811, G40812, G40813, G40814, G4082, G40821, G40822, G40823, G40824, G40833, G40834, G4089, G409, G4090, G40901, G40909, G409090, G409091, G4091, G40911, G40919, G40949, G4099, G40991, G40A, G40A0, G40A01, G40A09, G40A11, G40A19, G40B, G40B0, G40B01, G40B09, G40B11, G40B19, R56, R560, R5600, R5601, R561, R5669, R5681, R569, or R5691

(We can provide a spreadsheet with these codes if necessary.)

- Do you need Protected Health Information (PHI)?
 - Do you need patient-specific dates (e.g., dates of service or DOB) or 5 digit zip code. If so, this is a request for a **Limited Data Set**.

Yes.

We will use dates of service (day and month) to measure treatment patterns for patients with epilepsy/seizure for patients who change treatment regimens during the course of the year.

We will use 5 digit zip codes to measure individuals' area-level socioeconomic status by linking zip code to Census data measuring educational attainment and the proportion of residents in households below the poverty level.

- Do you need direct patient identifiers such as name, address, or city? If so, this is a request for an **Identifiable Data Set** (requires IRB approval).

No.

- If you do not require any PHI, please only complete PART ONE of the application.

Please note: your CIVHC representative will work with you to complete **Addendum I – Analyst Supplement** to address data warehouse specific questions.

If you are requesting a Custom Report with analytics to be provided by CIVHC; please stop here and submit the information above to your CIVHC representative.

PART TWO

1. **Type of CO APCD Analytic Data Set Requested**

Please select the type of data set that you are requesting by checking one of the boxes below (**select only ONE option**). Details on each type of CO APCD data set can be found in *The CO APCD Companion Instruction Guide* (available from your CIVHC representative):

Types of Analytic Data Sets (Please select ONE below)

For users interested in a wide range of data to analyze on their own.

- ☐ De-Identified Data Set
- ☒ Limited Data Set*
- ☐ Identified Data Set *

*These types of data requests include Protected Health Information (PHI). Under HIPAA, PHI may only be released in limited circumstances for public health, health care operations, and research purposes under the terms of a HIPAA compliant data use agreement (DUA).

2. **Requested Data Elements – Limited and Fully Identifiable Data Sets**

The CO APCD is committed to protecting the privacy and security of Colorado's health care claims data. The CO APCD will limit the use of the data to purposes permitted under applicable laws, including APCD Statute/Rule and HIPAA/HITECH, to information reasonably necessary to accomplish the project purpose as described in this Application.

Data Element Selection and Justification

If you have not already done so, please use the Data Element Dictionary (DED) to identify the specific data elements that are required for this project. In keeping with the minimum necessary standard established under HIPAA, CO APCD policy is to release only those data elements that are required to complete your project.

Type of Data	Justification for Elements on the DED
Names	N/A
Street Address	N/A
City	N/A
Zip Code	Measure area-level socioeconomic status
Health Plan Beneficiary Numbers	N/A
Dates (including Day and Month detail.) Specify which date fields are needed and why.	To determine the sequencing of medications and whether physicians switch medications following emergency department visits and hospitalizations.
Provider Identifying Information	We would like to determine physicians' specialty.

A. Counts, Totals and other Summary Statistics

The CO APCD seeks to provide aggregated summary data whenever possible. Applicants are encouraged to request counts, totals, rates and other summary values whenever such information can reasonably accomplish the purpose of the project (add rows to the table below if necessary). The CO APCD supports the federal CMS minimum cell size suppression policy that requires any cell in any report or data table, printed or electronic, with less than eleven records or observations to be replaced by "Less than eleven" or similar text. You must also apply complementary cell suppression techniques to ensure that cells with fewer than eleven records cannot be identified by manipulating data in adjacent rows and columns.

Field Number and Name	Requested Count or Sum
	<i>[add rows as needed]</i>

B. Linkages to Other Data Sets

The CO APCD seeks to ensure that data cannot be re-identified if it is linked to or combined with information obtained from other sources. If this project requires claims line level detail or includes linkages to other databases, or if CO APCD data will be combined with other information, provide a justification for each proposed linkage. Be sure to describe how this will contribute to achieving the project purpose, including whether the project can be completed without this linkage, and the steps you will take to prevent the identification of individual patients:

Will you link the CO APCD data to another data source?

☐ No.

☒ Yes. If yes, please answer the following questions.

- Other publicly available data that includes zip code characteristics and physician practice settings and demographics

- Once the linkage is made, what non-CO APCD data elements will appear in the new linked file?
- Zip code-level education (e.g., percent of residents who attended college).
- Zip code-level poverty level (e.g., percent of households with incomes below the federal poverty level.)
- Physician age and practice setting (independent group, hospital-owned practice)
- Have all necessary approvals been obtained to receive and link with the other data files (e.g., IRB or Privacy Board approval)?
 - ☐ Yes, if so please provide copy
 - ☒ In progress, anticipated approval date: March 1, 2022
 - ☐ No or N/A, reason: _____

C. Distribution of the Report or Product:
Prior Review by the CO APCD Administrator

If you are producing a report for publication in any medium (print, electronic, lecture, slides, etc.) the CO APCD Administrator must review the report prior to public release. The CO APCD Administrator will review the report for compliance with CMS cell suppression rules; risk of inferential identification; and consistency with the purpose and methodology described in this Application.

- Please describe your audience and how to you will make your project publicly available?

We will produce manuscripts for peer-reviewed medical journals. We will disclose aggregate results, making sure to suppress results with a cell size smaller than 11 patients. We will not release the raw data.

- If the report is not to be made publicly available, then briefly describe how the information derived from this data will be used and by whom:

Other Organizations: Do you intend to engage third parties who will have access to the data requested as part of this project? If so, list the organizations below, describe their role(s); and explain why they will be granted access to the requested data.

Organization/Company Name:	N/A
Contact Person:	
Title:	
Address:	
Telephone Number:	
E-mail Address:	
Role or responsibility in this project	<i>[add rows as needed]</i>

Project Schedule:

Proposed Project Start Date:	March 1, 2022
Project End Date:	December 31, 2024
Proposed Publication or Release Date:	We plan to submit 2-3 papers for publication, beginning September 1, 2022.
End of Date Retention Period:	August 31, 2025 (to allow for revisions to the analysis requested by journal reviewers).

D. Frequency

Data in the CO APCD Warehouse is refreshed every other month and data products can be provided on a one time basis or under a subscription model (e.g., quarterly, bi-annually or annually). Please select frequency below.

☒ One Time

OR

Subscription (Please select subscription model below)

☐ Quarterly

☐ Bi-annually

☐ Annually

E. Project Reporting

CIVHC highlights projects and data analysis on the public website: www.civhc.org/change-agents. This display of CO APCD projects provides future data requesters with ideas of how they can structure their analysis, and allows CIVHC's stakeholders to see how CO APCD data recipients are working to accomplish the Triple Aim for Colorado. Data recipients have the option of choosing whether to be identified or to not be identified.

☒ Yes, it is okay for CIVHC to identify my organization

☐ No, I do NOT wish for CIVHC to identify my organization

PART THREE

DATA MANAGEMENT PLAN (Not applicable for Custom Report Requests)

1. Organizational Capacity

As an Attachment, please provide copies of the Data Privacy and Security Policies and Procedures for the Requesting Organization as well as those of any third parties that will have access to the requested CO APCD data.

We have attached Emory University's IT Security Standards and Guidelines.

- Has the Requesting Organization or any member of the project team ever been involved with a project that experienced a data security incident? If so, describe the incident, the response procedures that were followed and any subsequent changes in procedures, processes or protocols to mitigate the risk of further events.
 - No.

To the extent that the Data Privacy and Security Policies and Procedures, provided as an Attachment, do not already do so, please answer or attach answers for the following:

- **Physical Possession and Storage of CO APCD Data Files:**
 - Describe how you will maintain an inventory of CO APCD data files and manage physical access to them for the duration of the project:

Dr. Howard will be responsible for managing the data and ensuring appropriate safeguards are in place to protect the data and prevent inadvertent disclosure of confidential information. Dr. Howard will create and maintain an inventory of all CO APCD data files and any derivate files created from the original data. The inventory will be stored on the Rollins School of Public Health server (see below). The inventory will be updated monthly.

See below for information about managing access.

- Describe your personnel/staffing safeguards, including:
 - Confidentiality agreements in place with individuals identified as being assigned to this study. Include, for example, agreements between the Principal Investigator or Data Custodian and others, including research team members, and information technology and administrative staff:
 - Staff training programs you have in place to ensure data protections and stewardship responsibilities are communicated to the research team:
 - Procedures to track the active status and roles of each member of the research team throughout the project and a process for notifying the CO APCD of any changes to the team:

Only two investigators will have access to the data: David Howard (Professor, Department of Health Policy and Management) and Nada Boualam (doctoral student, Department of Health Policy and Management). All personal must undergo Human

Subjects Training (i.e., CITI training) and receive training on compliance with HIPAA. Additionally, Dr. Howard and Ms. Boualam will meet regularly to discuss analyses with the data and ensure that the analysis, handling of the data, and reporting of results is compliant with the data use agreement and Emory data security policies.

Only authorized, trained system administrators have administrative privileges on the servers in which data will be stored. System administrators monitor security mailing lists and sites and patch/update systems based on priority of the patch. All servers are periodically scanned for vulnerabilities and any identified vulnerabilities are assessed and managed. If a member of the research team drops out of the study while it is still in process, all access to data will be revoked from this individual, and the CO APCD will be contacted and the respective incident reported.

All information technology personnel go through background checks before gaining access to administrative privileges. At point of termination with Emory, all information technology personnel's administrative privileges are removed.

- Describe your technical and physical safeguards. Examples include:
 - Actions taken to physically secure data files, such as site and office access controls, secured file cabinets and locked offices.
 - Safeguards to limit access to CO APCD data and analytical extracts among the research team (Note: if the distribution of analytical data extracts among the researcher team is part of your data management plan, the extracts remain subject to the terms of your Data Use Agreement).

Hardcopies: David Howard, the Principal Investigator, will be responsible for data security. Hardcopies of data (on USB drives or DVDs) will be stored in a locked file drawer in the Principal Investigator's office (Grace Crum Rollins Building, Emory University, 1518 Clifton Road NE, Room 656). Only Prof. Howard has a key to the file drawer. The room in which the file drawer is located is locked at all times. Only Prof. Howard and cleaning staff have a copy of the key

Electronic files: Electronic data, including the original data and extracts, will be stored on the "S drive", a dedicated space for storing research data, of the Rollins School of Public Health (RSPH) network. The data will be stored in Dr. Howard's personal folder "S:\hpm\DHoward".

The folder where the data are stored is password protected. Only Dr. Howard and Ms. Boualam will have access to the folder. The data will be accessed only from on-campus computers or via Emory's virtual desktop platform, Apporto. Dr. Howard and Ms. Boualam will lock their computers when they are not in use.

RSPH and Emory network are protected by firewalls and intrusion detection devices. Rules on these devices are set to deny all traffic by default and "allows" are written as exceptions. These devices are updated as appropriate through Emory University's

change management process and evaluated to ensure they provide the appropriate level of protection based on the sensitivity level of the data.

Servers are housed within a secured network operating center (NOC). The NOC has environmental controls (fire, water, temperature), is accessible only through a two-factor authorization system (key card and passcode), and is accessible only by authorized information technology personnel. In the event of a power outage, the NOC devices will draw UPS power then from a backup generator.

All servers are configured based on RSPH and Emory University best practices. Only authorized, trained system administrators have administrative privileges on the servers. System administrators monitor security mailing lists and sites and patch/update systems based on priority of the patch. All servers are periodically scanned for vulnerabilities and any identified vulnerabilities are assessed and managed.

- Provide a brief description of your policies and procedures for ensuring that CO APCD data are protected when stored on a server.
 - Describe how your organization prevents the copying or transfer of data to local workstations and other hard media devices (CDs, DVDs, hard drives, etc.). Note that Applicants are required to encrypt CO APCD data both in motion and at rest:

The folder where the data are stored is password protected. Only Dr. Howard and student assistant will have access to the folder. The data will be accessed only from on-campus computers or through the Rollins School of Public Health virtual desktop. Dr. Howard and student assistant will lock their computers when they are not in use.

RSPH and Emory network are protected by firewalls and intrusion detection devices. Rules on these devices are set to deny all traffic by default and "allows" are written as exceptions. These devices are updated as appropriate through Emory University's change management process and evaluated to ensure they provide the appropriate level of protection based on the sensitivity level of the data. Security patches are installed regularly, and accesses to services are logged or protected. Servers are physically located in a secured and access-controlled space.

- Data Reporting and Publication
 - Your organization must ensure that all analytic extracts, analyses, findings, presentations, reports, and publications based on CO APCD data files adhere to specific requirements of the Data Use Agreement (DUA: refer to sections 6, 7 and 8 in the Data Use Agreement). **Briefly describe your plan for demonstrating that data reporting and publication processes will be consistent with the DUA, including adhering to CO APCD cell suppression policies:**

- a. The Receiving Organization's compliance with minimum cell size and complimentary cell suppression rules;
- b. That the report or output has incorporated appropriate protections to prevent inferential identification; and
- c. That the report or output is consistent with the project description contained in the Receiving Organization's Application, as approved.

To demonstrate adherence to APCD-DUA we will assure that no cell with less than 11 observations will be displayed in public reports or materials. Furthermore, no mathematical formulas will be used, or percentages will be calculated using a cell with less than 11 observations. Furthermore, there will be no attempt within this project to identify any individuals within the APCD data or link records to any individually identifiable source of information.

No attempt will be made to identify patients or providers or profile specific providers based on patterns of care or patient outcomes. There will be no need to make printouts of patient-specific data. Only tabulated and summarized data (based on the records of thousands of patients) will be printed.

Our research team will additionally provide results to the APCD administrator and obtain approval from the administrator before releasing reports or outputs to distribution outside our project team.

2. Completion of Research Tasks and Data Destruction

Your organization must ensure that it has policies and procedures in place to destroy the CO APCD data files upon completion of the project and that you have safeguards to ensure the data are protected when researchers terminate their participation in the research project. Describe your plan for demonstrating that your organization has policies and procedures in place to reliably destroy the data files upon completion of the research:

It is the responsibility of individual investigators at Emory to ensure compliance with data destruction policies. The principal investigator, David Howard, will destroy the data upon project completion. All electronic copies of the data, and datasets created using the original data, will be deleted from the server. Hardcopies (CDs or USB drives) will be taken to Emory Shredding Services in Emory's Facilities Management division for destruction.

3. Request for Privacy Board Approval *(Only Applicable to Identifiable Data Requests)*

Projects that request Identifiable information for a research purpose may require approval from the DRRC acting as a Privacy Board if an IRB is not available.

- The DRRC, acting as a Privacy Board, may approve a waiver of the individual authorization normally required to release PHI under CFR § 164.508 if:
- It would be impracticable for researchers to obtain written authorization from patients that are the subject of the research; and

- The research could not practicably be conducted without access to and use of the PHI.
- The DRRC, acting as a Privacy Board, is required to evaluate certain criteria in considering whether to approve an authorization waiver. If you are requesting Identifiable Information for a research purpose, explain why your proposed use of PHI involves no more than a minimal risk to the privacy of patients that are the subject of the research. Evidence of minimal risk to the privacy of patients that should be addressed in your explanation includes:
 - An adequate plan to protect PHI identifiers from improper use and disclosure;
 - An adequate plan to destroy PHI identifiers at the earliest opportunity; and
 - Adequate written assurances that PHI will not be reused or disclosed.

Appendix I

Certification of Project Completion and Destruction or Retention of Data

(Please Save)

Name:	
Title:	
Organization:	
Address:	
Tel Number:	
Fax Number:	
E-mail Address;	
Project Title:	
Data Sets:	
Years:	
<input type="checkbox"/> Certification of Data Destruction	Date the Data was Destroyed:
<input type="checkbox"/> Request to Retain Data	Date Until Data Will Be Retained:

Instructions: Data must be destroyed so that it cannot be recovered from electronic storage media in accordance with the methods established by the “Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals,” as established by the U.S. Department of Health and Human Services (HHS).

I hereby certify that the project described in the Application is complete as of this date
_____, ___, 20__.

Complete the appropriate section, below:

☐ I/we certify that we have destroyed all Data received from the CO APCD Administrator in connection with this project, in all media that were used during the research project. This includes, but is not limited to data maintained on hard drive(s), diskettes, CDs, etc.

☐ I/we certify that we are retaining the data received in connection with the aforementioned project, pursuant to the following health or research justification (provide detail, use as much additional space as necessary and state how long the data will be retained).

☐ I/we hereby certify that we are retaining the Data received from the APCD Administrator in connection with the aforementioned project, as required by the following law. [Reference the appropriate law and indicate the timeframe].

By signing this Agreement, the Receiving Organization agrees to abide by all provisions set out in this Agreement.

SIGNATURES:

For the CO APCD:

For Receiving Organization:

Signature:



Signature:

Name: Pete Sheehan

Name: David H. Howard

Title: VP of Client Solutions & State Initiatives

Title: Professor