CHIA.

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

I.   INSTRUCTIONS

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

Before completing this Application, please review the data request information on CHIA's website:
- Data Availability
- Fee Schedule
- Data Request Process

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

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

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

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

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

II.   FEE INFORMATION

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

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

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

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

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

III.   ORGANIZATION & INVESTIGATOR INFORMATION

Project Title:	Price regulation in the prescription drug market
IRBNet Number:	2044038-1
Organization Requesting Data (Recipient):	The Regents of the University of California- Berkeley
Organization Website:	https://www.berkeley.edu/
Authorized Signatory for Organization:	Nicole Hensley
Title:	Industry Liaison and Contracts Manager
E-Mail Address:	nhensley@berkeley.edu
Telephone Number:	(510) 642-5766
Address, City/Town, State, Zip Code:	2150 Shattuck Ave., Suite 408, Berkeley, CA 94704
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	Jason C. Christopher
Title:	Service Lead and Information Security Officer, Research IT
E-Mail Address:	jchristo@berkeley.edu
Telephone Number:	(510) 643-9633
Address, City/Town, State, Zip Code:	2195 Hearst Avenue, Berkeley, CA 94720
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	Benjamin Handel
Title:	Associate Professor of Economics
E-Mail Address:	handel@berkeley.edu
Telephone Number:	(510) 643-0708
Address, City/Town, State, Zip Code:	530 Evans Hall #3880, Berkeley, CA 94720
Names of Co-Investigators:	Catherine Che
E-Mail Addresses of Co-Investigators:	cjche@berkeley.edu

IV.   PROJECT INFORMATION

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

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

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

Click here to enter text.

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

The US prescription drug market has been a topic of policy concern for some time. It is well known that Medicaid pays some of the lowest prescription drug prices within the US, perhaps due to the "best price" clause first introduced in 1990 by the federal government. This provision compels a given drug manufacturer to provide the lowest (or best) price to Medicaid, where lowest price is defined as the higher of a flat rebate rate or the highest rebate enjoyed by a private sector insurance plan. Economic intuition suggests that such a linkage between government and private sector prices would have distortionary effects; indeed, researchers have studied and found such distortions, which tend to push up private sector prices (e.g. Scott Morton 1997, Duggan and Scott Morton 2006, Feng et al. 2021).

Our study aims to understand how distortions introduced by upstream pricing regulations like the "best price" clause in Medicaid impact the various market participants in the overall prescription drug market.

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

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

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

V.   PUBLIC INTEREST

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

How to best regulate prescription drug prices is a topic of great policy implication. When a market has a complicated structure, it is important to account for strategic, inter-player interactions when designing regulation. Otherwise, a policy that is ostensibly aimed to achieve one goal may lead to inadvertent (and often undesirable) outcomes. Moreover, MA, like any US state, may have an interest in this research because of its provision of Medicaid, which is subject to the pricing regulation studied in this research.

VI.   DATASETS REQUESTED

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

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

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

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

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

ANNUAL RELEASE 2020	**ANNUAL RELEASE 2021**
☒ 2016	☒ 2017
☐ 2017	☒ 2018
☐ 2018	☒ 2019
☐ 2019	☒ 2020
☐ 2020	☒ 2021

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 need medical claims to estimate costs associated with non-drug health care consumption, which will enter the insurer's cost function.

☒ **Pharmacy Claims**
Describe how your research objectives require Pharmacy Claims data:
Pharmacy claims data is needed to estimate drug demand, which is a part of the consumer demand for insurance product.

☐ **Dental Claims**
Describe how your research objectives require Dental Claims data:
Click here to enter text.

☒ **Member Eligibility**
Describe how your research objectives require Member Eligibility data:
Since the population of enrolled people (not just those who incurred a claim) are the consumers of a given insurance product, we need eligibility data and price (premiums paid) to estimate insurance plan demand.

☐ **Provider**

Describe how your research objectives require Provider data:
Click here to enter text.

☒ **Product**
Describe how your research objectives require Product data:
This data is needed to ensure we are correctly modeling consumers' choice set among insurance plans. Our estimation approach will likely rely on using individuals covered by the merged market or health exchange, and so we need the product file to isolate the individuals.

VII. DATA ENHANCEMENTS REQUESTED

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

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

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

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

a. Geographic Subdivisions

ZIP code and state geographic subdivisions are available for Massachusetts residents and providers only. Small population ZIP codes are combined with larger population ZIP codes. One ZIP Code per person (MEID) per year has been assigned based on the ZIP code/state reported in the member eligibility record's earliest submission year month. If the record does not have an MEID, assignment is based on distinct OrgID/Carrier Specific Unique Member ID.

Non-Massachusetts ZIP codes and sate codes except for CT, MA, ME, NH, NY, RI, and VT are suppressed.

Select *one* of the following options.

☐ 3-Digit Zip Codes (standard)	☒ 5-Digit Zip Codes***
***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology:	
We would like to merge in demographics data from the Census. Since Census data is available at the Census tract level, which is a finer unit than county, we would like to have the 5-digit zip code. Demographics data would be part of the covariates in the demand estimation, which is useful for a more precise estimate of preferences.	

b. Date Resolution

Select *one* option from the following options.

☐ Year (YYYY) (Standard)	☐ Month (YYYYMM) ***	☒ Day (YYYYMMDD) *** [for selected data elements only]
*** If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology:	

1. Drug rebates are allowed to change on a quarterly basis, and so we want to be able to estimate our model conditional on quarter of year.
2. We anticipate needing to aggregate prescription fills to a "standardized" quantity, which may involve adding up fills within a week or a shorter time frame than a month.

c. National Provider Identifier (NPI)

Select *one* of the following options.

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

VIII. MEDICAID (MASSHEALTH) DATA

1. Please indicate whether you are seeking Medicaid Data:

☒ Yes
☐ No

2. Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are ***directly connected to the administration of the Medicaid program***. If you are requesting MassHealth Data, please describe, in the space below, why your use of the Data meets this requirement. *Your description should focus on how the results of your project could be used by the Executive Office of Health and Human Services in connection with the administering the MassHealth program*. Requests for MassHealth Data will be forwarded to MassHealth for a determination as to whether the proposed use of the Data is directly connected to the administration of the MassHealth program. CHIA cannot release MassHealth Data without approval from MassHealth. This may introduce significant delays in the receipt of MassHealth Data.

We need Medicaid data to understand how the "best price" Medicaid pricing clause has impacted cost and benefit in the state of MA. With Medicaid data, we can capture drug consumption choices of Medicaid recipients and bring that dimension of behavior into the model, and answer questions such as how much would MA have spent on Medicaid drug consumption in the absence of the "best price" clause.

The project directly relates to the administration of Medicaid because it is expected to be informative about the types of polices that a policy maker can pursue to reduce cost. Currently, each state and the federal government split a rebate from the drug manufacturer for each prescription dispensed to Medicaid recipients. The details of the rebate are specified by the Medicaid Drug Rebate Program (https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html). While this program is implemented at the federal level, states can and have been known to negotiate supplemental rebates

on top of the standard Medicaid rebates. The project investigates how the MDRP, which links Medicaid drug prices to private sector drug prices, may (adversely) impact private sector insurance plans. Under the assumption that the relevant MA policy makers care about all residents of MA (and not just Medicaid recipients), we think our work can inform what additional policies MA can take to constrain costs without unduly impacting the private sector.

One deliverable we plan to make available to any MA policy maker is an estimate of how the MDRP has impacted expenditure under MA Medicaid and what the cost of this policy has been in terms of potential price or quantity distortions in the MA private insurance sector.

We are also very open to working together with the relevant state authorities to study policy relevant questions with regard to drug pricing.

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

IX.   DATA LINKAGE

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

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

☒ Yes

☐ No linkage or merger with any other data will occur

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

☐ Individual Patient Level Data (e.g. disease registries, death data)

☐ Individual Provider Level Data (e.g., American Medical Association Physician Masterfile)

☐ Individual Facility Level Data (e.g., American Hospital Association data)

☒ Aggregate Data (e.g., Census data)

☒ Other (please describe): drug-level information (linked using the drug code, or NDC)

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.

1.   We plan to link CHIA data to Census data in order to build a richer demand model that accounts for demographics.
2.   We hope to be able to bring in information at the drug level (as defined by the national drug code, or NDC) to estimate our structural model.

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.

1. We will link CHIA data, at the 5-digit zip code level, to US Census data on demographics such as average home price. We will create a matching from 5-digit zip code to the suitable Census unit, likely a Census county or tract.
2. We will linke CHIA drug claims data, using the NDC, to 3rd party information on drug rebates (e.g. from SSR) and information on drug prices (e.g. First Databank).

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.

1. Census data: age, sex, race, over 65, income, household size
2. SSR: drug rebate; First Databank: list prices

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

The Census dataset is no more granular than CHIA data and has only aggregate information. Hence, there is no added risk from this linkage in terms of putting protected information at risk. The other datasets we are interested in linking to CHIA data are at the drug level and so also don't pose any added risk of individual identification.

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 the research project to lead to a publication in a peer-reviewed journal. Any publication will include only descriptive statistics (to help the audience understand the setting), estimation results, and counterfactuals. The most disaggregated level at which we will display summary statistics is at the county level, and we will exclude any county with less than 11 observations.

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.

In addition to the publication, we expect to give seminar presentations, where the content will also be restricted to summary statistics, estimation results, and counterfactuals. We will remove any county with less than 11 observations whenever we show descriptive statistics at the county level.

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

The lowest level of data analysis for presentation will be at the county level. We will not be presenting maps.

4. Will you be using CHIA Data for consulting purposes?
   ☐ Yes
   ☒ No

5. Will you be selling standard report products using CHIA Data?
   ☐ Yes
   ☒ No

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

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

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

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

Click here to enter text.

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

Click here to enter text.

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

Click here to enter text.

XI.   APPLICANT QUALIFICATIONS

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

Benjamin Handel is an associate professor of economics at the University of California, Berkeley, where he has taught since 2010. He received his A.B. from Princeton and his Ph.D. from Northwestern. Handel's work is primarily concerned with the economic analysis of health insurance markets. He has studied the role of adverse selection, the nature of competition between insurance providers, and the role of behavioral economics in explaining insurance plan choice. In addition to his work in health insurance markets, he has researched incentive design and adoption of information technology by health care providers, as well as behavioral interventions to improve consumer health care behaviors. Handel has worked with a variety of health care claims data, starting with the data used in his job market while he was a graduate student at Northwestern. Presently, Handel is working with Medicare claims data on a project that seems to understand the role of Pharmacy Benefit Managers in the prescription drug market.

Catherine Che is an economics PhD student at UC Berkeley. Che works with Handel on the PBM project, which uses Medicare claims data. Che also has experience using sensitive individual level information from outside the health care sector. In her undergraduate thesis, she worked with a New Jersey school district superintendent on investigating the causes of college attainment.

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

XII.   USE OF AGENTS AND/OR CONTRACTORS

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

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

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

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

Click here to enter text.

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

Click here to enter text.

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

    ☐ Yes
    ☐ No

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

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

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

Click here to enter text.

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

Click here to enter text.

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

☐ Yes
☐ No

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

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

XIII. ATTESTATION

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

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

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

Signature: (Authorized Signatory for Organization)	The Regents of the University of California- Berkeley *Nicole Hensley*
Printed Name:	**Nicole Hensley**
Title:	Industry Liaison and Contracts Manager
Date:	4/27/2023

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.