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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
7/26/2023	V.01	Initial version drafted with client.	Eddy Costa , Sr. Health Data Consultant
8/14/2023	V.02	Adding Census Block Information and age change to ages 18 and older from 50+ (please see justification on Page I, I A & B)	Eddy Costa , Sr. Health Data Consultant
8/29/2023	V.03	8/29 Analyst Meeting Updates	Eddy Costa, Sr. Health Data Consultant
8/30/2023	V.04	Adjusted Value Add Data Elements	Eddy Costa, Sr. Health Data Consultant
9/14/2023	V.05	Added DUA members – Financial details page 9.	Eddy Costa, Sr. Health Data Consultant
9/19/2023	V.06	Added 2023	Eddy Costa , Sr. Health Data Consultant
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DATA REQUESTOR DETAILS

General Project Details

Project Title:	Improving medication adherence and disease control for patients with multimorbidity: the role of price transparency tools
Application Start Date:	8/14/2023
Requested Project Delivery Date:	11/1/2023
Client Organization:	Duke University
Client Organization Address:	710 W Main St, 1st Floor, Durham, NC 27701
To be completed by CIVHC staff	
CIVHC Contact:	E. Costa
Project Number:	22.16
Condensed Project Title:	Improving medication adherence

Project Contacts

Project Contact Name:	Caroline Sloan
Title:	Assistant Professor of Medicine
Email:	Caroline.sloan@duke.edu
Phone Number:	504-250-6143
Analytic Contact Name:	Caroline Sloan
Title:	Assistant Professor of Medicine
Email:	Caroline.sloan@duke.edu
Phone Number:	504-250-6143
Invoice Contact Name:	Melanie S. Eberhart
Title:	Sr. Grants/Contracts Administrator, Team Lead
Email:	<u>Melanie.Eberhart@Duke.edu</u>
Phone Number:	919.660.1388

Data Release Fee Signatory

Name:	Melanie S. Eberhart
Title:	Sr. Grants/Contracts Administrator, Team Lead
Email:	<u>Melanie.Eberhart@Duke.edu</u>

Data Use Agreement Signatory

Name:	Susan Hayden, JD
Title:	Director of Research Contracts
Email:	Susan.Hayden@duke.edu



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PROJECT SCHEDULE AND PURPOSE

Proposed Project Start Date ¹ :	11/1/2023
Anticipated Project End Date:	4/1/2025
Proposed Publication or Release Date:	5/1/2025

- I. 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.

Many patients with multimorbidity struggle to pay for their medications. These patients have lower medication adherence, resulting in a higher risk of disease progression, functional limitations, hospitalization, and death. Patients cannot account for medication costs in their medical decisions, because they rarely know what those costs will be before getting to the pharmacy. If clinicians could access information about their patients' medication-related out-of-pocket costs at the point-of-prescribing, they could help their patients apply for financial support, or prescribe lower-cost alternatives. New out-of-pocket drug price transparency tools could fill this need. The Centers for Medicare and Medicaid Services recently mandated that Medicare Part D plans make clinician-facing out-of-pocket drug price transparency tools available to clinics and hospitals via the electronic health record (EHR). No one has described the uptake and acceptability of these tools, or their impact on clinical outcomes among middle-aged and older patients with multimorbidity. The goal of this project is to evaluate how primary care providers at one large academic health system use a widely available out-of-pocket medication price transparency tool and how price transparency at the point-of-prescribing affects clinical outcomes for middle-aged and older patients with multimorbidity. The University of Colorado Health (UCHealth) price transparency tool, adopted in 2019, is compatible with all Medicare plans and ~95% of private insurance plans in the state. It provides clinicians with medication cost estimates in real-time, as well as lower-cost alternative medications in the same therapeutic class.

- A. Expanding the patient population to age 18 years and older: The [National Institute on Aging](#), which funds my grant, strongly encourages research teams to include individuals in clinical research across the lifespan. Their intent is to ensure that research is inclusive and therefore that research findings are applicable to as many people as possible. The patient population I will be studying is adults with multimorbidity who are seen in primary care clinics across UCHealth. In my initial data request proposal, I planned to include patients with multimorbidity who are 50 years or older. But in a recent study (manuscript is in preparation), I found that a not insignificant proportion of patients with multimorbidity who are seen in primary care clinics are aged 18-50. By expanding the patient population to individuals aged 18 years and older, I believe that my research will be more inclusive and will produce more generalizable results.

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.



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B. Including census tract/blocks in the dataset: In my study, I will be evaluating the impact of an out-of-pocket price transparency tool on medication fill rates, out-of-pocket costs, and clinical outcomes. In my analysis, I will control for potential confounders such as number of chronic conditions, number of medications, age, race/ethnicity, and socioeconomic factors. One validated way to measure levels of socioeconomic disadvantage is the [area deprivation index](#). The ADI measure combines information on an area's average income, education level, employment, and housing quality. Area deprivation index is measured at the census block group level (rather than zip codes or counties). Having patient census block information in APCD will allow me to estimate ADIs for all patients in my dataset.

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.

Aims 1 and 2 will describe the uptake and acceptability of the price transparency tool using an explanatory sequential mixed methods design. Aim 1 is an electronic health record (EHR)-based retrospective cohort study of ~700 clinicians and ~140,000 patients aged 18 years of age and older with multimorbidity aimed at determining the clinician and patient factors associated with use. Aim 2 will involve ~24 semi-structured interviews exploring reasons for use / non-use that may not be readily available in EHR data. Interviews will also assess the tool's acceptability and usability for patients with multimorbidity. Aim 3 will be an EHR- and claims-based (from the Colorado All Payer Claims Data) longitudinal retrospective cohort study evaluating how use of the tool affects adherence and diabetes control in a subgroup of ~29,000 patients aged 18 years of age and older with diabetes and multimorbidity.

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

Results from this project will inform the development of an intervention to improve the implementation of UCHHealth's price transparency tool. Our goal is to increase use of the tool in primary care offices throughout the health system, so that as many Coloradans as possible have access to accurate out-of-pocket medication cost estimates when making important decisions about their care.

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

We hope that by having access to the cost of their medications before getting to the pharmacy, patients will be better able to account for financial tradeoffs when making medical decisions. We hypothesize that patients whose doctors use the price transparency tool to estimate drug costs and/or switch to lower cost alternatives will

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.



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have lower out-of-pocket costs and better medication adherence compared to patients whose doctors do not use the price transparency tool.

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.

We hope that information about a prescribed medication's cost (and any lower cost alternative medications in the same therapeutic class) will ultimately reduce total out-of-pocket costs and thus increase financial access to important medications.



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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)?
UC Health EHR/EMR Data
Who will perform the data linkage?
Duke University



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

De-identified patient ID & DOB, which will be provided in the finder file by UCHealth

What non-CO APCD data elements will appear in the new linked file?

Data will include all request field and response fields from UCHealth's price transparency tool (e.g., which medications were queried, OOP obligation estimate per medication, therapeutic alternatives suggested, OOP estimates for therapeutic alternative suggested, date of query, clinician ID, date, location from where query sent); outpatient encounter data (date, encounter ID, provider ID (National Provider Identifier), Department, Department ID, provider type, indication, encounter diagnosis, blood pressure, creatinine, Hemoglobin A1C), data on medication order if any (prescription number, Medication order time, pharmaceutical class, Medication generic name, Medication display name, Medication ID, therapeutic class, strength, route), patient characteristics (race, ethnicity, financial class, age, gender, zip code, prior diagnoses), and characteristics of UCHealth clinic sites (e.g., geographic location, primary care only vs multi-specialty).



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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:		
<input checked="" type="checkbox"/> Member 5-Digit Zip Code	<input checked="" type="checkbox"/> Member Census Tract	<input type="checkbox"/> Member County
<input type="checkbox"/> Member City	<input type="checkbox"/> Member Eligibility Date	<input type="checkbox"/> Employer Tax ID
<input checked="" type="checkbox"/> Member Dates of Service		
Available for Identifiable extracts only (see also Identifiable Data Use Approval):		
<input checked="" type="checkbox"/> Member Name	<input checked="" type="checkbox"/> Member Date of Birth (if requesting more than year only)	
<input type="checkbox"/> Member Street Address	<input checked="" type="checkbox"/> Member Geocoded Address	
Provide detailed justification for the inclusion of all PHI data selected above. ³		
<p>DOS: Need Dates of Service for medication fills and when medication was ordered. All RX Dates are necessary for this project. Align patient care with the medication/Rx intervention.</p> <p>Census Tract/Member 5 Digit Zip: A validated way to measure levels of socioeconomic disadvantage is the area deprivation index. The ADI measure combines information on an area's average income, education level, employment, and housing quality. Area deprivation index is measured at the census block group level (rather than zip codes or counties). Having patient census block information in APCD will allow me to estimate ADIs for all patients in my dataset.</p>		

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 2023⁶

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):
No Limitation
Procedure(s) (list CPT, HCPCS, DRG, ICD, and/or CDT codes):
No Limitation
Drug(s) (list pharmacy NDC and/or HCPCS codes):
N/A
Facility Type(s):
UCHealth only
Facilities (list NPIs and/or Pharmacy IDs):
N/A
Facilities within these geographical areas (list county, zip code, Census Tract , etc.):
UC Health
Provider Type(s):
5 Digit Zip Only
Provider(s) (list NPIs):
N/A
Providers within these geographical areas (list county, zip code, Census Tract , etc.):
Provider Health Statistic Region http://www.cohid.dphe.state.co.us/brfssdata.htm
Specific payers (minimum of five):
Not limited
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):



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Ages:		
We are looking at members 18 years and older		
<input checked="" type="checkbox"/> At the time of service.	<input type="checkbox"/> At year end	<input type="checkbox"/> By another anchor date: Please specify here.
With these ICD Diagnosis Code(s):		
All		
Who have had the following procedure(s) (list CPT, HCPCS, DRG, ICD, and/or CDT codes):		
N/A Medications Only		
Within these geographical areas (list county, zip code, Census Tract , etc., in keeping you're your selected Protected Health Information):		
See Finder File		

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.



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- 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 8/24/2023
- 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 [Click or tap to enter a date based on the Anticipated Project End Date.](#)

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.

Name	Role	Organization
Caroline Sloan	Principal Investigator	Duke University
Sarah Morton	Biostatistician	Duke University
Clemontina Davenport	Biostatistician	Duke University
Valerie Smith	Biostatistician	Duke University
Matthew Maciejewski	Mentor, co-investigator	Duke University
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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.06 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Initials:	EC	Initials:	CS
Name:	Eddy Costa	Name:	Caroline Sloan
Title:	Sr. Health Data Consultant	Title:	Assistant Professor of Medicine
Date:	8/24/2023	Date:	8/24/2023

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

The Client Organization has reviewed and confirms that V.06 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Initials:	EC	Initials:	CS
Name:	Eddy Costa	Name:	Caoline Sloan
Title:	Sr. Health Data Consultant	Title:	Assistant Professor of Medicine
Date:	10/4/2023	Date:	10/4/2023

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.



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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.06 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:	CS
Name:	Eddy Costa	Name:	Caroline Sloan
Title:	Sr. Health Data Consultant	Title:	Assistant Professor of Medicine
Date:	9/14/2023	Date:	9/14/2023

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

The Client Organization has reviewed and confirms that V.06 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:	CS
Name:	Eddy Costa	Name:	Caroline Sloan
Title:	Sr. Health Data Consultant	Title:	Assistant Professor of Medicine
Date:	10/4/2023	Date:	10/4/2023

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.