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Data Release Application
Limited and Identifiable Extracts

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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 (full name, complete title)
12/4/2024	V.01	Initial version drafted with client.	Lucía Sanders, Key Account Manager
12/11/2024	V.02	Expansion of project purpose and methodology.	Lucía Sanders, Key Account Manager
12/13/2024	V.03	Added filtering by gender and added details regarding control group creation.	Lucía Sanders, Key Account Manager
	V.04		
	V.05		
	V.06		
	V.07		
	V.08		
	V.09		
	V.10		

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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:	11/26/2024
Requested Project Delivery Date:	2/1/2025
Client Organization (legal name):	University of Colorado School of Medicine, Division of Complex Family Planning
Client Organization Address:	8111 E Lowry Blvd, Ste 220, Denver, CO 80230
CIVHC can publicly share the Client Organization's name in its Change Agent Index.	☒ Yes ☐ No
To be completed by CIVHC staff	
CIVHC Contact (full name, complete title):	Lucía Sanders, Key Account Manager
Project Number:	25.26
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

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Analytic Contact Name:	Mary Sammel, ScD
Title:	Professor, Associate Director, Center for Innovative Design & Analysis
Email:	Mary.sammel@cuanschutz.edu
Phone Number:	n/a
Invoice Contact Name:	Pamela Alvarez Moran
Title:	Administrative Research Core Manager
Email:	Pamela.alvarezmoran@cuanschutz.edu
Phone Number:	303-724-6501
Data Release Fee Signatory:	Chrissy Alexander
Title:	Senior Purchasing Agent
Email:	chrissy.alexander@cu.edu
Phone Number:	303-764-3472
Data Use Agreement Signatory:	Chrissy Alexander
Title:	Senior Purchasing Agent
Email:	chrissy.alexander@cu.edu
Phone Number:	303-764-3472

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Project Schedule and Purpose

Proposed Project Start Date[1]:	2/1/2025
Anticipated Project End Date:	2/1/2030
Proposed Publication or Release Date:	2/1/2028

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.

> This project is both a continuation and expansion of past project 24.26 (What is emergent enough? Quantifying life-threatening pregnancy complications for a post-Dobbs world). Project 24.26 included CO APCD data across all lines of business with dates of service from 1/1/2018-12/31/2020 for female individuals younger than 55 years of age. As an expansion of the initial project, this data request will include non-pregnant individuals as a comparison group to pregnant individuals at risk of morbidity and mortality due to their pre-existing chronic conditions.
>
> *Individual research questions:*
>
> i. What is the incidence of pregnant people in Colorado that have pre-existing chronic health conditions that increase their risk of morbidity and mortality?
>
> ii. What is the incidence of pregnant people in Colorado that have pregnancy complications?
>
> iii. What is the incidence of pregnant people in Colorado who receive an abortion secondary to threat to maternal health? How does their risk of severe maternal morbidity and mortality differ from a cohort of non-pregnant individuals with similar medical conditions?
>
> iv. Develop a risk prediction model for severe maternal mortality among reproductive aged females with conditions that are a threat to maternal health.
>
> v. Does geographic location affect pregnancy outcomes?
>
> vi. 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?

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[1] After all required documents have been signed, 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.

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 as well as a corresponding cohort of non-pregnant individuals with similar conditions.
>
> 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 and compare them to a non-pregnant cohort with similar 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 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 it 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

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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 to 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.

6. Describe any publication you plan to develop based on your use of CO APCD data, its intended audience, and whether it will be made publicly available.

> We plan to share our findings for the stated research questions in a peer-reviewed medical journal such as Obstetrics & Gynecology and American Journal of Public Health. We anticipate these publications will attract interest from news media outlets such as NPR or local news outlets.

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 separate Data Element Selection Form specifying the data elements that should be used to create the Member Match File.

    Answer the following:

Who will receive the Member Match File?
Vital Statistics Program at CDPHE

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 CIVHC to create a Control Group as part of this project?

- ☒ No
- ☐ Yes. Consult with your CIVHC Contact about completing a separate Control Group Data Element Selection Form specifying the data elements that should be used to define the Control Group.

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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)   Colorado Vital Records
Who will perform the data linkage?
Anschutz Research Team (to ACS)   CDPHE (to birth and fetal death records)
What identifying data elements will be used to perform the data linkage?
Census tract   Unique identifier and baby's date of birth
What non-CO APCD data elements will appear in the new linked file?
Social Vulnerability Index (SVI) and the Area Deprivation Index (ADI), Birth and fetal death records

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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 (PHI)

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 County	☐ Member City
☒ Member Dates of Service	☒ Member Eligibility Dates	☐ Claim Paid Dates
☐ Employer Name	☒ Member Census Tract	☐ Member Census Block
☐ Member Census Block Group		
Available for Identifiable extracts only (see also Identifiable Data Use Approval):		
☐ Member Name	☐ Member Date of Birth (if requesting more than year only)	
☐ Member Street Address	☐ Member 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:		

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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.

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 for the requested dates.

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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
☐ 2024[6]					

Claim Type(s)

- ☒ 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

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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 and not fully adjudicated. Consult with your CIVHC Contact to find out what data is available at the time of your request.

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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):

Procedure(s) (list CPT, HCPCS, DRG, ICD, and/or CDT codes):

Drug(s) (list pharmacy NDC and/or HCPCS codes):

Facility Type(s):

Facilities (list NPIs and/or Pharmacy IDs):

Facilities within these geographical areas (list county, zip code, Census Tract, etc.):

Provider Type(s):

Provider(s) (list NPIs):

Providers within these geographical areas (list county, zip code, Census Tract, etc.):

Specific payers (minimum of five):

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Other claim specification:

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:		
Females younger than 55		
☐ At the time of service	☒ At year end	☐ By another anchor date: *Specify here*
With these ICD Diagnosis Code(s):		
Who have had the following procedure(s) (list CPT, HCPCS, DRG, ICD, and/or CDT codes):		
Within these geographical areas (list county, zip code, Census Tract, etc.):		

Value-Add Data Elements

☐ Medicare Severity Diagnosis Related Group Codes (MS-DRGs)
☐ 3M All Patient Refined Diagnosis Related Group Codes (3M APR DRGs)
☐ Medicare Repricer (available at the claim line level)
☐ Fields from the American Community Survey (available at the Census Tract level):

Specify here

Additional Documentation

Data Element Selection Form (DESF)

The Data Release Application must be accompanied by a completed Data Element Selection Form. 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.

☐ If applicable, 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.

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

Approval Type

☐ Approval request not yet submitted.
Anticipated submission date:

☐ Approval request submitted and under review.
Anticipated project approval 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.

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.

Date Submitted to CIVHC:	1/30/2024
Date Approved by CIVHC:	2/19/2024

Client Acknowledgements and Signatures

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 Size Suppression Policy, 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 3/1/2030 based on the Anticipated Project End Date.

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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 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.

Full Name	Title/Role	Organization
Nancy Fang	Assistant Professor, PI	School of Medicine, CU Anschutz
Jeanelle Sheeder	Professor, Co-Investigator	School of Medicine, CU Anschutz
Mary Sammel	Professor, data analyst	School of Medicine, CU Anschutz
Grace Bosma	Research Instructor, data analyst	School of Medicine, CU Anschutz
Yue Wang	Assistant Professor, data analyst	School of Medicine, CU Anschutz

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Data Release Application Version Approvals

The Client Organization has reviewed and confirms that the final version number of the Data Release Application reflected below correctly represents the project objectives.

Version	Checkpoint
V.03	Presented at CIVHC Application Review
V.03	Presented to the Data Release Review Committee (DRRC)
V.00	Final version approved for production

CIVHC Sign-Off		Receiving Organization Sign-Off	
Signature:		Signature:	
Name:		Name:	
Title:		Title:	
Date:		Date:	

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Data Element Selection Form Version Approvals

The Client Organization has reviewed and confirms that the final version number of the Data Element Selection Form reflected below correctly represents the data specifications needed to meet the project objectives.

Version	Checkpoint
V.03	Presented at CIVHC Application Review
V.03	Presented to the Data Release Review Committee (DRRC)
V.00	Final version approved for production

CIVHC Sign-Off		Receiving Organization Sign-Off	
Signature:		Signature:	
Name:		Name:	
Title:		Title:	
Date:		Date:	