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Data Release Application

Limited and Identifiable Extract

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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
2/8/2024	V.01	Initial version drafted with client.	Lucía Sanders, Key Account Manager
3/28/2024	V.02	Updates provided by PI.	Lucía Sanders, Key Account Manager
5/15/2024	V.03	Updated DMP approval.	Lucía Sanders, Key Account Manager
5/23/2024	V.04	Updated project purpose and linkage.	Lucía Sanders, Key Account Manager
Date	V.05	Click or tap here to enter text.	Name, Title
Date	V.06	Click or tap here to enter text.	Name, Title
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:	Outcomes and Affordability of Observation Status for Children (OASIS)
Application Start Date:	2/8/2024
Requested Project Delivery Date:	9/30/2024
Client Organization:	Northwestern University
Client Organization Address:	633 Clark Street, Evanston, IL, 60208
To be completed by CIVHC staff	
CIVHC Contact:	Lucía Sanders
Project Number:	24.11
Condensed Project Title:	Observation Status Children

Project Contacts

Project Contact Name:	Mehul V. Raval
Title:	Professor of Surgery and Pediatrics
Email:	mraval@luriechildrens.org
Phone Number:	(312) 227-4210
Analytic Contact Name:	Yao Tian
Title:	Research Assistant Professor
Email:	yao.tian@northwestern.edu
Phone Number:	(312)503-6351
Invoice Contact Name:	Deysi Paniagua-Perez
Title:	Research Project Coordinator
Email:	deysi.paniaguaperez@northwestern.edu
Phone Number:	(312) 503-3261

Data Release Fee Signatory

Name:	Click or tap here to enter text.
Title:	Click or tap here to enter text.
Email:	Click or tap here to enter text.

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Data Use Agreement Signatory

Name:	Click or tap here to enter text.
Title:	Click or tap here to enter text.
Email:	Click or tap here to enter text.

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Project Schedule and Purpose

Proposed Project Start Date ¹ :	10/1/2024
Anticipated Project End Date:	9/29/2028
Proposed Publication or Release Date:	1/1/2029

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.

Over the past three decades, observation status has evolved and is now widely applied as an administrative designation for patients with a “short-term” hospital stay, typically falling “under the 2-midnight rule” as originally defined for Medicare patients and widely adopted by commercial insurers and Medicaid agencies. Our previous work demonstrates an increasing use of observation stays among pediatric hospitalizations in the United States. For example, more than 50% of children undergoing appendectomy are designated as observation stays. An observation stay is typically billed as an “outpatient” encounter; therefore, insurance benefits for inpatient care, which adjust for severity of illness and have a more comprehensive coverage (such as medications), do not apply. Without this broad coverage, observation-status patients who utilize as many resources as inpatients may encounter a substantial uncovered financial liability. In fact, the Office of Inspector General disclosed that Medicare patients receiving surgical procedures have higher Out-of-Pocket (OOP) expenses when billed as observation stays compared to inpatient stays. Despite the sharply rising use of observation stays, such expenses have not, to date, been quantified for pediatric patients. This research project examines the affordability of observation stays for children by (1) characterizing/describing OOP expenses of observation stays by common pediatric conditions (e.g., appendectomy, epilepsy, and asthma) and (2) comparing OOP expenses between observation stays and inpatient stays under different patient and health insurance characteristics. Specifically, the OOP expenses of an observation stay are higher than OOP expenses of an inpatient stay for patients who require more healthcare resources, have a prolonged length of stay, and are covered by a high-deductible plan. We hypothesize that prolonged length of stay (>48 hours) and greater healthcare resource use (e.g., medications, radiology tests, and surgical procedures) are associated with higher OOP expenses and observation stay.

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.

We plan a retrospective observational study using the Colorado All Payer Claims Database (CO APCD) from 2017 through 2019. The CO APCD includes de-identified claims data that capture complete episodes of care (outpatient, inpatient, provider, professional, and pharmacy) as well as

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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eligibility, provider, and plan files from both private and public payers. Specifically, the medical and pharmacy claims data will be used to identify patients' clinical conditions, capture inpatient and outpatient services received by each patient, measure length of stay, and quantify associated out-of-pocket costs. The decrypted National Provider Identifier (NPI) in the provider data will be used to link to the National Plan and Provider Enumeration System (NPPES) to identify and validate whether a provider is an organization (i.e., hospital). Existing literature indicates a significant variation in the use of observation stays at hospitals. Thus, it is necessary to control for the correlation within hospitals when assessing the OOP costs of observation stays. The professional and pharmacy data will also be used to quantify associated out-of-pocket costs, which is particularly important for observation stays. The Member Eligibility data provides detailed information about health insurance plans, such as risk type, insurance type, coinsurance maximum, medical and pharmacy deductibles. This information will be used as predictors of out-of-pocket costs and stratification factors in sub-analysis by health insurance plan characteristics.

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

Findings of this study will improve price transparency and protect observation stay pediatric patients in Colorado from higher OOP costs.

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

The findings of this study will improve price transparency, protect observation stay pediatric patients from higher OOP costs, and therefore increase health care value for Colorado residents.

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.

This study compares OOP costs between inpatient and observation stay patients. Findings of this study will facilitate future policy to protect observation stay pediatric patients from higher OOP costs than inpatients, such as setting up a price cap.

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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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:

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What is (are) the other data source(s)?
We plan to link the National Drug Code (NDC) product file using NDC drug codes available in the pharmacy data. This will help us identify the use and costs of medications for both patients with inpatient and observation stays.
Who will perform the data linkage?
Yao Tian, Northwestern University
What identifying data elements will be used to perform the data linkage?
NDC drug code
What non-CO APCD data elements will appear in the new linked file?
Pharm_Classes (available in NDC data)

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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 type="checkbox"/> Member 5-Digit Zip Code	<input type="checkbox"/> Member Census Tract	<input type="checkbox"/> Member County
<input type="checkbox"/> Member City	<input checked="" 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 type="checkbox"/> Member Name	<input type="checkbox"/> Member Date of Birth (if requesting more than year only)	
<input type="checkbox"/> Member Geocoded Address	<input type="checkbox"/> 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		
<p>We need the exact date information to construct several key measures of this study, such as Length of Stay (LOS) and Out-of-Pocket costs. For example, to calculate LOS, we need the first and last dates of inpatient or outpatient services during each hospital stay. Date of service measures are particularly important to capture information related to observation stay (outpatient encounters), as admission date and discharge date are not available in outpatient data. Date information is required to construct length of stay and corresponding services received during the same encounter. Member eligibility date is needed to confirm that services are covered.)</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

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.

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Year(s) of Data

- 2012 2013 2014 2015 2016 2017
 2018 2019 2020 2021 2022 2023⁶

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.
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.):

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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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:		
0-18 years old		
<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):		
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 with your selected Protected Health Information):		
Please specify here.		

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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.

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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 **3/28/2024**
- Approved by CIVHC on **5/15/2024**

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.

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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 10/29/2028 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
Yao Tian	Co-PI	Northwestern University
Lynn Huang	Data analyst	Northwestern University
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Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
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Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

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:	YT
Name:	Lucía Sanders	Name:	Yao Tian
Title:	Key Account Manager	Title:	Research Assistant Professor
Date:	5/10/2024	Date:	5/22/2024

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

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	
Initials:	LS	Initials:	Click or tap here to enter text.
Name:	Lucía Sanders	Name:	Yao Tian
Title:	Key Account Manager	Title:	Research Assistant Professor
Date:	5/23/2024	Date:	Date

Checkpoint 3: Final approval to begin project production

The Client Organization has reviewed and confirms that V.00 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:	Yao Tian
Title:	Key Account Manager	Title:	Research Assistant Professor
Date:	Date	Date:	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.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:	YT
Name:	Lucía Sanders	Name:	Yao Tian
Title:	Key Account Manager	Title:	Research Assistant Professor
Date:	5/10/2024	Date:	5/22/2024

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:	Click or tap here to enter text.
Name:	Lucía Sanders	Name:	Yao Tian
Title:	Key Account Manager	Title:	Research Assistant Professor
Date:	5/23/2024	Date:	Date

Checkpoint 3: Final approval to begin production

The Client Organization has reviewed and confirms that V.00 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:	Yao Tian
Title:	Key Account Manager	Title:	Research Assistant Professor
Date:	Date	Date:	Date