Data Release Application
Limited and Identifiable Extract

Application Navigation

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Client Application Revision History

The following reflects the history of changes made to this document during the application process prior to project production. Once in production, any further changes to the application may result in additional cost and production delays.

To be completed by CIVHC staff			
Date	New Version Number	Description of Change(s)	CIVHC Change Author
1/23/2024	V.01	Initial version drafted with client.	Lucía Sanders, Key Account Manager
1/30/2024	V.02	Minor updates after internal CSSI review.	Lucía Sanders, Key Account Manager
2/19/2024	V.03	Updated DMP approval. Collected sign off for DRRC.	Lucía Sanders, Key Account Manager
3/8/2024	V.04	Added Professional claims and noted linkage to ACS data.	Lucía Sanders, Key Account Manager
3/14/2024	V.05	Updated invoice contact.	Lucía Sanders, Key Account Manager
4/1/2024	V.06	Added member eligibility dates.	Lucía Sanders, Key Account Manager
Date	V.07	Click or tap here to enter text.	Name, Title
Date	V.08	Click or tap here to enter text.	Name, Title
Date	V.09	Click or tap here to enter text.	Name, Title
Date	V.10	Click or tap here to enter text.	Name, Title
Date	V.11	Click or tap here to enter text.	Name, Title
Date	V.12	Click or tap here to enter text.	Name, Title
Date	V.13	Click or tap here to enter text.	Name, Title
Date	V.14	Click or tap here to enter text.	Name, Title
Date	V.15	Click or tap here to enter text.	Name, Title

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Data Requestor Details

General Project Details

Project Title:	**What is emergent enough? Quantifying life-threatening pregnancy complications for a post-Dobbs world**
Application Start Date:	1/12/2024
Requested Project Delivery Date:	4/15/2024
Client Organization:	University of Colorado School of Medicine, Division of Complex Family Planning
Client Organization Address:	8111 E Lowry Blvd, Ste 220, Denver, CO 80230
To be completed by CIVHC staff	
CIVHC Contact:	Lucía Sanders
Project Number:	24.26
Condensed Project Title:	Quantifying Pregnancy Complications

Project Contacts

Project Contact Name:	Nancy Fang, MD MS
Title:	Assistant Professor
Email:	Nancy.fang@cuanschutz.edu
Phone Number:	508-733-6187
Analytic Contact Name:	Nancy Fang, MD MS
Title:	Assistant Professor
Email:	Nancy.fang@cuanschutz.edu
Phone Number:	508-733-6187
Invoice Contact Name:	Majik Abidzhanova
Title:	Business Support Director
Email:	majik.abidzhanova@cuanschutz.edu
Phone Number:	N/A

Data Release Fee Signatory

Name:	Chrissy Alexander
Title:	Senior Purchasing Agent

Email:	chrissy.alexander@cu.edu

Data Use Agreement Signatory

Name:	Alison Lakin
Title:	Vice Chancellor for Regulatory Compliance
Email:	Alison.Lakin@cuanschutz.edu

Project Schedule and Purpose

Proposed Project Start Date[1]:	1/15/2024
Anticipated Project End Date:	1/15/2029
Proposed Publication or Release Date:	1/15/2027

1. Detail the specific research question(s) you are trying to answer or problem(s) you are trying to solve with this data request. Please list and number the individual questions.

> 1. What is the incidence of pregnant people in Colorado that have pre-existing chronic health conditions that increase their risk of morbidity and mortality?
> 2. What is the incidence of pregnant people in Colorado that have pregnancy complications?
> 3. What is the incidence of pregnant people in Colorado who receive an abortion secondary to threat to maternal health?
> 4. Does geographic location affect pregnancy outcomes?
> 5. How do these results compare to another state (Virginia)? What are the possible differences in health policy that contribute to these findings found between the two states?

2. Describe your methodology or how you will be using data from the Colorado All Payer Claims Database (CO APCD) to answer your research questions.

> Using codes that identify diagnoses, procedures and surgeries (i.e., International Classification of Diseases (ICD) and Current Procedural Terminology (CPT) as well as demographic information about the patients, we can use this dataset to identify pregnant people and common conditions that threaten maternal health.
>
> We will characterize pregnancy outcomes (live birth, miscarriage, ectopic pregnancy, stillbirth, induced abortion) as well as any sequelae that may be related to underlying conditions. We will use findings on the prevalence of underlying health conditions to model the population impact of legal changes to abortion access.
>
> We will also conduct a spatial analyses using ArcGis. We will generate maps of census tracts related to maternal outcomes and access to hospitals with labor and delivery.
>
> We are requesting all lines of business in this dataset, including Medicare, due to

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[1] After all required documents have been signed and the Data Release Review Committee has approved the project, typical production time is 30-60 days for a Limited or Identifiable Extract. Anticipate a longer production period for projects including a Finder File or creation of a Member Match File.

> Medicare's coverage of patients under 65 for those with a confirmed medical disability. Many patients who are of reproductive age and medical disability have increased risk to health during pregnancy.
>
> We are also requesting pharmacy claims for medications as there are certain medications that are teratogenic during pregnancy or that are associated with medical conditions that place a person at risk of severe medical morbidity or mortality during pregnancy.

3. Explain how this project will benefit Colorado and its residents.[2]

> There is a maternal morbidity and mortality crisis in the United States and affects our residents in Colorado. This project aims to quantify the number of Colorado residents who are living with health conditions that are dangerous in pregnancy and describe their pregnancy outcomes. This baseline information will be important to establish as Colorado continues to be a leader in supporting efforts in accessing reproductive healthcare and improving maternal, fetal, and neonatal outcomes. In collaboration with my colleagues at Duke University, we plan to use this data to create a model that can predict the impacts of supportive or unsupportive health policy related to reproductive health.

4. Describe how your project will improve health care quality, increase health care value, or improve health outcomes for Colorado residents.[2]

> By characterizing people with health conditions that affect the health of their pregnancy and comparing them to other states (including Virginia), our team will be able to identify risk markers associated with different pregnancy outcomes. While our team understands that maternal morbidity and mortality involves a complex interplay of socioeconomic and structural factors that may not be captured in the claims database, this project can help identify specific populations that may benefit from further support or services due to inequities revealed by our analysis.

5. Health equity is defined as the state in which everyone has a fair and just opportunity to attain their highest level of health. Explain how your project addresses health equity.

> Our team is especially interested in health disparities. Already, non-Hispanic Black women have three times greater maternal mortality than other groups. Abortion bans are projected to worsen health disparities because of the racial and ethnic demographics in states banning abortion, economic limitations on ability to travel out-of-state to seek abortion care, and disparate access to health care in general. Colorado remains a state that has protected access to abortion while Virginia has not. Our analysis aims to decipher if differences in health policy can affect maternal health outcomes.

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[2] It is a statutory requirement for all non-public releases of CO APCD data to benefit Colorado or its residents. Contributions to generalizable knowledge alone are not sufficient to satisfy this requirement.

Data Matching and Linkage

Finder File

A Finder File is a file you submit to CIVHC with information about a pre-selected cohort for matching to CO APCD data. Ask your CIVHC Contact for more information about this process and requirements for Finder File submission.

Will you provide CIVHC with a Finder File as part of this project?

☒ No
☐ Yes

Member Match File

A Member Match File is a file that CIVHC creates on your behalf to send to a registry or other outside entity to create a crosswalk connecting data from the CO APCD to the other entity's data.

Does this project require the creation of a Member Match File?

☒ No
☐ Yes. Consult with your CIVHC Contact about completing a Member Match File Data Element Selection Form. Answer the following:

Who will receive the Member Match File?
Please specify here.

Control Group

A Control Group is a group of individuals who can be used to compare against the cohort identified in the Finder File.

Will you need to create a Control Group as part of this project?

☒ No
☐ Yes. Consult with your CIVHC Contact about completing a Control Group Data Element Selection Form.

Linkage

Data Linkage is a method of joining data from different sources together to create a new data set.

Will the CO APCD data be linked to another data source?

☐ No
☒ Yes. Answer the following:

What is (are) the other data source(s)?
American Community Survey (ACS)

Who will perform the data linkage?
Anschutz Research Team

What identifying data elements will be used to perform the data linkage?
Census tract

What non-CO APCD data elements will appear in the new linked file?
Social Vulnerability Index (SVI) and the Area Deprivation Index (ADI)

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Data Inclusion Criteria

Make selections in the following sections based on what data you want to have included in this extract. If you will be creating a Control Group, complete this section for your study population and not the Control Group.

Protected Health Information

Indicate which Protected Health Information data elements you require for your project purpose:

Available for Limited and Identifiable extracts:		
☒ Member 5-Digit Zip Code	☒ Member Census Tract	☐ Member County
☐ Member City	☒ Member Eligibility Date	☐ Employer Tax ID
☒ Member Dates of Service		
Available for Identifiable extracts only (see also Identifiable Data Use Approval):		
☐ Member Name	☐ Member Date of Birth (if requesting more than year only)	
☐ Member Geocoded Address	☐ Member Geocoded Latitude and Longitude	
Provide detailed justification for the inclusion of all PHI data selected above, and explain how its inclusion meets the Minimum Necessary Requirement.[3]		

Including the 5 digit zip code, census tract and member dates of service will be beneficial in our analyses for several reasons:

Geographic Analysis: Member zip codes and census tracts provide geographical information that can be used for regional trends, demographic profiling, and resource allocation. Understanding where services are being utilized can help identify areas for resource allocation.

Service Utilization Patterns: Dates of service enable analysis of when services are being utilized by members. This information can help in identifying patterns such as seasonal variations, or trends over time.

Quality of Care Evaluation: Disparities in service utilization across different zip codes may indicate areas where additional resources or interventions are needed to ensure equitable access to care.

Finally, member eligibility date is required to understand the patient's 5-digit zip code and census tract at the time of service, since a member could have multiple addresses from 2018-2020.

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[3] Limited and Identifiable extracts must adhere to the Minimum Necessary Requirement under the HIPAA Privacy Rule; only that data required to answer the project purpose can be included in the request.

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Line(s) of Business

- ☒ Commercial Payers
- ☒ Health First Colorado (Colorado's Medicaid and CHP+ programs)[4]
- ☒ Medicare Advantage
- ☒ Medicare Fee for Service (FFS)[5]

Year(s) of Data

☐ 2012	☐ 2013	☐ 2014	☐ 2015	☐ 2016	☐ 2017
☒ 2018	☒ 2019	☒ 2020	☐ 2021	☐ 2022	☐ 2023[6]

Claim Types

- ☒ Inpatient Facility   ☒ Outpatient Facility   ☒ Professional
- ☒ Pharmacy   ☐ Dental

Financial Detail by Line Item

- ☐ Charged Amount   ☐ Allowed Amount   ☐ Plan Paid Amount
- ☐ Plan Pre-Paid Amount   ☐ Member Copay   ☐ Member Deductible
- ☐ Member Coinsurance   ☐ Total Member Liability

Filter Criteria – Services, Providers, Facilities

If you need data for specific services, providers and/or facilities, specify that filter criteria below (ask your CIVHC Contact about including an additional file with this application for large code lists):

ICD Diagnosis Code(s):
Please specify here.
Procedure(s) (list CPT, HCPCS, DRG, ICD, and/or CDT codes):
Please specify here.
Drug(s) (list pharmacy NDC and/or HCPCS codes):
Please specify here.

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[4] Medicaid-only data requests must be approved by the Colorado Department of Health Care Policy and Financing.
[5] Medicare FFS data are not available for all requests and must go through a separate approval process.
[6] This year's data is incomplete. Consult with your CIVHC Contact to find out what data is available at the time of your request.

Facility Type(s):
Please specify here.
Facilities (list NPIs and/or Pharmacy IDs):
Please specify here.
Facilities within these geographical areas (list county, zip code, Census Tract, etc.):
Please specify here.
Provider Type(s):
Please specify here.
Provider(s) (list NPIs):
Please specify here.
Providers within these geographical areas (list county, zip code, Census Tract, etc.):
Please specify here.
Specific payers (minimum of five):
Please specify here.
Other claim specification:
Please specify here.

Filter Criteria – Members/Patients

If you need data for specific member/patient groups, specify that filter criteria below (ask your CIVHC Contact about including an additional file with this application for large code lists):

Ages:		
Younger than 55		
☐ At the time of service.	☒ At year end	☐ By another anchor date: Please specify here.
With these ICD Diagnosis Code(s):		
Please see "ICD10 codes-Filter" tab in the CIVHC Data Request Form		
Who have had the following procedure(s) (list CPT, HCPCS, DRG, ICD, and/or CDT codes):		
Please specify here.		

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<table>
<tr><td>Within these geographical areas (list county, zip code, <u>Census Tract</u>, etc., in keeping with your selected <u>Protected Health Information</u>):</td></tr>
<tr><td>Please specify here.</td></tr>
</table>

Value-Add Data Elements

Indicate which (if any) of the following value-add options you would like included with this extract:

- ☐ <u>Medicare Severity Diagnosis Related Group</u> Codes (MS-DRGs)
- ☐ <u>3M All Patient Refined Diagnosis Related Group</u> Codes (3M APR DRGs)
- ☐ <u>Medicare Repricer</u>
- ☐ Fields from the <u>American Community Survey</u>:

    Please specify here.

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Additional Documentation

Data Element Selection Form

The Data Release Application must be accompanied by a completed Data Element Selection Form to be reviewed internally and by the Data Release Review Committee. Ask your CIVHC Contact for more information about completing this form.

☒ By checking this box, the Client Organization confirms that the Data Element Selection Form has been completed.

☐ By checking this box, the Client Organization confirms that a separate Member Match File Data Element Selection Form has been completed, if applicable.

☐ By checking this box, the Client Organization confirms that a separate Control Group Data Element Selection Form has been completed, if applicable.

Identifiable Data Use Approval

If you are requesting Identifiable information, approval from an Institutional Review Board (IRB) or a Privacy Board is required before such data can be released.

☐ Not applicable; the Client Organization is requesting a Limited Extract.

Approval Type
☒ IRB approval
☐ Privacy Board approval

State of Approval

☐ Approval request not yet submitted.
    Anticipated submission date: Date

☐ Approval request submitted and under review.
    Anticipated project approval date: Date

☒ Approval already received.

Approval Documentation

☒ By checking this box, the Client Organization confirms that the IRB or Privacy Board application and approval documents have been provided to CIVHC.

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Data Management Plan

An organization requesting CO APCD data must submit an organizational Data Management Plan to CIVHC outlining the organization's data security and data management policies and procedures to safeguard the data. This Data Management Plan must be approved by CIVHC prior to any data release.

☐ Submitted to CIVHC on Date

☒ Approved by CIVHC on **2/19/2024**

Client Acknowledgements and Signatures

Change Agent Index

CIVHC can publicly share the Client Organization's name in its Change Agent Index.

☒ Yes   ☐ No

Report or Product Distribution

If your project results in the production of a report for public distribution in any format (print, electronic, lecture, slides, etc.), including peer-reviewed publication, it must be submitted to CIVHC for review prior to public release. CIVHC will assess compliance with CMS cell suppression rules, risk of inferential identification, CIVHC and CO APCD citations, and consistency with the purpose and methodology described in this Data Release Application. CIVHC will not assess the accuracy of the study results or attempt to recreate results.

This requirement is further defined in the Data Use Agreement. Failure to pursue and obtain CIVHC approval prior to publication will be a violation of the Data Use Agreement and may put the organization's future access to data from the CO APCD at risk.

☒ By checking this box, the Client Organization acknowledges this requirement.

Data Destruction Period

All data must be destroyed within 30 days of the project end date. If your project end date changes from this application, please reach out to your CIVHC Contact for a project extension request form.

☒ By checking this box, the Client Organization acknowledges that CIVHC's Data Destruction Certificate[7] must be completed and returned to DataCompliance@CIVHC.org by 2/15/2029 based on the Anticipated Project End Date.

Data Users

List any individuals that will be working with the data. The Data Use Agreement must be updated through your CIVHC Contact every time individuals are granted access to the data during the course of the project.

Name	Role	Organization
Nancy Fang, MD MS	PI	School of Medicine, CU Anschutz
Jeanelle Sheeder, PhD, MSPH	Co-Investigator	School of Medicine, CU Anschutz
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[7] Available on the Data Release Application and Documents page of CIVHC's website under *Privacy, Security, and Regulatory Information*.

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Data Release Application Version Approvals

Checkpoint 1: Preparation for CIVHC's internal Application Review Meeting

The Client Organization has reviewed and confirms that V.02 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Initials:	LS	Initials:	NF
Name:	Lucía Sanders	Name:	Nancy Fang
Title:	Key Account Manager	Title:	Assistant Professor
Date:	1/30/2024	Date:	1/30/2024

Checkpoint 2: Preparation for presentation to the Data Release Review Committee

The Client Organization has reviewed and confirms that V.03 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Initials:	LS	Initials:	NF
Name:	Lucía Sanders	Name:	Nancy Fang
Title:	Key Account Manager	Title:	Assistant Professor
Date:	2/19/2024	Date:	2/20/2024

Checkpoint 3: Final approval to begin project production

The Client Organization has reviewed and confirms that V.05 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Signature:		Signature:	
Name:	Lucía Sanders	Name:	Nancy Fang
Title:	Key Account Manager	Title:	Assistant Professor
Date:	Date	Date:	Date

Data Release Application

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Data Element Selection Form Version Approvals

Checkpoint 1: Preparation for CIVHC's internal Application Review Meeting

The Client Organization has reviewed and confirms that V.02 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Initials:	LS	Initials:	NF
Name:	Lucía Sanders	Name:	Nancy Fang
Title:	Key Account Manager	Title:	Assistant Professor
Date:	1/30/2024	Date:	1/30/2024

Checkpoint 2: Preparation for presentation to the Data Release Review Committee

The Client Organization has reviewed and confirms that V.03 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Initials:	LS	Initials:	NF
Name:	Lucía Sanders	Name:	Nancy Fang
Title:	Key Account Manager	Title:	Assistant Professor
Date:	2/19/2024	Date:	2/20/2024

Checkpoint 3: Final approval to begin production

The Client Organization has reviewed and confirms that V.04 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Signature:		Signature:	
Name:	Lucía Sanders	Name:	Nancy Fang
Title:	Key Account Manager	Title:	Assistant Professor
Date:	Date	Date:	Date