DATA RELEASE APPLICATION

LIMITED AND IDENTIFIABLE EXTRACT

APPLICATION NAVIGATION

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
9/26/2023	V.01	Initial version drafted with client.	Everett Costa, Sr. Health Data Consultant
9/27/2023	V.02	Added Census Tract and Financial Information.	Everett Costa, Sr. Health Data Consultant
10/4/2023	V.03	Added Geo Coding and Mbr Cty & IRB Approval	Everett Costa, Sr. Health Data Consultant
10/10/2023	V.04	Added Mbr Eligibilty and DOS	Everett Costa, Sr. Health Data Consultant
10/24/2023	V.05	Updated CIVHC Contact to Lucía Sanders, Data Management Plan submitted to CIVHC on 10/24/2023, Data Destruction Date changed to match project end date	Lucía Sanders, Key Account Manager
Date	V.	Click or tap here to enter text.	Name, Title
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Data Release Application
Limited and Identifiable Extract

DATA REQUESTOR DETAILS

General Project Details

Project Title:	**PR**edicting **O**perational **S**ustainability and **P**atient- and pharmacist-level **E**ffects for **R**etail pharmacies (**PROSPER**)
Application Start Date:	6/15/2023
Requested Project Delivery Date:	12/15/2023
Client Organization:	University of Colorado
Client Organization Address:	12850 E. Montview Blvd, Aurora, CO, 80045
To be completed by CIVHC staff	
CIVHC Contact:	Lucía Sanders
Project Number:	24.15
Condensed Project Title:	**PROSPER**

Project Contacts

Project Contact Name:	Kelly E. Anderson, PhD, MPP
Title:	Assistant Professor
Email:	Kelly.e.anderson@CUAnschutz.edu
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Analytic Contact Name:	Kelly E. Anderson, PhD, MPP
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Invoice Contact Name:	Courtney Koelsch
Title:	Senior Grants Administrator
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Data Release Fee Signatory

Name:	Karen Kimes
Title:	Director of Research Administration
Email:	Karen.kimes@CUAnschutz.edu

Data Use Agreement Signatory

Name:	Alison Lakin
Title:	Associate Vice Chancellor of Regulatory Compliance
Email:	Alison.lakin@cuanschutz.edu

CENTER FOR IMPROVING
VALUE IN HEALTH CARE

PROJECT SCHEDULE AND PURPOSE

Proposed Project Start Date[1]:	1/1/2024
Anticipated Project End Date:	6/30/2026
Proposed Publication or Release Date:	6/30/2026

1. Detail the 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.

   - **Aim 1. Identify and assess the drivers of pharmacy closures.** In this aim, we will model pharmacy revenue, gross profit, and net income using pharmacy claims and net cost estimates.
   - **Aim 2. Measure the effects of pharmacy closures on patients**. In this aim, we will assess the impact of pharmacy closure on patient out-of-pocket costs and estimate changes in travel time and distance and access to pharmacy services by constructing a cohort of patients with exposure to a pharmacy closure compared to patients who were not exposed to a pharmacy closure using Colorado APCD claims data and National Council for Prescription Drug Programs (NCPDP) pharmacy licensure data. https://www.ncpdp.org/

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.

   Aim 1. Analysis Plan. In the base-case pharmacy-level analysis, we will compare annual data on patient-, pharmacy-, and community-level factors for active and closed pharmacies over the period of 2018-2022. We will conduct descriptive analyses for all outcome variables and covariates of interest to first provide a summarized overview of our data stratified by closed and active pharmacies. Reviewing the descriptive statistics measures of central tendency, dispersion, and data distribution will inform our subsequent model for our primary outcomes (**Equation 1**).

   Equation 1: $OperatingStatus_{p,t} = \alpha + \beta X_{p,t-1} + \gamma Year_t + \varepsilon_{p,t}$

   We will use logistic regression for our main model with a primary outcome operationalized as a binary variable (closed vs. active pharmacy). In this equation, $\boldsymbol{OperatingStatus_{p,t}}$ is a dichotomous variable for whether pharmacy "p" closes during a given year "t". $\boldsymbol{\alpha}$ is the intercept (constant term). $\boldsymbol{X_{p,t-1}}$ represents a vector of lagged covariates including variables for prescription utilization mix, payer mix, patient & prescriber characteristics, and pharmacy operational variables for each pharmacy during the prior year. $\boldsymbol{\beta}$ is a vector of coefficients corresponding to the covariates in $\boldsymbol{X_{p,t-1}}$. $\boldsymbol{Year_t}$ is a vector of year fixed effects to account for time-varying effects such as the COVID-19 pandemic. $\boldsymbol{\gamma}$ is a vector of coefficients

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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.

corresponding to the year fixed effects. $\varepsilon_{p,t}$ is the error term and we will cluster standard errors at the pharmacy level. The model will be assessed for prediction discrimination, calibration, and overall performance.[1]

Aim 2. Analysis Plan. We will begin by adapting code we have previously developed to analyze enrollee travel distance to in-network providers to analyze enrollee travel time and distance to the nearest pharmacy.[11] This process requires geocoding the location of enrollees at a ZIP-code level, drawn from the Colorado APCD enrollment files, and the precise location of pharmacies, drawn from the NCPDP data. This mapping process uses a Bing Mapping API queried through RStudio. We will then calculate the travel distance (by road) or travel time (by car or public transit) from each ZIP code to pharmacies in the area, pre- and post-pharmacy closure, for each enrollee in our treatment group and their matched control. Using a difference-in-differences approach, we will then compare the difference (pre vs post) in time and distance to the nearest pharmacy for our treatment group compared to our control group. Next, we will focus on out-of-pocket costs. For each enrollee included in the treatment group, we will identify the set of medications they filled at a closing pharmacy in the 12 months prior to closure, based on prescription drug name. For each of these enrollees, we will then check using all pharmacy claims in the Colorado all-payer claims database whether the patient filled the same medication one or more times in the 12 months following pharmacy closure at a different pharmacy in the state. To study the effect on out-of-pocket costs, we will use this smaller cohort of enrollees, typically taking a medication for a chronic condition, and compare out-of-pocket costs before and after pharmacy closure (***Equation 2***).

Equation 2: $Y_{icdt} = \alpha + \beta PostClosure_t + \gamma X_i + \delta W_d + \varepsilon_{icdt}$

We will use a generalized linear model with a log-link and gamma distribution to account for the non-negative and skewed nature of spending data. In this equation, Y_{icdt} is patient i's out-of-pocket cost for a drug "d" on claim "c" at time "t". α is the intercept (constant term). $PostClosure_t$ is the independent variable and is specified as a dichotomous variable indicating whether the claim was paid during the pre-closure period or post-closure period. β is the coefficient for the closure variable. X_i is a vector of categorical variables for characteristics such as an enrollee's age, sex, insurance type, race/ethnicity, number of comorbid conditions, and urbanicity. β is a vector of coefficients corresponding to the covariates in X_i. W_d is a vector of drug-level fixed effects, and δ is the vector of coefficients for the drug-level fixed effects. ε_{icdt} is the error term.

Finally, we will analyze whether pharmacy closures negatively affect access to a range of pharmacy services. We will run logistic regressions with the independent variable (closure) and covariates described in Equation 2, to assess whether pharmacy

closures change access to each of the seven pharmacy services. We will also construct a composite (index) measure of how many pharmacy services promoting access to care are offered at each pharmacy.

For both aims, we will also conduct stakeholder interviews with pharmacists with experience with pharmacy closures. As those interviews are not linked to or dependent on the APCD data, we do not describe the methodology for the stakeholder interview for the sake of brevity.

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

Colorado has experienced more than 100 community pharmacy closures since 2012. While research has documented the communities most affected by pharmacy closures the type and magnitude of the effects on patient outcomes, such as out-of-pocket spending, medication adherence, and access to pharmacy services is unknown. If the effects are large in scale and/or negatively affect vulnerable populations in Colorado, the evidence generated in this project will support additional research and policy efforts. Understanding the causes of pharmacy closures will allow us to propose policy options to proactively address the root causes of this problem, rather than react after a pharmacy has already shut its doors.

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

Research shows that when patients have inadequate access to community pharmacies, they experience higher rates of medication non-adherence, leading to worse health outcomes.[1] The critical role of community pharmacies also goes far beyond dispensing medications, including counseling patients on medication use, conducting care coordination, offering vaccinations, and more broadly serving as an entry point to the health care system, particularly for individuals who may not have a regular source of care, all of which contribute to patient health outcomes and can reduce the need for more expensive interventions in the long-run.[2] Despite the importance of community pharmacies in the health and well-being of communities, several studies have highlighted concerning trends related to pharmacy closures. By examining the causes and effects of pharmacy closures, we can identify policies that will reduce the risk of pharmacy closures, improving patient health and access to care, and reducing downstream health care expenditures.

[1] Qato DM, Wilder J, Zenk S, Davis A, Makelarski J, Lindau ST. Pharmacy accessibility and cost-related underuse of prescription medications in low-income Black and Hispanic urban communities. Journal of the American Pharmacists Association2017. p. 162-169.e1.
[2] Pantasri T. Expanded roles of community pharmacists in COVID-19: A scoping literature review. *J Am Pharm Assoc (2003)*. May-Jun 2022;62(3):649-657. doi:10.1016/j.japh.2021.12.013

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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.

5. Health equity is 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.

> By examining community pharmacy closures in Colorado, we will identify factors that place community pharmacies at risk of closure. This research will enable policy interventions to support community pharmacies at risk of closure. This research is particularly important for urban and low-income communities where previous research has shown lower levels of pharmacy access.

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. Answer the following:

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

What data elements will be required in 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 or Member Match File.

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

☒ No
☐ Yes. Consult with your CIVHC Contact about completion of an additional Data Element Selection form for your Control Group.

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)?
We will link the CO APCD data with an extract of data from the National Council for Prescription Drug Programs database.

Who will perform the data linkage?

The project team at CU will complete the data linkage following data delivery.
What identifying data elements will be used to perform the data linkage?
Pharmacy NPI
What non-CO APCD data elements will appear in the new linked file?
The additional data elements will include information on pharmacy ownership, pharmacy services (e.g., offering immunizations), and changes in operational status (e.g., opening date, closure date, etc.).

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 Street Address	☒ Member Geocoded Address	
Provide detailed justification for the inclusion of all PHI data selected above.[3]		

*Requesting Census Tract and 5-digit ZIP code: to estimate member travel distance to the nearest pharmacy. This level of granularity is necessary to understand how certain populations within a county may be more/or less affected by a pharmacy closure

*Geocoding and Member County: allows for pin point mapping and adds more value to this analysis.

*Member Eligibility. Member eligibility information is required to understand the payer mix for medications filled at each pharmacy

*Member DOS (Rx Fill Date). Rx fill date is required to identify where patients fill medication prior to and following pharmacy closure. We need this level of granularity as pharmacies may close at any point during the year.

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]

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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.

[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.

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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

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.

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):

Data Release Application
Limited and Identifiable Extract

Ages:		
18-89 years		
☐ At the time of service.	☒ At year end	☐ By another anchor date: Please specify here.
With these ICD Diagnosis Code(s):		
Please specify here.		
Who have had the following procedure(s) (list CPT, HCPCS, DRG, ICD, and/or CDT codes):		
Please specify here.		
Within these geographical areas (list county, zip code, Census Tract, etc., in keeping you're your selected Protected Health Information):		
Please specify here.		

Value-Add Data Elements

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

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

> Please specify here.

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.

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: Click or tap to enter a date.

☐ Approval request submitted and under review.

Anticipated project approval date: Click or tap to enter a 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.

☒ Submitted to CIVHC on 10/24/2023

☐ Approved by CIVHC on Click or tap to enter a date.

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 6/30/2026 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*.

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
Kelly E. Anderson, PhD, MPP	PI	University of Colorado
Eric Gutierrez, MPH	Professional Research Assistant	University of Colorado
Michael DiStefano, PhD	Co-Investigator	University of Colorado
Joey Mattingly, PharmD, MBA, PhD	Co-PI	University of Utah
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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.03 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Initials:	EC	Initials:	KA
Name:	Everett Costa	Name:	Kelly Anderson
Title:	Sr. Health Data Consultant	Title:	Assistant Professor
Date:	10/4/2023	Date:	10/4/2023

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:	KA
Name:	Lucía Sanders	Name:	Kelly Anderson
Title:	Key Account Manager	Title:	Assistant Professor
Date:	10/24/2023	Date:	10/23/2023

Checkpoint 3: Final approval to begin project production

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

CIVHC Sign-Off		Receiving Organization Sign-Off	
Signature:		Signature:	
Name:	Click or tap here to enter text.	Name:	Click or tap here to enter text.
Title:	Click or tap here to enter text.	Title:	Click or tap here to enter text.
Date:	Click or tap to enter a date.	Date:	Click or tap to enter a date.

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.   of the Data Element Selection Form represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Initials:	EC	Initials:	KA
Name:	Everett Costa	Name:	Kelly Anderson
Title:	Sr. Health Data Consultant	Title:	Assitant Professor
Date:	10/4/2023	Date:	10/4/2023

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

The Client Organization has reviewed and confirms that V.   of the Data Element Selection Form represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Initials:	LS	Initials:	KA
Name:	Lucía Sanders	Name:	Kelly Anderson
Title:	Key Account Manager	Title:	Assistant Professor
Date:	10/24/2023	Date:	10/23/2023

Checkpoint 3: Final approval to begin production

The Client Organization has reviewed and confirms that V.   of the Data Element Selection Form represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Signature:		Signature:	
Name:	Click or tap here to enter text.	Name:	Click or tap here to enter text.
Title:	Click or tap here to enter text.	Title:	Click or tap here to enter text.
Date:	Click or tap to enter a date.	Date:	Click or tap to enter a date.