Commonwealth of Massachusetts
Center for Health Information & Analysis (CHIA)
Non-Government MA APCD Request for Data

This form is to be used by all applicants, except Government Agencies as defined in 957 CMR 5.02.

<u>**NOTE:**</u> **In order for your application to be processed, you must submit the required application fee. Please consult the fee schedules for MA APCD data for the appropriate fee amount. A remittance form with instructions for submitting the application fee is available on the CHIA website.**

I. GENERAL INFORMATION

APPLICANT INFORMATION	
Applicant Name:	Elizabeth Schoenfeld, MD
Title:	Assistant Professor, Emergency Medicine
Organization:	Baystate Medical Center
Project Title:	Patterns and predictors of urologic intervention following an Emergency Department visit for renal colic
Mailing Address:	Center for Quality of Care Research 280 Chestnut Street, 3rd Floor Springfield, MA 01199-1000
Telephone Number:	413-794-2285
Email Address:	Elizschoen@gmail.com
Names of Co-Investigators:	Peter Lindenauer, Penelope Pekow
Email Addresses of Co-Investigators:	Peter.Lindenauer@baystatehealth.org, Penny.Pekow@baystatehealth.org
Original Data Request Submission Date:	June 2016
Dates Data Request Revised:	
Project Objectives (240 character limit)	To describe the natural history and treatment course of renal colic among Massachusetts emergency department patients from 2011-2015, specifically examining hospital admission, ED revisits, and the rate and timing of urologic interventions.
Project Research Questions (if applicable) or Business Use Case(s):	1. What percent of discharged patients will have a urologic intervention within 7 days and 30 days? 2. What percent will return to the emergency department in 7 days and 30 days? 3. What percent will be admitted upon initial evaluation?

II. PROJECT SUMMARY
Briefly describe the purpose of your project and how you will use the requested CHIA data to accomplish your purpose.

Over 600,000 CT scans are performed each year in the US to diagnose renal colic (kidney stones).

Recent data has suggested that an ultrasound-first pathway could curb radiation exposure, but guidelines from urology literature reiterate the need for CT imaging in patients who may undergo a urological intervention. If clinicians could predict the likelihood that an individual will need a urologic intervention, prior to CT scan, clinicians could avoid or delay CT use in low-risk patients, or use this information to inform a shared decision-making (SDM) conversation with patients. Developing a better understanding of the rate and timing of urologic interventions, and developing a model to predict patients' estimated risk of having a urologic intervention, could help reduce unnecessary CT scanning in renal colic.

   Aims: To use the Massachusetts APCD to describe the natural history and treatment course of renal colic among Massachusetts ED patients from 2011-2015, specifically examining hospital admission, ED revisits, and the rate and timing of urologic interventions; to identify patient, hospital, and geographic factors associated with receipt of a urologic intervention; and to develop a clinical prediction model to determine an individual's estimated risk of needing a urologic intervention after an ED visit.

   This study will be the first to accurately capture a large cohort's outpatient urologic procedure rate. This information has the potential to curb CT overuse and decrease the national radiation burden by helping clinicians decide whether or not an immediate CT scan is necessary.

III. FILES REQUESTED

Please indicate which MA APCD file(s) you are requesting, the year(s) of data requested, and your justification for requesting *each* file. Please refer to the MA APCD Release 4.0 Documentation Guides for details of the file contents.

MA ALL PAYER CLAIMS DATABASE FILES	Year(s) Of Data Requested Current Yrs. Available ☐ 2010 ☒ 2011 ☒ 2012 ☒ 2013 ☒ 2014
☒ **Medical Claims**	**Please provide justification for requesting Medical Claims file:** **We are attempting to learn about subjects' emergency department care – both in the ED and afterwards, and therefore need to know what was done (CT scans, medicines administered, procedures, visits after the ED visit, etc.)**
☒ **Pharmacy Claims**	**Please provide justification for requesting Pharmacy Claims file:** **Part of ED care is the prescriptions received by the patient, therefore we need to know what prescriptions were filled after the subject's visit to the ED. We intend to examine the use of medication that helps pass kidney stones and note any disparities in its use, as well as examine its effectiveness.**
☐ **Dental Claims**	**Please provide justification for requesting Dental Claims file:**
☐ **Member Eligibility**	**Please provide justification for requesting Member Eligibility file:**
☒ **Provider** (encrypted NPI) Standard or ☐ **Provider*** (unencrypted NPI)	**Please provide justification for requesting Provider file:** Emergency department care varies by provider, therefore it will be helpful to be able to control for provider in our analysis.

	*Please provide justification for requesting unencrypted NPI (if requested). Refer to specifics in your methodology:
☐ **Product**	**Please provide justification for requesting Product file:**

IV. GEOGRAPHIC DETAIL
Please choose _one_ of the following geographic options for MA residents:

☐ 3 Digit Zip Code (MA)	☒ 5 Digit Zip Code (MA)
***Please provide justification for requesting 5 digit zip code. Refer to specifics in your methodology: There is substantial data that medical care varies by region. In the case of our study, it is very likely that proximity to a urologist, or urologist density, plays a role in the receipt of care. Similarly, the sociodemographics of a subject may play a role in the care they receive. By having 5 digit zip codes, we can link claims data to Area Resource Files information and examine the role of SES and specialist density on the receipt of care.	

V. DATE DETAIL
Please choose _one_ option from the following options for dates:

☐ Year (YYYY) (Standard)	☐ Month (YYYYMM) ***	☒ Day (YYYYMMDD) *** [for selected data elements only]
*** If requested, lease provide justification for requesting Month or Day. Refer to specifics in your methodology: One of the most important aims of this study is to determine how many days after an ED visit patients are having their urologic interventions, therefore it's very important to have exact dates of ED visits and interventions.		

VI. FEE INFORMATION
Please consult the fee schedules for MA APCD data, available at http://chiamass.gov/regulations/#957_5, and select from the following options:

APCD Applicants Only
- ☒ Academic Researcher
- ☐ Others (Single Use)
- ☐ Others (Multiple Use)

Are you requesting a fee waiver?
- ☒ Yes
- ☐ No

If yes, please refer to the Application Fee Remittance Form and submit a letter stating the basis for your request (if required). Please refer to the fee schedule for qualifications for receiving a fee waiver. If you are requesting a waiver based on the financial hardship provision, please provide documentation of your financial situation. Please note that non-profit status alone isn't sufficient to qualify for a fee waiver.

VII. MEDICAID DATA [APCD Only]

Please indicate here whether you are seeking Medicaid Data:

☒ Yes
☐ No

Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are directly connected with the administration of the Medicaid program. If you are requesting Medicaid data from Level 2 or above, please describe in detail why your use of the data meets this requirement. Applications requesting Medicaid 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 Medicaid program. MassHealth may impose additional requirements on applicants for Medicaid data as necessary to ensure compliance with federal laws and regulations regarding Medicaid.

> Previous data, including our own work, suggests that patients with Medicaid who have kidney stones get treated differently than patients with private insurance. For example, in our most recent analysis of Premier Database data, patients with private insurance were more likely to get an inpatient urologic procedure than patients with Medicaid or Medicare. Obviously it is extremely important to know if patients on Medicaid are getting different care than those with private insurance - this disparity has not been thoroughly examined due to lack of follow-up data. The APCD will allow a more accurate evaluation of the disparities in care that seem to be present between Medicaid patients and privately insured patients when it comes to the diagnosis and treatment of kidney stones.

VIII. PURPOSE AND INTENDED USE

1. Please explain why completing your project is in the public interest.

> 1. This study will examine the use of urologic interventions and elucidate disparities in care around renal colic.
> 2. This study will inform the creation of a study promoting shared decision-making in the emergency room. Shared decision-making has been shown to improve patient knowledge, satisfaction, and engagement. In the case of this study, the results from this study will help doctors safely decrease the use of CT scans, which would decrease the amount of dangerous radiation the public is exposed to, resulting in fewer future cancers. Furthermore, shared decision-making has shown to have increased benefits in underserved populations, making this study even more relevant to the Medicaid population.

2. **Attach** a brief (1-2 pages) description of your research methodology. (This description will not be posted on the internet.) See attached protocol

3. Has your project received approval from your organization's Institutional Review Board (IRB)? Please note that CHIA will not review your application until IRB documentation has been received (if applicable).

☒ Yes, and a copy of the approval letter is attached to this application.
☐ No, the IRB will review the project on _____.
☐ No, this project is not subject to IRB review.
☐ No, my organization does not have an IRB.

IX. APPLICANT QUALIFICATIONS

1. Describe your qualifications to perform the research described or accomplish the intended use of CHIA data.

> Dr. Schoenfeld (PI) is a physician-researcher with Baystate Medical Center. She has experience working with large datasets in conjunction with the Co-investigators. She has been the PI on multiple research projects examining the care of patients with renal colic including a recent study on outcomes in renal colc performed with the Premier database, a large claims-based dataset.
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> Dr. Peter Lindenauer is the Director of the Center for Quality of Care Research (CQCR) at Baystate Medical Center, an affiliate of both Tufts University School of Medicine and UMass Medical School. Together with Penelope Pekow, PhD, the head biostatistician at the CQCR, and other CQCR faculty, Dr. Lindenauer has published over 150 scientific papers. Many of these papers utilize claims-based data (such as the Premier database) for population-wide studies and comparative effectiveness research.

2. Attach résumés or curricula vitae of the applicant/principal investigator, key contributors, and of all individuals who will have access to the data.   (These attachments will not be posted on the internet.)

X. DATA LINKAGE AND FURTHER DATA ABSTRACTION

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

1. Do you intend to link or merge CHIA Data to other datasets?
    - ☒ Yes
    - ☐ No linkage or merger with any other database will occur

2. If yes, will the CHIA Data be linked or merged to other individual patient level data (e.g. disease registries, death data), individual provider level data (e.g., American Medical Association Physician Masterfile) , facility level (e.g., American Hospital Association data) or with aggregate data (e.g., Census data)? [check all that apply]
    - ☒ Individual Patient Level Data
      What is the purpose of the linkage:

> To obtain sociodemographic information and factors such as physician supply to population density. These factors may influence timing and use of procedures.

What databases are involved, who owns the data and which specific data elements will be used for linkage:

> Area Resource Files (ARF) – publicly available census data at the zipcode level. We will link to patient and facilities by zipcode.

    - ☐ Individual Provider Level Data
      What is the purpose of the linkage:

>

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What databases are involved, who owns the data and which specific data elements will be used for linkage:

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☒ ☒ <u>Individual Facility Level Data</u>

What is the purpose of the linkage:

To obtain characteristics of the facilities providing care to patients. Characteristics of the facility including staffing, number of beds, teaching status and

What databases are involved, who owns the data and which specific data elements will be used for linkage:

AHA survey data has already been purchased by the Center for Quality of Care Research. We will use facility ID to link.

☐ <u>Aggregate Data</u>

What is the purpose of the linkage:

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What databases are involved, who owns the data and which specific data elements will be used for linkage:

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3. 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 .

Our intent is to use a deterministic linking, based upon available IDs in the files.

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

5. If yes, and the data mentioned above is not in the public domain, please attach a letter of agreement or other appropriate documentation on restrictions of use from the data owner corroborating that they agree to have you initiate linkage of their data with CHIA data and include the data owner's website.

XI. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from such data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting.

> Abstracts and manuscripts from this data will be submitted for presentation at the national meetings of the Society for Academic Emergency Medicine and the American College of Emergency Physicians. Dr. Schoenfeld has a strong track record of presenting at these meetings. The manuscripts will be submitted to the highest impact factor journals in the fields of emergency medicine and urology. We have a collaborator who is a nationally-known researcher in health services stone research who will also be part of the dissemination of this work (Charles Scales, MD)

2. Will the results of your analysis be publicly available to any interested party? Please describe how an interested party will obtain your analysis and, if applicable, the amount of the fee.

> Several of the journals we publish in are open access, and therefore articles are freely available online. Other journals are available through libraries or online for a small fee per article (such as $5 per day or $15 per article). The authors are able to share the article freely and can send copies to interested parties.

3. Will you use the data for consulting purposes?
☐ Yes
☒ No

4. Will you be selling standard report products using the data?
☐ Yes
☒ No

5. Will you be selling a software product using the data?
☐ Yes
☒ No

6. Will you be reselling the data?
☐ Yes
☒ No

If yes, in what format will you be reselling the data (e.g., as a standalone product, incorporated with a software product, with a subscription, etc.)?

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7. If you have answered "yes" to questions 3, 4 or 5, please describe the types of products, services or studies.

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XII.   USE OF AGENTS AND/OR CONTRACTORS

<u>Third-Party Vendors</u>. Provide the following information for all agents and contractors who will work with the CHIA Data.

Company Name:	
Contact Person:	
Title:	
Address:	
Telephone Number:	
E-mail Address:	
Organization Website:	

8. Will the agent/contractor have access to the data at a location other than your location, your off-site server and/or your database?

☐   Yes
☐   No

If yes, please provide information about the agent/contractor's data management practices, policies and procedures in your Data Management Plan.

9. Describe the tasks and products assigned to this agent or contractor for this project.

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10. Describe the qualifications of this agent or contractor to perform such tasks or deliver such products.

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11. Describe your oversight and monitoring of the activity and actions of this agent or subcontractor.
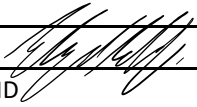

XIII.   ASSURANCES

Applicants requesting and receiving data from CHIA pursuant to 957 CMR 5.00 ("Data Recipients") will be provided with data following the execution of a data use agreement that requires the Data Recipient to adhere to processes and procedures aimed at preventing unauthorized access, disclosure or use of data, as detailed in the DUA and the applicant's CHIA-approved Data Management Plan.

Data Recipients are further subject to the requirements and restrictions contained in applicable state and federal laws protecting privacy and data security, and will be required to adopt and implement policies and procedures designed to protect CHIA data in a manner consistent with the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

By my signature below, I attest to: (1) the accuracy of the information provided herein; (2) my organization's ability to meet CHIA's minimum data security requirements; and (3) my authority to bind the organization seeking CHIA data for the purposes described herein.

Signature:	
Printed Name:	Elizabeth Schoenfeld, MD
Title	Assistant Professor, Emergency Medicine
Original Data Request Submission Date:	June 2016
Dates Data Request Revised:	