CHIA.
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:	SPOiLER – Towards Safer Prescribing of Legal Opioids in the Emergency Room
IRBNet Number:	1290731
Organization Requesting Data (Recipient):	The Institute for Healthcare Delivery and Population Science, University of Massachusetts Medical School – Baystate Campus
Organization Website:	**https://www.baystatehealth.org/education-research/research/research-centers/institute-for-healthcare-delivery-and-population-science**
Authorized Signatory for Organization:	**Jennifer L Pacheco**
Title:	Director, Healthcare Research Compliance
E-Mail Address:	Jennifer.pacheco@baystatehealth.org
Address, City/Town, State, Zip Code:	759 Chestnut St, M/S 3601 Main St, Springfield, MA 01199
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	**Meng-Shiou Sheh, PhD**
Title:	Biostatistician, Institute of Healthcare Delivery and Population Science
E-Mail Address:	Meng-shiou.shieh@baystatehealth.org
Telephone Number:	413-794-7904
Address, City/Town, State, Zip Code:	3601 Main St, Springfield, MA 01199
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	William Soares MD, MS
Title:	Fellow, Institute of Healthcare Delivery and Population Science, University of Massachusetts Medical School – Baystate Campus Emergency Medicine, Baystate Medical Center
E-Mail Address:	William.soaresmd@baystatehealth.org
Telephone Number:	413-794-6244
Names of Co-Investigators:	Peter Friedmann, Peter Lindenauer, Paul Visintainer, Niels Rathlev, Meng-Shiou Shieh, Penelope Pekow
E-Mail Addresses of Co-Investigators:	Peter.Friedmannmd@baystatehealth.org, Peter.lindenauer@baystatehealth.org, paul.visintainer@baystatehealth.org, Meng-Shiou.Shieh@baystatehealth.org, penny.pekow@baystatehealth.org

IV. PROJECT INFORMATION

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

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

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.

State governments, including the Commonwealth of Massachusetts, have reacted to the opioid crisis in part by crafting legislation to broadly limit legal opioid prescriptions. However, opioid medications remain an important treatment option for some acute painful conditions, and evidence based guidance on appropriate prescribing is lacking, in part because the factors that impact providers opioid prescribing behaviors and subsequent patient associated adverse outcomes remains unknown. Understanding the underlying factors that influence opioid prescribing behaviors and future patient outcomes, including state legislation, peer behaviors, and hospital culture, is a critical step in developing integrated, evidence-based recommendations that focus on transforming the culture surrounding safe opioid prescribing practices.

Using the theory of planned behavior as a framework, the purpose of this project is to understand opioid prescribing behaviors and adverse patient outcomes following the 2016 Massachusetts (MA) Opioid Law. We will use claims data from the MA-APCD to evaluate the impact of the 2016 MA Opioid Law on statewide opioid prescribing. We will also use the APCD to examine the association of an initial opioid prescription on clinically relevant patient outcomes in order to better understand how restricting opioid prescriptions through legislation may impact emergency department patients presenting with an acute painful condition.

The APCD's comprehensive data collection will allow evaluation of initial emergency based opioid prescriptions, stratified by hospital as well as by provider. Further, the APCD captures the maximum possible number of future healthcare utilization, both inpatient and outpatient, as well as future opioid and non-opioid prescriptions. Use of the APCD will allow unprecedented depth and detail in evaluating the provider and patient effects of the 2016 MA Opioid Law.

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.*

The proposed project will provide the groundwork and training to effect meaningful change in prescribed opioid policy and research. To date, attempts to manage prescription opioids have centered on legislation directed towards the individual provider. Our research broadens the understanding of prescribing behaviors and patient outcomes by incorporating culture and social norm variables, including peer behaviors, hospital attitudes, and local regulations. From our results, we will create evidence-based recommendations for changes in current policy, as well as develop implementation trials that focus on transforming the group culture and social norms that influence opioid prescribing behaviors. Through our research, we will identify modifiable situational

variables, such as type of opioid and number of pills per prescription, which may be amenable to change to promote consistent and safe opioid prescribing behaviors among providers still struggling to balance the benefits and risks of opioid therapy.

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 requested (only list years available in the current Release Version): 2015, 2016, 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:

This is the most critical data. We are evaluating emergency department patients who present with an acute painful condition as our study population. Details regadrding their ED visit will help us to both select our population as well as decrease confounding, allowing us to control over multiple patient level variables during their index ED visit as detailed in the IRB application.

In assessing the future outcomes of patients prescribed an opioid medication for an acute painful condition, information on future hospital observation admissions will impart important information regarding their future clinical course.

Hospital Inpatient Discharge data is critical to the study to evaluate patient level outcomes after an initial opioid prescription for an acute painful condition as detailed in the attached methods.

☒ Pharmacy Claims

Describe how your research objectives require Pharmacy Claims data:

Pharmacy claims data are another critical component of the project. We will be evaluating the prescriptions filled after an index ED visit, then follow the patient for 4 months to evaluate subsequent filled prescriptions. Including the type of medication filled, the number of pills per prescription, and being able to associate the prescription with reasonable accuracy to the healthcare visit are critical aspects of the project proposal.

☒ Dental Claims

Describe how your research objectives require Dental Claims data:

As one of our index ED measures for acute painful conditions is dental pain, evaluating follow up dental visits after the index ED visit is an important component of follow up in the proposed project.

☒ **Member Eligibility**
Describe how your research objectives require Member Eligibility data: Member eligibility information, including type of insurance, will help stratify and identify differences by insurance carrier with regards to initial prescriptions as well as follow up.
☐ **Provider**
Describe how your research objectives require Provider data:
☐ **Product**
Describe how your research objectives require Product data: no product data required

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:** Aim 1 involves evaluating temporal changes in provider opioid prescribing patterns for patients presenting to the emergency department with an acute painful condition. Incorporating 5 digit zip codes will allow us to address patient location as a possible confounder – as patient location is associated with socioeconomoic status and other factors that may contribute to confounding as we attempt to more clearly define the impact of the 2016 MA opioid law.	

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: It is critical to have day, month, year, as we will be linking the initial emergency department visit and future hospitalizations in AIM 2 with opioid prescription data via the MA-APCD pharmacy data. Comprehensive evaluation of when a future heathcare event occurred is critical to accurate data analysis.		

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:**

In order to complete our study, we must be able to link the initial ED vist with the provider prescribing data. Further, we plan to stratify along provider variables in the MA-APCD. After speaking to APCD staff, it appears that the APCD provider file does not contain enough provider variables to complete the study. By having the Decrypted NPI data, we will be able to include provider variables by matching APCD NPI variables to open access NPI data sets.

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.

The goal of our project is to identify the impact of the 2016 MA Opioid law on ED prescribing for acute painful conditions in patients who are opioid naïve without evidence of prior ED visits. Further, we will complete the most in depth analysis of the subsequent course of these ED patients with acute painful injuries over the ensuing short term follow up (4 months). We believe our findings will help guide programs, such as Mass Health, to refine legislation and provider policies in treatment of acute painful conditions to minimize risks including future opioid prescriptions and recurrent healthcare utilization, with the ultimate goal of providing excellent patient care while preserving healthcare resources. Of note, as we are interested in opioid naïve patients with an acute painful condition, we are excluding any patients with a history of substance use disorder from the study population.

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.

We plan to link provider NPI numbers in the APCD to the CMS National Plan and Provider Enumeration System (NPPS) NPI database.

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.

We will directly link APCD reported NPI numbers with those NPI numbers provided in the CMS National Plan and Provider Enumeration System (NPPS) NPI database.

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.

Variables from the CMS National Plan and Provider Enumeration System (NPPS) NPI database are attached in a separate excel file.

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

The linkage contains no patient level data, only additional publically accessible provider variables. MA APCD data will note be merged, stacked, linked, or otherwise combined to NH claims data.

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 expect to publish at least two manuscripts in high impact substance use disorder / policy journals, as well as disseminate information through emergency and addiction medicine regional and national conferences. Further, we plan to make results available to Massachusetts public health and government officials as they continue to refine current opioid law.

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.

No plans to disseminate data other than as is 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?

We will be presenting aggregate patient and hospital level data only, we will not be presenting or disseminating any individual patient or provider level data. Zip code / city level data will be used only to describe the area / patterns around associated hospitals

and their catchment area.

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?

9. If you have answered "yes" to questions 5, 6, 7 or 8, please describe the types of products, software, services, or tools.

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?

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.

I am an academic emergency physician at Baystate Medical Center in Springfield, MA and fellow of the Institute of Healthcare Delivery and Population Science (IHDPS) at the University of Massachusetts Medical School (UMMS) – Baystate Campus. I have dedicated my professional career to clinical research, completing a two year emergency medicine research fellowship and a master's degree in Clinical and Translation Science at Tufts University. My prior research has focused on education theory as well as database analysis. The proposed project is part of a 5 year NIH K08 early career investigator award, which includes protected time for training in advanced statistical analysis, research methods, and implementation science and addiction medicine.

As part of the NIH K08, I will benefit from in-depth mentorship and the resources of the IHDPS. My primary mentor, Dr. Peter

Friedmann, is the Director of Research at UMMS-Baystate and has been continuously funded by NIDA since 1996. He has extensive experience with opioid use disorders, retrospective analyses and clinical trial development. Further, he has successfully mentored multiple prior early career investigators through KO8 and K23 awards.

Dr. Peter Lindenauer is director of the IHDPS, which, since its inception in 2008, has successfully competed for 14 million in NIH, AHRQ and foundation funding and has published more than 250 papers. Dr. Lindenauer works closely with a comprehensive bio statistical department specializing in large database analysis, including Premier and the MA-APCD. Currently, the IHDPS is utilizing the APCD to evaluate outcomes of patients presenting to the emergency department with renal colic.

In summary, my dedicated 5 year NIH K08 funding, my mentorship from leaders in opioid use disorder research and large database analysis, as well as the familiarity of the IHDPS bio statistical department with the APCD and other large hospital level database analysis, will allow our research group to successfully utilize the MA-APCD to attain our stated goals and complete the proposed project.

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)	Jennifer L Pacheco Digitally signed by Jennifer L Pacheco DN: cn=Jennifer L Pacheco, o=Baystate Health - UMMS, ou=Office of Research, email=Jennifer.pacheco@baystatehealth.org, c=US Date: 2018.12.14 13:23:21 -05'00'
Printed Name:	**Jennifer L. Pacheco, MPH, CIM, CIP**
Title:	Director, Healthcare Research Compliance & Chief Research Compliance Officer Baystate Health University of Massachusetts Medical School – Baystate Campus

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)