center for health information and analysis

Application for Massachusetts All-Payer Claims Data (Non-Government) [Exhibit A – Data Application]

I. INSTRUCTIONS

This form is required for all Applicants, Agencies, or Organizations, hereinafter referred to as "Organization", except Government Agencies as defined in 957 CMR 5.02, requesting protected health information. *All Organizations must also complete the Data Management Plan, and attach it to this Application. The Application and the Data Management Plan must be signed by an authorized signatory. This Application and the Data Management Plan will be used by CHIA to determine whether the request meets the criteria for data release, pursuant to 957 CMR 5.00. Please complete the Application documents fully and accurately. Prior to receiving CHIA Data, the Organization must execute CHIA's Data Use Agreement. Organiations may wish to review that document prior to submitting this Application.*

Before completing this Application, please review the data request information on CHIA's website:

- Data Availability
- Fee Schedule
- Data Request Process

After reviewing the information on the website and this Application, please contact CHIA at apcd.data@state.ma.us if you have additional questions about how to complete this form.

The Appliciaton and all attachments must be uploaded to IRBNet. All Application documents can be found on the CHIA website.

Information submitted as part of the Application may be subject to verification during the review process or during any audit review conducted at CHIA's discretion.

Applications will not be reviewed until the Application and all supporting documents are complete and the required application fee is received.

A Fee Remittance Form with instructions for submitting the application fee is available on the CHIA website. If you are requesting a fee waiver, a copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet. Please be aware that if your research is funded and under that funding you are required to release raw data to the funding source, you may not receive CHIA Data.

II. FEE INFORMATION

1. Consult the most current Fee Schedule for All-Payer Claims Database data.

2. After reviewing the Fee Schedule, if you have any questions about the application or data fees, contact apcd.data@state.ma.us.

3. If you believe that you qualify for a fee waiver, complete and submit the Fee Remittance Form and attach it and all required supporting documentation with your application. Refer to the Fee Schedule (effective Feb 1, 2017) for fee waiver criteria.

4. Applications will not be reviewed until the application fee is received.

5. Data for approved Applications will not be released until the payment for the Data is received.

III. ORGANIZATION & INVESTIGATOR INFORMATION

Project Title:	Observation Stays and Costs for Pediatric Patients
IRBNet Number:	1931933-1
Organization Requesting Data (Recipient):	Northwestern Univerisity
Organization Website:	http://www.northwestern.edu/
Authorized Signatory for Organization:	**Manny Robert**
Title:	Contracts & Negotiations Manager
E-Mail Address:	m-robert2@northwestern.edu
Telephone Number:	(312)503-7941
Address, City/Town, State, Zip Code:	633 Clark Street, Evanston, IL, 60208
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	**Yao Tian**
Title:	Research Assistant Professor
E-Mail Address:	yao.tian@northwestern.edu
Telephone Number:	(312)5036351
Address, City/Town, State, Zip Code:	633 North Saint Clair Street, 20th Floor, Chicago, IL, 60611
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	**Mehul V. Raval**
Title:	Professor of Surgery and Pediatrics
E-Mail Address:	mraval@luriechildrens.org
Telephone Number:	(312) 227-4210
Address, City/Town, State, Zip Code:	633 North Saint Clair Street, 20th Floor, Chicago, IL, 60611
Names of Co-Investigators:	Yao Tian
E-Mail Addresses of Co-Investigators:	yao.tian@northwestern.edu

IV. PROJECT INFORMATION

IMPORTANT NOTE: Organization represents that the statements made below as well as in any study or research protocol or project plan, or other documents submitted to CHIA in support of the Data Application are complete and accurate and represent the total use of the CHIA Data requested. Any and all CHIA Data released to the Organization under an approved application may ONLY be used for the express purposes identified in this section by the Organization, and for no other purposes. Use of CHIA Data for other purposes requires a separate Data Application to CHIA written request to CHIA, with approval being subject to CHIA's regulatory restrictions and approval process. Unauthorized use is a material violation of your institution's Data Use Agreement with CHIA.

1. What will be the use of the CHIA Data requested? [Check all that apply]

☐ Epidemiological	☐ Health planning/resource allocation	☒ Cost trends
☒ Longitudinal Research	☒ Quality of care assessment	☐ Rate setting
☐ Reference tool	☒ Research studies	☐ Severity index tool (or other derived input)
☐ Surveillance	☐ Student research	☐ Utilization review of resources
☐ Inclusion in a product	☐ Other (describe in box below)	

Click here to enter text.

2. Provide an abstract or brief summary of the specific purpose and objectives of your Project. This description should include the research questions and/or hypotheses the project will attempt to address, or describe the intended product or report that will be derived from the requested data and how this product will be used. Include a brief summary of the pertinent literature with citations, if applicable.

Research Questions

The last two decades have witnessed a shifting landscape in the use of observation status. The concept of observation status was created initially as a clinical designation, primarily in the Emergency Department (ED), for clinicians to determine a patients' need for inpatient care (e.g., admission). Nowadays, observation status is applied as an administrative assignment for patients who have 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 that hospital-based treatment under observation status (i.e. observation stay) has become a substantial component of pediatric health care delivery. For example, more than 50% children undergoing appendectomy are designated as observation status, instead of inpatient. An observation stay is typically billed as an "outpatient" encounter and, 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 the broad coverage, patients in observation stays who utilize as many resources as inpatients may encounter a substantial uncovered financial liability. In fact, an investigation conducted by the Office of Inspector General discloses that Medicare patients receiving surgical procedures have a higher Out-of-Pocket (OOP) costs 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 patients' affordability for the most common pediatric observation stays by answering the following questions (1) characterize OOP costs of observation stays over years for common pediatric conditions (e.g. appendectomy and medications), and our hypothesis is that greater use of healthcare resource (e.g., medications and surgical procedures) are associated with higher OOP expenses of an observation stay; (2) Identify conditions for which patients in observations stays pay more than they would as inpatients. Specifically, conditions requiring greater resource (e.g., appendectomy and medications) will confer higher OOP costs in observation stays than in inpatient stay.

Intended Products

Intended products of this study include presentations at academic conferences and publications in peer-reviewed academic journals (e.g. *JAMA Pediatrics, Pediatrics*). The findings of this study will be informative to patients and policy makers about cost sharing of observation stays determined by the current payment policies and provide evidence for refinement to protect patients in observation stays from paying more than they would have paid as inpatients

3. Has an Institutional Review Board (IRB) reviewed your Project?

☐ Yes [*If yes, a copy of the approval letter and protocol must be included with the Application package on IRBNet.*]
☒ No, this Project is not human subject research and does not require IRB review.

4. **Research Methodology**: Applicantions must include either the IRB protocol or a written description of the Project methodology (typically 1-2 pages), which should state the Project objectives and/or identify relevant research questions. This document must be included with the Application package on IRBNet and must provide sufficient detail to allow CHIA to understand how the Data will be used to meet objectives or address research questions.

Please see the project methodology attachment for detailed description.

V. PUBLIC INTEREST

1. Briefly explain why completing this Project is in the public interest. Use quantitative indicators of public health importance where possible, for example, numbers of deaths or incident cases; age-adjusted, age-specific, or crude rates; or years of potential life lost. *Uses that serve the public interest under CHIA regulations include, but are not limited to: health cost and utilization analysis to formulate public policy; studies that promote improvement in population health,*

health care quality or access; and health planning tied to evaluation or improvement of Massachusetts state government initiatives.

This will be the first study that examines patients' Out-of-Pocket (OOP) costs for pediatric observation stays, and results of this project will shed light on affordability of observation stays for privately insured pediatric patients. Furthermore, the results of this project can support evidence-based payment policy that ensures equitable cost sharing for pediatric patietns and their families.

VI. DATASETS REQUESTED

The Massachusetts All-Payer Claims Database is comprised of medical, pharmacy, and dental claims and information from the member eligibility, provider, and product files that are collected from health insurance payers licensed to operate in the Commonwealth of Massachusetts. This information encompasses public and private payers as well as data from insured and self-insured plans. APCD data are refreshed and updated annually and made available to approved data users in Release Versions that contain five calendar years of data and three months of run-out. For more information about APCD Release Versions, including available years of data and a full list of elements in the release please refer to release layouts, data dictionaries and similar documentation included on CHIA's website.

Data requests are typically fulfilled on a one time basis, however; certain Projects may require future years of data that will become available in a subsequent release. Projects that anticipate a need for future years of data may request to be considered for a subscription. Approved subscriptions will receive, upon request, the same data files and data elements included in the initial Release annually or as available. Please note that approved subscription requests are subject to the Data Use Agreement, will require payment of fees for additional Data for Non-Government Entities, and subject to the limitation that the Data can be used only in support of the approved Project.

1. Please indicate below whether this is a one-time request, or if the described Project will require a subscription.

   ☒ One-Time Request **OR** ☐ Subscription

2. Select Release Version and years of data requested (Release Versions and years not listed are not available).

☐ **Release Version 8.0**	☐ **Release Version 10.0**
☐ 2014	☒ 2016
☐ 2015	☒ 2017
☐ 2016	☒ 2018
☐ 2017	☒ 2019
☐ 2018	☐ 2020

3. Specify below the data files requested for this Project, and provide your justification for requesting *each* file.

☒ **Medical Claims**
Describe how your research objectives require Medical Claims data:

Medical claims data allow us to identify patients' clinical conditions, capture inpatient and outpatient services received by each observation stay, measure length of stay, and quantify associated Out-Of-Pocket costs.

☒ Pharmacy Claims

Describe how your research objectives require Pharmacy Claims data:

Pharmacy claims data allow us to capture Out-Of-Pocket (OOP) costs of drugs prescribed for patients during their hospital stays. Unlike the broad coverage of inpatient bundled payment system, drugs prescribed during observation stays are often not covered by outpatient payment system, and patients may pay for pharmaceutical products in addition to medical services. Thus, the OOP costs for the prescribed drugs is an essential component of the overall patients' OOP costs.

☐ Dental Claims

Describe how your research objectives require Dental Claims data:

Click here to enter text.

☒ Member Eligibility

Describe how your research objectives require Member Eligibility data:

Member Eligibility data allow us to obtain health insurance information, such as insurance type, copay, deductible, and coninsurance. These data are fundamental components to measure Out-Of-Pocket costs of a hospital stay by various plan types.

☒ Provider

Describe how your research objectives require Provider data:

Provider data provides encrypted provider IDs that will be used to account for correlation within providers. Existing literature indicates significant variation in the use of observation stays among hospitals. It is necessary to control for the correlation within providers when assess the Out-Of-Pocket costs of observation stays.

☒ Product

Describe how your research objectives require Product data:

Product data provides plan characteristics (e.g. risk type and product benefit type) that will be used to characterize the Out-Of-Pocket costs of observation stays. Without these key plan information, we can't successfully quantify Out-Of-Pocket costs of observation stays stratified by these characteristics.

VII. DATA ENHANCEMENTS REQUESTED

State and federal privacy laws limit the release and use of CHIA Data to the minimum amount of data needed to accomplish a specific Project objective.

All-Payer Claims Database data is released in Limited Data Sets (LDS). All Organizations receive the "Core" LDS, but may also request the data enhancements listed below for inclusion in their analyses. Requests for enhancements will be reviewed by CHIA to determine whether each represents the minimum data necessary to complete the specific Project objective.

For a full list of elements in the release (i.e., the core elements and additional elements), please refer to release layouts, data dictionaries and similar documentation included on CHIA's website.

1. Specify below which enhancements you are requesting in addition to the "Core" LDS, provide your justification for requesting each enhancement.

a. Geographic Subdivisions

The geographic subdivisions listed below are available for Massachusetts residents and providers only. Select *one* of the following options.

☒ 3-Digit Zip Codes (standard)	☐ 5-Digit Zip Codes***
***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology: Click here to enter text.	

b. Date Resolution

Select *one* option from the following options.

☐ Year (YYYY) (Standard)	☐ Month (YYYYMM) ***	☒ Day (YYYYMMDD) *** [for selected data elements only]
*** If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology: 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 the last dates of inpatient or outpatient services during each hospital stay. The date of service measures are particularly important to capture information related to observaiton stay (outpatient encounters), as admission date and discharge date are not available in outpatient data and we need the date information to construct length of stay and corresponding services received during the same encounter.		

c. National Provider Identifier (NPI)

Select *one* of the following options.

☒ Encrypted National Provider Identifiers (standard)	☐ Decrypted National Provider Identifiers***
*** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your methodology: Click here to enter text.	

VIII. MEDICAID (MASSHEALTH) DATA

1. Please indicate whether you are seeking Medicaid Data:

☐ Yes
☒ No

2. Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are ***directly connected to the administration of the Medicaid program***. If you are requesting MassHealth Data, please describe, in the space below, why your use of the Data meets this requirement. *Your description should focus on how the results of your project could be used by the Executive Office of Health and Human Services in connection with the administering the MassHealth program*. Requests for MassHealth Data will be forwarded to MassHealth for a determination as to whether the proposed use of the Data is directly

connected to the administration of the MassHealth program. CHIA cannot release MassHealth Data without approval from MassHealth. This may introduce significant delays in the receipt of MassHealth Data.

Click here to enter text.

3. Organizations approved to receive Medicaid Data will be required to execute a Medicaid Aknowlegment of Conditions MassHealth may impose additional requirements on applicants for Medicaid Data as necessary to ensure compliance with federal laws and regulations regarding Medicaid.

IX. DATA LINKAGE

Data linkage involves combining CHIA Data with other data to create a more extensive database for analysis. Data linkage is typically used to link multiple events or characteristics within one database that refer to a single person within CHIA Data.

1. Do you intend to link or merge CHIA Data to other data?

- ☐ Yes
- ☒ No linkage or merger with any other data will occur

2. If yes, please indicate below the types of data to which CHIA Data will be linked. [Check all that apply]

- ☐ Individual Patient Level Data (e.g. disease registries, death data)
- ☐ Individual Provider Level Data (e.g., American Medical Association Physician Masterfile)
- ☐ Individual Facility Level Data (e.g., American Hospital Association data)
- ☐ Aggregate Data (e.g., Census data)
- ☐ Other (please describe):

3. If yes, describe the dataset(s) to which the CHIA Data will be linked, indicate which CHIA Data elements will be linked and the purpose for each linkage.

Click here to enter text.

4. If yes, for each proposed linkage above, please describe your method or selected algorithm (e.g., deterministic or probabilistic) for linking each dataset. If you intend to develop a unique algorithm, please describe how it will link each dataset.

Click here to enter text.

5. If yes, attach or provide below a complete listing of the variables from all sources to be included in the final linked analytic file.

Click here to enter text.

6. If yes, please identify the specific steps you will take to prevent the identification of individual patients in the linked dataset.

Click here to enter text.

X. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Do you anticipate that the results of your analysis will be published or made publically available? If so, how do you intend to disseminate the results of the study (e.g.; publication in professional journal, poster presentation, newsletter, web page, seminar, conference, statistical tabulation)? Any and all publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications ***will not disclose a cell less than 11***, and percentages or other mathematical formulas that result in the display of a cell less than 11.

We anticipate that the results of this study will be presented at academic conferences, such as AcademyHealth Annual Research Meeting, and be published in peer-reviewed academic journals, such as *Pediatrics* and *JAMA Pediatrics*. Descriptive results will be displayed only for the overall study samples and subgroups (e.g. observation versus inpatient stays) in tables, and **we will not release or disclose information where the number of observations (including but not limited to, patients and hospital stays) in any given cell of tabulated data is less than 11.** Coefficient results from regressions will also be reported, such as observation-status patients pay $xxx (95% confidence interval) more than they would have paid as inpatients. **The publication of values, percentages of other mathematical formulas that can result in the display of 1 to 11 is prohibited in all text and tables.**

2. Describe your plans to use or otherwise disclose CHIA Data, or any Data derived or extracted from such Data, in any paper, report, website, statistical tabulation, seminar, or other setting that is not disseminated to the public.

We also plan to present the results of this study at academic seminars. All contents of these presentations will follow the CHIA's cell size suppression policy, as described above.

3. What will be the lowest geographical level of analysis of data you expect to present for publication or presentation (e.g., state level, city/town level, zip code level, etc.)? Will maps be presented? If so, what methods will be used to ensure that individuals cannot be identified?

The lowest geographical level of analysis of data we expect to present is county level. For example, the use of observation stays ranges from 40 to 65 out of every 100 hospital stays per county. We will replace the value of a cell less than 11 using "Not Applicable", if there is any county has less than 11 observations. No maps will be presented.

4. Will you be using CHIA Data for consulting purposes?

☐ Yes
☒ No

5. Will you be selling standard report products using CHIA Data?

☐ Yes
☒ No

6. Will you be selling a software product using CHIA Data?
☐ Yes
☒ No

7. Will you be using CHIA Data as in input to develop a product (i.e., severity index took, risk adjustment tool, reference tool, etc.)
☐ Yes
☒ No

8. Will you be reselling CHIA Data in any format not noted above?
☐ Yes
☒ No

If yes, in what format will you be reselling CHIA Data?

Click here to enter text.

9. If you have answered "yes" to questions 5, 6, 7 or 8, please provide the name and a description of the products, software, services, or tools.

Click here to enter text.

10. If you have answered "yes" to questions 5, 6, 7 or 8, what is the fee you will charge for such products, software, services or tools?

Click here to enter text.

XI. APPLICANT QUALIFICATIONS

1. Describe your previous experience using claims data. This question should be answered by the primary investigator and any co-investigators who will be using the Data.

Dr. Mehul V. Raval (Principle Investigator) is a pediatric surgeon and physician scientist in pediatric health service research. As a principle investigator, he has received a federal grant fund for research project (R01) from the National Institute of Health to assess both quality and costs of pediatric surgical care using the Health Care Cost Institute claims data. He has also utilizaed the MarketScan Research databases (formerly Truven) to investigate the association of health care utilization prior to presentation with perforated appendicitis. Using claims data, he has published several studies on academic journals, such as JAMA Surgery and Annals of Surgery.

Dr. Yao Tian (Co- Investigator) is a health economist and health services researcher at Northwestern University Feinberg School of Medicine. She has used the Surveillance, Epidemiology, and End Results (SEER)-Medicare

linked database to investigate the impact of pre-existing diabetes mellitus on the survival of patients with HCC and further explore whether the impact varies among hepatocellular carcinoma patients with/without hepatitis in the United States. The SEER-Medicare data reflect a combination of two large population-based data source: The SEER data collect clinical, demographic and cause of death information for patients diagnosed with cancer and the Medicare claims data include Medicare enrollment, healthcare services occurred in various settings and health care assessment.

2. **Resumes/CVs**: When submitting your Application package on IRBNet, include résumés or curricula vitae of the principal investigator and co-investigators. (These attachments will not be posted on the internet.)

XII. USE OF AGENTS AND/OR CONTRACTORS

By signing this Application, the Organization assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors. The Organization must have a written agreement with the agent of contractor limiting the use of CHIA Data to the use approved under this Application as well as the privacy and security standards set forth in the Data Use Agreement. CHIA Data may not be shared with any third party without prior written consent from CHIA, or an amendment to this Application. CHIA may audit any entity with access to CHIA Data.

Provide the following information for **all** agents and contractors who will have access to the CHIA Data. [*Add agents or contractors as needed.]*

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	Click here to enter text.
Company Website	Click here to enter text.
Contact Person:	Click here to enter text.
Title:	Click here to enter text.
E-mail Address:	Click here to enter text.
Address, City/Town, State, Zip Code:	Click here to enter text.
Telephone Number:	Click here to enter text.
Term of Contract:	Click here to enter text.

1. Describe the tasks and products assigned to the agent or contractor for this Project and their qualifications for completing the tasks.

Click here to enter text.

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

Click here to enter text.

3. Will the agent or contractor have access to and store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

☐ Yes
☐ No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	Click here to enter text.
Company Website	Click here to enter text.
Contact Person:	Click here to enter text.
Title:	Click here to enter text.
E-mail Address:	Click here to enter text.
Address, City/Town, State, Zip Code:	Click here to enter text.
Telephone Number:	Click here to enter text.
Term of Contract:	Click here to enter text.

1. Describe the tasks and products assigned to the agent or contractor for this Project and their qualifications for completing the tasks.

Click here to enter text.

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

Click here to enter text.

3. Will the agent or contractor have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

☐ Yes
☐ No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

[INSERT A NEW SECTION FOR ADDITIONAL AGENTS/CONTRACTORS AS NEEDED]

XIII. ATTESTATION

By submitting this Application, the Organization attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* confirms that it is compliant with such use, privacy and security standards. The Organization further agrees and understands that it is solely responsible for any breaches or unauthorized access, disclosure or use of CHIA Data, including, but not limited to, any breach or unauthorized access, disclosure or use by any third party to which it grants access.

Organizations approved to receive CHIA Data will be provided with Data following the payment of applicable fees and upon the execution of a Data Use Agreement requiring the Organization to adhere to processes and procedures designed to prevent unauthorized access, disclosure or use of data.

By my signature below, I attest: (1) to the accuracy of the information provided herein; (2) this research is not funded by a source requiring the release of raw data to that source; (3) that the requested Data is the minimum necessary to accomplish the purposes described herein; (4) that the Organization will meet the data privacy and security requirements described in this Application and supporting documents, and will ensure that any third party with access to the Data meets the data use, privacy and security requirements; and (5) to my authority to bind the Organization.

Signature: (Authorized Signatory for Organization)	Drag signature image here or delete and physically sign
Printed Name:	**Manny Robert**
Title:	Contracts & Negotiations Manager
Date:	Click here to enter text.

Attachments:
A completed Application must have the following documents attached to the Application or uploaded separately to IRBNet:
☒ 1. IRB approval letter and protocol (if applicable), or research methodology (if protocol is not attached)
☒ 2. Data Management Plan (including one for each agent or contractor that will have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database);
☒ 3. CVs of Investigators (upload to IRBNet)

APPLICATIONS WILL NOT BE REVIEWED UNTIL THEY ARE COMPLETE, INCLUDING ALL ATTACHMENTS.