

Non-Government Application for Re-Use of Massachusetts All-Payer Claims Data Extract [Exhibit A: Data Application]

I. INSTRUCTIONS

This form is required for all Applicants, except Government Agencies as defined in [957 CMR 5.02](#), who wish to re-use Data received pursuant to a previously approved Data Application (“Extract”). **If the applicant requires data not presently held by its Organization the applicant should not use this form.** Re-use of All-Payer Claims Database data is limited to data released in Limited Data Set format (i.e., Release Versions 4.0 and later).

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. A copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet.

II. ALL-PAYER CLAIMS DATABASE EXTRACT TO BE RE-USED

Project Title:	Integrating Behavioral Health Into the Pediatric Medical Home for Low-Income Children
Extract Number:	313_BU_Cole
IRBNet Number:	1327778-1
Date of Data Use Agreement	August 1, 2018

III. ORGANIZATION AND INVESTIGATOR INFORMATION

Project Title:	Implications of the US 340B Drug Pricing Program for the Availability, Quality of Care, and Equitability of Syndemic (HIV/SUD/MH) health Services (340B AQCESS)
IRBNet Number:	1951814
Organization Name:	Trustees of Boston University
Organization Website:	http://www.bumc.bu.edu/
Authorized Signatory for Organization	William P. Segarra, JD, MPH
Title:	Director, Industry Contracts & Agreements
E-mail Address:	industry@bu.edu
Address, City/Town, State, Zip Code	25 Buick Street, Suite #200, Boston, MA 02215
Primary Investigator:	Megan Cole, PhD
Title:	Assistant Professor
E-mail Address:	mbcole@bu.edu
Telephone Number:	617-358-1901
Names of Co-Investigators:	Timothy Levengood
E-mail Address of Co-Investigators:	tleven@bu.edu

IV. FEE INFORMATION

1. Consult the [Fee Schedule](#) for All-Payer Claims Database data and select from the following options:

- Researcher
 Other
 Reseller

2. Are you requesting a fee waiver?

- Yes
 No

3. Complete and submit the [Fee Remittance Form](#). If requesting a fee waiver, submit a letter stating the basis for your request (if required). Please refer to the [Fee Schedule](#) (effective Feb 1, 2017) for fee waiver criteria. (Please note that fee must be paid in order to re-use the Data, even if no new extract of data is required upon application approval.)

V. PROJECT INFORMATION

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

- | | | |
|---|--|--|
| <input type="checkbox"/> Epidemiological | <input type="checkbox"/> Health planning/resource allocation | <input type="checkbox"/> Cost trends |
| <input checked="" type="checkbox"/> Longitudinal Research | <input checked="" type="checkbox"/> Quality of care assessment | <input type="checkbox"/> Rate setting |
| <input type="checkbox"/> Reference tool | <input checked="" type="checkbox"/> Research studies | <input type="checkbox"/> Severity index tool |
| <input type="checkbox"/> Surveillance | <input checked="" type="checkbox"/> Student research | <input type="checkbox"/> Utilization review of resources |
| <input type="checkbox"/> Inclusion in a product | <input type="checkbox"/> Other (describe in box below) | |

The work to be conducted will be an academic research study, which will assess longitudinal changes in quality of care and health care utilization for beneficiaries at hospitals that enroll in 340B following Medicaid expansion in 2014 (2013 vs. 2017) compared to changes at hospitals that did not change enrollment status over the same period (2013 vs 2017).

2. Provide a summary of the specific purpose and objectives of your Project. This may include research questions and/or business use Projects.

The objective of the overall project is to assess the role of the 340B Drug Pricing Program in the provision of low profit, HIV and behavioral health care services in safety-net care providers.

The specific aim for the study using APCD data is to assess the utilization and quality syndemic HIV and mental health care following 340B enrollment for DSH hospitals in Massachusetts.

Although not part of this APCD application, other analyses in the broader project using Medicare Cost Reports, IRS form 990, American Hospital Association Annual Survey, American Community Survey (ACS) and a qualitative survey of LGBTQ-focused federally-qualified health centers will help to contextualize results, particularly with how revenue from participation in the 340B program is used by safety-net care providers.

- To clarify, we will not link individual-level data between these sources. Medicare cost reports, AHA survey, and IRS form 990 data will be linked at the facility level to understand the connection between aggregate averages in spending and provision of care and average utilization and quality of care. ACS will be linked at 5 digit ZIP level to better characterize aggregate community characteristics.
- Please see Section X for more details of these proposed linkages.

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.

VI. PUBLIC INTEREST

1. Briefly explain why completing your Project is in the public interest. *Uses that serve the public interest under CHIA regulation 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 340B Drug Pricing Program is described by safety-net providers as a critical source of funding. Safety-net care providers serve a disproportionate share of Medicaid-insured, low-income and marginalized populations that face disparities in HIV and behavioral health conditions. However, how the 340B program works in practice is not well understood.

Therefore, the findings of this study would have implications for the formulation of public policy or policy implementation, and would test one policy lever that may promote improvement in population health, health care quality or access.

VII. DATASETS REQUESTED

The Recipient will use Data included in the Extract referenced above for use in this Project; no new Data will be released under this Application.

1. Specify below the dataset(s) and year(s) of data requested for this Project, and provide your justification for requesting each dataset.

Medical Claims

2011 2012 2013 2014 2015

Describe how your research objectives require Medical Claims data:

Medical claims will be used to capture utilization measures (e.g. number of visits with HIV or mental health principal diagnosis code, hospitalizations), quality of care measures (e.g. National Quality Forum-identified measures for HIV and mental health service quality), and patient diagnoses. Medical claims will also be used in conjunction with the member eligibility files and

<p>provider files to attribute members to a primary care site, based on where the patient receives the majority of their primary care and other hospital health services. Years: 2013 and 2017.</p>
<p><input checked="" type="checkbox"/> Pharmacy Claims <input type="checkbox"/> 2011 <input type="checkbox"/> 2012 <input checked="" type="checkbox"/> 2013 <input type="checkbox"/> 2014 <input type="checkbox"/> 2015</p>
<p>Describer how your research objectives require Pharmacy Claims data: The 340B Drug Pricing Program operates through acquisition and sale of discounted drugs. 340B-covered hospital entities are entitled to purchase deeply discounted drugs from manufacturers, but how they then sell these drugs to patients is not well understood. Hospitals may pass along discounts to patients to help with affordability of medications, but they are not required to. They may also sell these drugs at regular price to any patient (e.g. privately insured patients) to generate revenue off of the markup. Pharmacy claims will enable us to see what insurers are paying and patients are cost-sharing on average at treatment (340B) and control hospitals, and give a sense as to how the quintessential mechanism of this policy (i.e. the drug discounts) is functioning in practice.</p>
<p><input type="checkbox"/> Dental Claims <input type="checkbox"/> 2011 <input type="checkbox"/> 2012 <input type="checkbox"/> 2013 <input type="checkbox"/> 2014 <input type="checkbox"/> 2015</p>
<p>Describer how your research objectives require Dental Claims data: N/A</p>
<p><input checked="" type="checkbox"/> Member Eligibility <input type="checkbox"/> 2011 <input type="checkbox"/> 2012 <input checked="" type="checkbox"/> 2013 <input type="checkbox"/> 2014 <input type="checkbox"/> 2015</p>
<p>Describer how your research objectives require Member Eligibility data: Member eligibility files will be used to capture key patient demographics as well as important inclusion and exclusion criteria. This includes member age, gender, zip code, attributed PCP, the Physician Group of the Member's PCP (eg MassHealth ACO), and dates of enrollment. Years: 2013 and 2017.</p>
<p><input checked="" type="checkbox"/> Provider <input type="checkbox"/> 2011 <input type="checkbox"/> 2012 <input type="checkbox"/> 2013 <input type="checkbox"/> 2014 <input type="checkbox"/> 2015</p>
<p>Describer how your research objectives require Provider data: The provide file will be used to assess the location and thus the practice of the provider. This will help us to identify intervention hospital systems/ practices versus non-intervention hospital systems / practices when creating our intervention and control groups. This will be used in conjunction with the MA RPOs. Years: 2013 and 2017.</p>
<p><input type="checkbox"/> Product <input type="checkbox"/> 2011 <input type="checkbox"/> 2012 <input type="checkbox"/> 2013 <input type="checkbox"/> 2014 <input type="checkbox"/> 2015</p>
<p>Describer how your research objectives require Product data: N/A</p>

2. If there are datasets that are included in the Extract that **are not** required for this Project indicate below.

- Medical Claims
 Pharmacy Claims
 Dental Claims
 Member Eligibility
 Provider
 Product

3. If there are datasets included in the Extract that are not required for this Project, describe below how those datasets will be segregated and protected from use in this Project.

The data sets approved for this project will be stored in a separate, secure folder that meets all requirements of the data management plan. Mr. Levengood will not have user access to the folder containing the original data.

VIII. DATA ELEMENTS 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). Applicants receive the “Core” LDS, but may also request additional elements listed below for inclusion in their analyses. Requests for additional elements will be reviewed by CHIA to determine whether each represents the minimum data necessary to complete the specific Project objective.

1. Specify below which elements you are requesting in addition to the “Core” LDS and provide your justification for requesting each element.

Geographic Data

The geographic sub-divisions listed below are available for Massachusetts residents and providers only. Choose one of the following geographic options. *[Extracts with 5 digit zip code, have been filter to remove all claims that include a substance abuse diagnosis or treatment.]*

<input type="checkbox"/> 3-Digit Zip Code (standard)	<input checked="" type="checkbox"/> 5-Digit Zip Code***
<p>***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology:</p> <p>Our study will require 5 digit ZIP codes. It will enable us to compare baseline community demographic characteristics between treatment and control groups, which will give a sense of the equity implications of the 340B policy we are studying. It is important that the zip codes are as precise as possible given the sheer number of hospitals in Massachusetts.</p> <p>We also require zip codes for providers, as this will allow us to validate practice designations.</p>	

Dates

Choose one option from the following options for dates:

<input type="checkbox"/> Year (YYYY) (Standard)	<input type="checkbox"/> Month (YYYYMM) ***	<input checked="" type="checkbox"/> Day (YYYYMMDD) *** [for selected data elements only]
<p>*** If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology:</p> <p>Knowing specific dates is necessary for capturing several outcomes. For example, all claim dates, inclusive of day, are needed to identify number of days from hospital discharge to follow-up visit; to identify the length of stay for hospital visit; to identify whether or not a readmission occurred within 30 days; and to ensure the sequence of claims is understood for claims occurring in the same month. When collapsing claim lines down to the visit-level, it's also critical to know if different claims occurred on the same day; in many instances, they are part of the same visit, but this may be unknown without an indicator of DD.</p> <p>Product start and end dates are also necessary to determine specific number of eligible days in a given time period (month, quarter).</p>		

National Provider Identifier (NPI)

Choose one of the following options for National Provider Identifier(s):

<input type="checkbox"/> Encrypted National Provider Identifier(s) (standard)	<input checked="" type="checkbox"/> Decrypted National Provider Identifier(s)***
<p>*** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your methodology:</p> <p>In order to attribute enrollees to hospital system place of service , and thus to the intervention vs control group, we will need NPIs. NPIs will be linked to the Massachusetts Registration of Provider Organizations (MA-RPO) data files in order to assign each patient to a practice.</p>	

2. If there are data elements that are included in the Extract that **are not** required for this Project indicate below.

5-Digit Zip Code Month (YYYYMM) Day (YYYYMMDD) Decrypted National Provider Identifier(s)

3. If there are data elements included in the Extract that are not required for this Project, describe below how the data elements will be segregated and protected from use in this Project.

N/A

IX. MEDICAID DATA

1. Is Medicaid Data included in the Extract?

Yes
 No

2. Indicate whether you are seeking to use Medicaid Data for this Project:

Yes
 No

3. 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 Medicaid Data, please describe, in the space below, why your use of the data meets this requirement. Requests for 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. This may introduce significant delays in the receipt of Medicaid Data.

Recipient may not use the Medicaid data for the new Project until Recipient is notified of MassHealth approval.

Studying the association between 340B enrollment and the provision, utilization, and quality of syndemic care services is directly connected to the administration of the Medicaid program for several reasons:

1. 340B hospital eligibility is determined in part by Medicaid patient volume, explicitly since 340B and Medicaid share an overlapping focus on the health care access of low income and marginalized populations.
2. Because of the Medicaid-based 340B enrollment criteria, much of the care Medicaid patients receive is, by definition, from 340B hospitals or affiliated clinics. The availability and quality of HIV and mental health care at 340B hospitals is therefore highly relevant to Medicaid patient populations and the administration of the Medicaid program

3. Medicaid is one of the largest payers for syndemic HIV and behavioral health care. Therefore, Medicaid patients are a key patient demographic for assessing hospitals' provision and quality of syndemic care.
4. Part of the justification for 340B program participation includes hospitals reporting their community benefit activities. The community benefit programming undertaken by these not-for-profit, disproportionately Medicaid serving hospitals could be considered an investment in Medicaid patient communities and a way of addressing social determinants of health.

4. If the Extract contains Medicaid Data and you are not seeking to use Medicaid Data for this Project, or this Application is not approved by MassHealth, describe below how Medicaid Data will be segregated and protected from use in this Project.

N/A

X. DATA LINKAGE AND FURTHER DATA ABSTRACTION

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.

MA-RPO will be linked via decrypted NPI
 Facility will be linked to Medicare Cost Reports, IRS Form 990, and AHA survey datasets
 Patient and facility ZIPcodes will be linked to ACS data

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.

When linking the APCD to the MA-RPO, we will use a m:1 merge using NPI as the unique identifier.

We will link the derived facility variable from the NPI-RPO to Medicare Cost Reports, IRS Form 990 Schedule H, and AHA survey using a crosswalk file that links facility name to Medicare Provider number, and link to Medicare Cost Reports and the other datasets via an m:1 merge using Medicare Provider Number.

When linking the APCD to the ACS, we will use a m:1 merge using 5 digit zip code as the unique identifier.

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

Our linked datasets do not include any individual patients, as they are provider-level and census-level data. Patients will not be identifiable.

XI. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from CHIA Data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting. 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 will result in the display of a cell less than 11.

Results from this project will be publicly disseminated through manuscripts, conference presentations, and seminar presentations. Results will be reported in aggregate, where we will compare outcomes for all patients in the intervention group versus the control group. Tens of thousands patients will comprise these respective groups.

We do not anticipate small cell sizes for any outcomes or subanalyses. However, we will ensure that no reported results will have a cell size less than 11. We will ensure this by reporting all sample sizes by cell. If any analyses were to result in a cell size <11, then we would not report that finding. Instead, we would include a note indicating that the cell size was insufficient for reporting.

2. Do you anticipate that the results of your analysis will be published and/or made publically available? If yes, describe how an interested party will obtain your analysis and, if applicable, the amount of the fee, that the third party must pay.

We would be happy to share statistical code and aggregate results from our analyses (no fee) if this is helpful to other researchers or stakeholders, but we will not provide third parties with data or any other product.

3. Will you use CHIA Data for consulting purposes?

- Yes
 No

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

- Yes
 No

5. Will you be selling a software product using CHIA Data?

- Yes
 No

6. Will you be reselling CHIA Data in any format?

- Yes
 No

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

N/A

7. If you have answered “yes” to questions 4, 5 or 6, please describe the types of products, services or studies.

N/A

8. If you have answered “yes” to questions 4, 5, or 6, what is the fee you will charge for such products, services or studies?

N/A

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.

Megan B. Cole, PhD, MPH: Dr. Cole is an Assistant Professor in the Dept. of Health Law, Policy, and Management at Boston University School of Public Health. For over a decade, she has worked extensively with claims data in conducting research and analyses. This includes the MA APCD. Examples of recent claims experiences include:

- Since 2017, Dr. Cole has led the economic impact evaluation of the TEAM UP intervention. This evaluation uses BMCHealth Net claims data to assess ED visits and inpatient admissions for children receiving care at a TEAM UP intervention site. These claims data are submitted to our study team in APCD format.
- Since 2018, Dr. Cole has used the MA APCD to evaluate how pediatric behavioral health integration into primary care has affected cost of care and utilization of care for low-income children. She serves as the PI of these analyses.
- Since 2020, Dr. Cole has used the MA APCD to evaluate how Medicaid ACOs affects quality of and access to care. She is the PI.

Timothy W. Levensgood, MPH: Mr. Levensgood is a 5th year PhD Candidate at Boston University School of Public Health. For the past four years of his program, he has been trained on quantitative analysis and data management methods using large health care data sets. Specific claims experiences:

- Tim is currently engaged in a project using Truven / IBM MarketScan data which is one of the longest-running and largest collections of proprietary de-identified claims data for privately and publicly insured people in the US. He is using this data to estimate average cost and cost sharing for Pre-Exposure Prophylaxis (PrEP) drugs to prevent HIV in the US.

Other large data set experiences:

- Youth Risk Behavioral Survey
- IQVIA Drug Dispensing data
- CDC Wonder
- Automation of Reports and Consolidated Orders System (ARCOS)
- Medicare Cost Reports
- IRS Form 990
- AHA Annual Survey

2. **Resumes/CVs:** If not submitted with a prior approved Application, 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

Please note: 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.

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:	None
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 and a Data Management Plan for this agent or contractor is not part of the Data Use Agreement, 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 Applicant's location, off-site server and/or database?

Yes

No

4. If yes and a Data Management Plan for this agent or contractor is not part of the Data Use Agreement, a separate Data Management Plan **must** be completed by the agent or contractor.

XIV. 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 its agents.

The Organization’s use of the Data for this Project will be governed by the executed Data Management Plan(s), Data Use Agreement, and any Amendment thereto.

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)	<i>William P. Segarra, MA, JD, MPH</i>
Printed Name :	William P. Segarra, JD, MPH

Attachments

A completed Application must have the following documents attached to the Application:

- 1. IRB approval letter and protocol (if applicable)
- 2. Research Methodology (if protocol is not attached)
- 3. CVs of Investigators (if not submitted previously)
- 5. Data Use Agreement

Applications will not be reviewed until they are complete, including all attachments. Applicant may not use the Extract for this Project until CHIA approval and the execution of an amendment to the Recipient’s Data Use Agreement.

TRACKING TABLE (to be completed by CHIA staff only)	
Complete Application Received	
Application Fee Received	
Data Privacy Committee Review	
Data Release Committee Review	
Linkages Approved (as described)	
Executive Director Approval	
Data Fee Received	
Data of First Audit	
IT Extract #	

Attachment #1 – IRB Approval Letter & Protocol or Research Methodology

Attachment #2 – Data Management Plan(s)