center for health information and analysis

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

I. INSTRUCTIONS

This form is required for all Applicants, except Government Agencies as defined in 957 CMR 5.02, requesting protected health information. *All Applicants must also complete the Data Management Plan, attached to this Application. The Application and the Data Management Plan must be signed by an authorized signatory of the Organization. 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. Applicants 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.

All attachments must be uploaded to IRBNet with your Application. All Application documents can be found on the CHIA website in Word and in PDF format or on IRBNet in Word format. If you submit a PDF document, please also include a Word version in order to facilitate edits that may be needed.

Applications will not be reviewed until the Application and all supporting documents are complete and the required application fee is submitted. A Fee Remittance Form with instructions for submitting the application fee is available on the CHIA website and IRBNet. If you are requesting a fee waiver, a copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet.

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:	**Exploring Factors Affecting Medication Adherence Trajectories**
IRBNet Number:	772446-1
Organization Requesting Data (Recipient):	**Institute of Urban Health Research and Practice Northeastern University (Northeastern University)**
Organization Website:	
Authorized Signatory for Organization:	**Eva Pasedas**
Title:	Director, Grants & Contracts
E-Mail Address:	oraf@northeastern.edu
Address, City/Town, State, Zip Code:	360 Hungtington Avenue, Bostong , MA 02115
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	**Dr. Gary Young**
Title:	Director, Center for Health Policy and Healthcare Research Professor, Strategic Management and Healthcare Systems Faculty Scholar, Institute of Urban Health Research and Practice
E-Mail Address:	ga.young@neu.edu
Telephone Number:	617 373 -2528
Address, City/Town, State, Zip Code:	360 Huntington Avenue, Boston MA 02115
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	**Dr. Gary Young**
Title:	Director, Center for Health Policy and Healthcare Research Professor, Strategic Management and Healthcare Systems Faculty Scholar, Institute of Urban Health Research and Practice
E-Mail Address:	ga.young@neu.edu
Telephone Number:	617 373 -2528
Address, City/Town, State, Zip Code:	360 Huntington Avenue, Boston MA 02115
Names of Co-Investigators:	
E-Mail Addresses of Co-Investigators:	

IV. PROJECT INFORMATION

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

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

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.

The purpose of the present project is to examine the factors associated with length of time to first and second consecutive points of medication non-adherence after starting a new chronic medication. It has been well described that initial medication adherence is critical to establishing a chronic pattern of medication adherence after starting a new medication. Individuals who become non-adherent during the initial months of therapy are more likely to remain non-adherent during later stages of therapy. There are no known explorations about the factors that affect the time course to initial medication non-adherence. Through such a longitudinal exploration using CHIA pharmacy data, we aim to identify potential intervention targets for a subsequent study to reduce initial medication non-adherence and promote sustained optimal medication adherence.

Specific reaserch aims are:

1. What is the average length of time to first and second consecutive points of non-adherence across different chronic medications?
2. What patient demographic and clinical characteristics, drug, pharmacy, prescriber, insurer, geographic and other factors affect the length of time to the first and second consecutive points of medication non-adherence associated with the start of a new medication across multiple chronic conditions?
3. What are the most significant factors predicting the length of time to the first and second consecutive points of medication non-adherence associated with the start of a new medication across multiple chronic conditions?
4. To develop and explanatory model for factors affecting the time and intiail medication non-adherence after starting a new chronic medication.

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**: Applicants must provide 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.

V. PUBLIC INTEREST

1. Briefly explain why completing your 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.*

Medication non-adherence is associated with several negative patient outcomes including poor clinical outcomes, greater morbidity and mortality. In addition, medication non-adherence costs the United States over an estimated $290 billion annually in direct and indirect costs. There is great need to characterize medication adherence trajectories (in particular initial medication non-adherence) so we might identify additional targets for subsequent intervention.

VI. DATA 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. Data requests will be fulfilled using the most current Release Version. For more information about the most current APCD Release Version, 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. Applicants who 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 request will be subject to the Data Use Agreement, will require payment of fees for additional Data, and subject to the limitation that the Data can be used only in support of the approved Project.

1. List years of data you already have for this poject:
APCD Release Version 3.0 CY 2011 – 2013: 206_NUE_Young (Member Eligibility, Pharmacy Claims)
APCD Releaxe Version 5.0 CY 2014 – 2015: 287_NEU_Young (Pharmacy Claims)

1. List years of data requested (only list years available in the current Release Version):
APCD Release Version 7.0 2013 – 2017

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

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

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:

We will use medical claims to construct variables as predictors of medication adherence. In particular, we plan to construct a variable to capture a patient's disease burden based on the number and type of chronic conditions as documented in medical claims in the form of ICD codes.

☒ Pharmacy Claims

Describe how your research objectives require Pharmacy Claims data:

We will use pharmacy claims to assess patients' medication adherence based on and frequency and duration of gaps in refills for prescribed medications pertaining to selected chronic conditions.

☐ Dental Claims

Describe how your research objectives require Dental Claims data:

☒ Member Eligibility

Describe how your research objectives require Member Eligibility data:

The member eligibility file offers information for constructing variables as predictors of medication adherence. In particular, we are interested in patients' type of health plan (HMO, PPO) as a predictor of adherence.

☐ Provider

Describe how your research objectives require Provider data:

☐ Product

Describe how your research objectives require Product data:

VII. DATA ENHANCEMENTS REQUESTED

State and federal privacy laws limit the release and use of 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 applicants 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.

Geographic Subdivisions

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

☐ 3-Digit Zip Code (standard)	☒ 5-Digit Zip Code***
***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology: We will use 5-digit zip code information for linking APCD to the Area Health Resource File (available from US Department of Health and Human Services). The purpose of the linkage is to obtain information regarding median household income of the zip code in which patients in the study sample reside.	

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 will also YYYYMMDD for assessing duration of gaps in medication refills from pharmacy data. We will also use YYYYMMDD to identify patients' clinical indicatations as documented in medical claims for prescription medications. We will use the dates to line up medical claims that precede claims for prescription medications.		

National Provider Identifier (NPI)

Select *one* of the following options.

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

We will use the National Provider Identifiers for linking APCD data with external sources of data that contain characteristics of clinicians, specifically the NPI files from the Centers for Medicare and Medcaid Services and files from the Massachusetts Board of Registation in Medicine. We will use clinician-level characteristics (e.g.,specialty training, experience) as predictors of patients' medication adherence.

VIII. MEDICAID (MASSHEALTH) DATA

1. Please indicate whether you are seeking Medicaid Data:

X 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.

The proposal is focused on improving medication adherence which is a critical goal of the administration of an efficient and less costly Medicaid program. The achievement of this goal will also help reduce Medicaid healthcare costs (hospitalizations, ER visits, etc.).

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)
   - X☐ 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.

The linkage will be with the American Community Survey for purposing of obtaining the median income for the zip code in which patients in the study sample reside. This information will be used as a measure of the socio-economic profile of the community in which patients reside and thus a predictor of medication adherence. The linkage will not provide information that can be used to identify patients.

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.

The linkage will be straightforward – based on merging for 5-digit zip code between the APCD and the American Community Survey.

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.

Median household income by zip code. Data specifications are the following from the American Community Survey.

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

The linked data will be in aggregate form and will not provide information for identifying patients in the study sample.

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 do plan to publish the data in a pharmacy or health services research journal. We are only interested in publishing data in the aggregate form and not to identify any individual or organization. We also plan to present data at scientific meetings such as the American Pharmacists Association, AcademyHealth, and/or the American Public Health Association.

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.

Our analysis will be made available to the public in the form of a published manuscript or presented data at a professional meeting. There will be no other effort to disseminate information to separate entities and no collection of any fees.

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?

Regions of the state based on clusters of Zip Codes – eastern, central and western parts of the state.

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?

NA

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

NA

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?

NA

XII. 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.

Gary Young, JD, PhD is Director of the Northeastern University Center for Health Policy and Healthcare Research as well as Professor of Strategic Management and Healthcare Systems, Northeastern University. He is also affiliated with the Health Services Research and Development Service of the Department of Veterans Affairs. Before joining Northeastern University, he was chairman of the Department of Health Policy and Management at Boston University. Dr. Young's research generally pertains to organizational, managerial, and policy issues associated with the delivery of healthcare services. He has extensive research experience regarding performance measurement and improvement for quality of care. His published work has appeared in such journals as the New England Journal of Medicine, Journal of the American Medical Association, Health Affairs, Medical Care, Journal of Health Politics, Policy and Law, and Academy of Management Journal. He is a recipient of an Investigator Award in Health Policy Research from The Robert Wood Johnson Foundation for his work on the application of pay-for-performance to the US health care industry. In 2012, he was appointed by the US Secretary of the Treasury to the Internal Revenue Service's Advisory Committee on Tax Exempt and Government Entities, one of several congressionally mandated committees that advise the IRS on policy issues including the agency's current responsibilities for implementing provisions of the Patient Protection and Affordable Care Act. He also currently serves on a committee for the National Quality Forum that is responsible for recommending concepts and methods for the development of value-based performance measures. He received a law degree and Ph.D. in Management from the State University of New York.

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.)

XIII. USE OF AGENTS AND/OR CONTRACTORS

By signing this Application, the Agency assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors. The Agency 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:	
Company Website	
Contact Person:	
Title:	
E-mail Address:	
Address, City/Town, State, Zip Code:	
Telephone Number:	
Term of Contract:	

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

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.

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.

AGENT/CONTRACTOR #2 INFORMATION	
Company Name:	
Company Website:	
Contact Person:	

Title:	
E-mail Address:	
Address, City/Town, State, Zip Code:	
Telephone Number:	
Term of Contract:	

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

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.

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]

IVX. 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.

Applicants 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) that the requested Data is the minimum necessary to accomplish the purposes described herein; (3) 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 (4) to my authority to bind the Organization.

Signature: (Authorized Signatory for Organization)	
Printed Name:	
Title:	

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.

[INSERT IRB approval letter and protocol, or research methodology]

Methodology

Our research plan entails linking patients' pharmacy claims and medical claims to accomplish two objectives: (1) identify key predictors of medication non-adherence for common chronic health conditions, and (2) assess the health consequences of medication non-adherence.

(1) Descriptive Statistics

Definition of medication non-adherence: Our analytic plan is to first describe first and second gaps in medication non-adherence after the initial start of drug therapy for an oral chronic medication. A gap will be defined any situation in which there appears to be continued medication use of 2 or more weeks before and after at least a 2 week period in which no medication was available. We will define a new start as the patient not having had the medication in the previous year. A chronic medication will be defined as a medication that is needed to treat an ongoing condition such as high blood pressure, diabetes, asthma, hyperlipidemia, depression, etc. Oral medications are those which come in tablets or capsules formulations.
We will compute lengths of time in days from start of therapy to first gap of medication non-adherence and then second gap of medication non-adherence. We will also examine mean and standard deviations on key population parameters-age and number of medications. We will also examine frequencies of those in sample according to gender, geographic location, race/ethnicity, pharmacy location.

(2) Bivariate Statistics

We will examine bivariate relationships (pearson correlations) between lengths of first and second gaps of medication non-adherence and demographic, clinical, health system, and pharmacy variables. Clinical variables will be constructed based on a patient's number of chronic conditions (e.g., comorbidity indices such as the Charlson comorbidity index and the Elixhauser index) and medications prescribed for the management of chronic conditions. This information will be obtained from a patient's medical claims that we will link with pharmacy claims. We will identify any variables that are highly correlated and potentially create multicollinearity issues for multivariate regression analyses.
(3) Multivariate Statistics
We will conduct two sets of analyses. One set is to examine models of clinical, socio-demographic health system, and pharmacy variables as predictors of first and second medication adherence gaps after initiation of therapy. Such analyses will enable us to identify potential interaction effects among variables. A key clinical variable will be based on a disease burden index based on number of chronic conditions and related medications. This information will come from medical claims. The index score will account for comorbidities other than the disease for which we are assessing medication non-adherence (i.e., diabetes, asthma, depression, hyperlipidemia). We will test the hypothesis that disease burden (as measured by the index score) is a strong predictor of medication non-adherence. Our analyses will be conducted according to therapeutic class to allow for switching possibilities and the possibility of overestimating non-adherence. We will also explore the use of path analysis as a way to examine models of relationships between study variables.
Another set is to examine the consequences of non-adherence based on frequency of hospitalizations that appear related to the patient's chronic condition. We will examine whether non-adherence is associated with more frequent hospitalizations over a period of several years. For the analyses, we will identify a cohort of patients who are newly diagnosed with one of the several clinical conditions of interest and prescribed a medication for treating the condition. For each patient in the cohort, we will construct scores for non-medication adherence (based on number and duration of gaps) and assess the statistical relationship between these scores and the frequency of relevant hospitalizations during the study period controlling for disease burden and socio-demographic characteristics.