IV.2, V, VI, VII, VIII and IX (all of these require project-specific answers) and edit XI (applicant qualifications).



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. Organizations 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 <u>apcd.data@chiamass.gov</u> if you have additional questions about how to complete this form.

The Application and all attachments must be uploaded to IRBNet. All Application documents can be found on the <u>CHIA</u> 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 <u>Fee Remittance Form</u> 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@chiamass.gov.
- 3. If you believe that you qualify for a fee waiver, complete and submit the <u>Fee Remittance Form</u> and attach it and all required supporting documentation with your application. Refer to the <u>Fee Schedule</u> (effective Feb 1, 2017) for fee waiver criteria.
- 4. Applications will not be reviewed until the application fee is received.

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

ORGANIZATION & INVESTIGATOR INFORMATION III.

Project Title:	Impact of a novel Medicaid value-based payment model
i roject rine.	on contraceptive access in primary care
IRBNet Number:	2182663-1
Organization Requesting Data (Recipient):	Harvard Pilgrim Health Care Institute
Organization Website:	https://www.populationmedicine.org
Authorized Signatory for Organization:	Sheila Fireman
Title:	VP Administration and Finance, Havard Pilgrim Health Care Institute
E-Mail Address:	Sheila Fireman@hphci.harvard.edu
Telephone Number:	617-867-4981
Address, City/Town, State, Zip Code:	401 Park Drive, Suite 401 East
-	Boston, MA 02215
Data Custodian:	Ed Rosen
(individual responsible for organizing, storing, and archiving	
Data)	
Title:	Lead Analyst, Research Support Data Center, Harvard Pilgrim Health Care Institute
E-Mail Address:	Edward_Rosen@hphci.harvard.edu
Telephone Number:	617-867-4263
Address, City/Town, State, Zip Code:	401 Park Drive, Suite 401 East Boston, MA 02215
Primary Investigator (Applicant):	Laura Garabedian, PhD, MPH
(individual responsible for the research team using the Data)	
Title:	Assistant Professor, Harvard Pilgrim Health Care Institute
E-Mail Address:	Laura_Garabedian@hphci.harvard.edu
Telephone Number:	617-867-4921
Address, City/Town, State, Zip Code:	401 Park Drive, Suite 401 E, Boston, MA 02215
Names of Co-Investigators:	Lydia Pace, Nancy Keating, Eleanor Schwarz, Fang Zhang
E-Mail Addresses of Co-Investigators:	lpace@bwh.harvard.edu, keating@hcp.med.harvard.edu, eleanor.schwarz@ucsf.edu, fang_zhang@hphci.harvard.edu

PROJECT INFORMATION

ırch e and zation ganization, or written rized use is

protocol or project plan, or other accurate and represent the total under an approved application and for <u>no</u> other purposes. Use request to CHIA, with approval a material violation of your Org	zation represents that the statements mader documents submitted to CHIA in supportuse of the CHIA Data requested. Any an may ONLY be used for the express purport CHIA Data for other purposes require being subject to CHIA's regulatory restrictions's Data Use Agreement with Cartesian and the contraction of the contrac	ort of the Data Application are completed all CHIA Data released to the Organizoses identified in this section by the Organizoses a separate Data Application to CHIA crictions and approval process. Unauthor CHIA.
1. What will be the use of the C	HIA Data requested? [Check all that application of the content of	oly]
☐ Epidemiological	☐ Health planning/resource allocation	□Cost trends
		Pa

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· ·	•	☐ Rate setting ☐ Severity index tool (or other derived input)
		☐ Utilization review of resources
☐ Inclusion in a product	☐ Other (describe in box below)	

This research study will be conducted by an academic study team at the Harvard Pilgrim Health Care Institute (HPHCI), which is a Harvard Medical School appointing department and is also part of Point32Health. The Institute is a limited liability corporation of Harvard Pilgrim Health Care and operates independently of the health plan (i.e., data shared with the Institute will not be shared with Point32Health).

For the project, we will use longitudinal data to describe the impact of the MassHealth 1115 waiver program on long-acting reversible contraceptive (LARC) provision through its value-based primary care payments and care delivery.

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.

Policy strategies to facilitate access to high-quality contraceptive care have never been more important in the United States. Long-acting reversible contraceptive methods (LARC, consisting of intrauterine devices and implants) are the most effective reversible contraceptive methods;¹ they are also highly acceptable to users and safe in most chronic conditions. LARC availability is considered an essential component of high-quality contraceptive care.² Despite rising demand for LARC, and even though many patients would prefer to receive their contraceptive care from their primary care clinician,³ provision of LARC services in primary care settings remains rare due to a host of implementation barriers.⁴⁻⁹ Although some state-level initiatives have tried to incentivize LARC provision in outpatient practices,^{10,11} there is growing recognition that policies and practices that focus narrowly on increasing LARC uptake, particularly among low-income communities, can be coercive, breed mistrust, exacerbate reproductive health inequities, and lead to lower rates of contraceptive persistence.¹²⁻¹⁴ To be effective, initiatives to promote LARC provision in primary care must overcome primary care-specific implementation barriers while prioritizing equitable, comprehensive, patient-centered contraceptive care. There is a critical need for research to identify policy approaches that can accomplish this.

The proposed research project will examine the impact of the new MassHealth 1115 waiver program that strives to incentivize LARC access through value-based primary care payments and care delivery. In 2018, MassHealth implemented a value-based contracting framework with practices participating in the MassHealth accountable care organization (ACO), enrolling about 900,000 individuals out of the approximately 1.75 million individuals insured by MassHealth. Organizations with ACO contracts share risks and are rewarded based on quality. However, the primary care practices and clinicians within MassHealth's ACOs have been paid by the ACOs on a fee-for-service basis, limiting the ACOs' impact in transforming primary care delivery. Starting on July 1, 2023, MassHealth implemented a new primary care sub-capitation program under a 1115 Waiver. In this sub-capitation initiative, all primary care practices that are part of MassHealth ACOs receive prospective monthly capitated payments for their ACO enrollees to cover the costs of all primary care for these enrollees. The amount paid to practices per member depends on a practice's "tier," which is determined by which pre-specified high-value services the practice offers, such as substance use treatment and after-hours care. To reach the highest tiers, practices must offer LARC services on-site. Organizations that care for MassHealth patients but do not have ACO contracts continue to be reimbursed using fee-for-service.

The MassHealth primary care sub-capitation initiative provides an invaluable opportunity to examine whether and how value-based contracting through tiered sub-capitation can impact contraceptive access, delivery and quality in primary care. Our team of experienced health services and policy researchers will leverage established collaborations with MassHealth policymakers and MassHealth ACO program leaders to optimize contextual relevance and the impact of our findings on policy and practice. Given the rapid expansion of value-based payment models nationally and the heightened

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recognition of the critical need for primary care practices to help individuals meet their reproductive goals, this is a timely issue with relevance to primary care policy throughout the United States. We will pursue the following Specific Aims:

Aim 1. Examine the impact of MassHealth's primary care sub-capitation and practice tiering on primary care LARC service provision through a difference-in-differences analysis comparing provision of LARC services at MassHealth ACO versus control primary care sites before and after the policy change.

Hypothesis 1: Sub-capitation will be associated with an increase in the proportion of MassHealth ACO primary care sites providing LARC services relative to control primary care sites.

Aim 2. Examine the impact of MassHealth's sub-capitation policy on monthly rates of provision of all contraceptive services among reproductive-age women attributed to MassHealth ACOs relative to patients attributed to control practices, overall, within primary care settings specifically, and by insurer type.

Hypothesis 2: Sub-capitation will be associated with an overall increase in contraceptive service provision, driven by an increase in primary care-provided LARC among both privately and publicly-insured individuals, with stable or decreased utilization of other contraceptive services.

3.	Has an	Institutional	Review	Board ((IRB)) reviewed	vour Pro	iect?
\sim .	IIWO WII	IIIDUITUIT	10011011	Doma		, 10,10,,00	,	,

- \boxtimes Yes [*If yes, a copy of the approval letter and protocol* <u>must</u> be included with the Application package on IRBNet.] \square No, this Project is not human subject research and does not require IRB review.
- 4. <u>Research Methodology</u>: Applications 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.

Rigorous evaluation of MassHealth's inclusion of LARC as a high-value service in their ACO contract will be critical to inform further rollout of the initiative and share lessons with other states. Several unique aspects of this policy change merit specific evaluation. MassHealth's approach to incentivizing LARC availability (including LARC provision and removals) could avoid some of the pitfalls of contraceptive policies in other states designed to incentivize LARC insertion, which can be coercive and undermine comprehensive patient-centered care. LARC availability at MassHealth ACO sites will also benefit non-MassHealth patients cared for at those sites (i.e., spillover benefits), broadening the impact of the policy. Further, ACO practices have flexibility in how to adopt LARC provision, which may allow tailored and innovative approaches to delivering this new service. However, whether tiered sub-capitation will provide practices with sufficient incentive to overcome training and logistical barriers to on-site LARC is not known. There is likely to be substantial variability in how and whether practices commit to provision of LARC services, which is critical to identify to understand the impact of the policy. Further, the sub-capitation program does not address other contraceptive services, which may or may not be adequately provided at participating primary care sites, so whether the tiered sub-capitation will facilitate comprehensive patient-centered contraceptive care beyond LARC is not known.

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. For more information about APCD Data, including available years of data and a full list of elements in the database please refer to 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. CHIA is currently supporting requests for claims data from 2016 to 2022. Requests made outside of these years may not be supported by CHIA and will be considered on a case-by-case basis. Please specify the years of data that are being requested: 2017-2024
- 3. Specify below the data files requested for this Project, and provide your justification for requesting *each* file.

⋈ Medical Claims

Describe how your research objectives require Medical Claims data:

We will use medical claims to measure: receipt, timing, and location (i.e., OB/Gyn or primary care) of contraceptive service; and patient attribution to primary care provider/practice.

☒ Pharmacy Claims

Describe how your research objectives require Pharmacy Claims data:

We will use pharmacy claims to measure: contraceptive characteristics and timing; prescribing provider ID.

☐ 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:

We will use member eligibility files, including MassHealth eligibility files, to measure: insurance type and enrollment/disenrollment dates (to identify MassHealth ACO enrollment and timing, and enrollment/timing of other types of insurance coverage); and patient characteristics (i.e., age, sex, zip code). We will use zip codes to link to the American Community Survey to obtain area-level measures (i.e., race/ethnicity, median household income).

⊠ Provider

Describe how your research objectives require Provider data:

. We will use provider data to identify provider type (i.e., Ob/Gyn or primary care) and link (using NPIs) to MA Health Quality Partners (MHQP) MA Provider Database (MPD). The Aim 1 analyses are at the practice level. The linkage to

the MPD will allow us to identify whether a practice is in a MassHealth ACO (i.e., our intervention group) and which providers are affiliated with each practice. The MHQP MPD will also help us determine other practice characteristics (i.e., academic/nonacademic, hospital/non-hospital affiliated), and measure practice group characteristics measurable in the data (i.e., size, patient population characteristics, insurance mix).

☒ Product

Describe how your research objectives require Product data:

We will use product files to help identify MassHealth ACOs, and define other coverage types (i.e., commercial) and characteristics.

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 <u>release layouts</u>, <u>data dictionaries</u> 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 <u>each</u> 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 state codes except for CT, MA, ME, NH, NY, RI, and VT are suppressed.

Select <u>one</u> of the following options.

☐ 3-Digit Zip Codes (standard)	☑ 5-Digit Zip Codes***
***If requested, provide justification for requesting 5-D	Pigit Zip Code. Refer to specifics in your methodology:
We will use 5-digit member zip codes to link to: (1) the U.S.	S. Census Bureau's American Community Survey to get data
on zip-code level race/ethnicity, income, and education level	el, and (2) the Rural Urban Commuting Area codes to get
data on rurality.	

b. Date Resolution

Select *one* option from the following options.

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☐ Year (YYYY) (Standard)	☐ Month (YYYYM	M) ***	☑ Day (YYYYMMDD) ***
			[for selected data elements only]
*** If requested, provide justification	for requesting Mon	th or Day. Refer to	specifics in your methodology:
We need data on day, month, and year	in order to measure: (1) the exact timing o	f receipt of contraceptives relative to
the MassHealth ACO subcapitation pay	ment reform and (2) t	to be able to measure	e: the proportion of days with
contraceptive coverage during the pre-	and post-intervention	periods and describe	e quarterly trends in the proportion of
individuals with contraceptive claims o	verall and by contrace	eptive type.	
c. National Provider Identifies Select <i>one</i> of the following options.	r (NPI)		
☐ Encrypted National Provider Identifie	ers (standard)	☑ Decrypted Nation	nal Provider Identifiers***
*** If requested, provide justification	for requesting decry	ypted National Pro	vider Identifier(s). Refer to
specifics in your methodology: We need decrypted NPIs in order to ide	ntify specialty types a	nd link providers to	practices, which we will identify
We need decrypted NPIs in order to identify specialty types and link providers to practices, which we will identify using the MHQP MPD. We will need to know exact practices to identify those which are enrolled in MassHealth			
ACOs.			
VIII. MEDICAID (MASSHEALTH)	DATA		
1. Please indicate whether you are seekin	g Medicaid Data:		
⊠ Yes			
□ No			
2. Federal law (42 USC 1396a(a)7) restri		•	
directly connected to the administration			
describe, in the space below, why your use of the Data meets this requirement. Your description should focus on how the			

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 identifiable MassHealth Data will be forwarded to MassHealth program. CHIA cannot release MassHealth Data without approval from MassHealth. This may introduce significant delays in the receipt of MassHealth Data.

Researchers must provide the following information for MassHealth to determire how the disclosure of indentifiable MassHeath claims data is directly related to the administration of the MassHealth program:

- How does the project relate directly to the administration of the Medicaid program?
- What specific Medicaid program, policy, rule or law will be affected or changed based on the outcome of this project?
- How will MassHealth's objectives be helped or impaired by approving this project?
- Will the results of the research have the potential for:
 - o reducing cost of the Medicaid program,
 - o improving access for recipients, and/or
 - o increasing quality of care to recipients?
- Please describe the project deliverables the researchers will provide to MassHealth

• Please describe how MassHealth can use the project deliverables in administration of the MassHealth program. The study will: examine the impact of MassHealth's primary care sub-capitation on primary care LARC service provision through a difference-in-differences analysis comparing provision of LARC services at MassHealth ACO versus control primary care sites before and after the policy change; and examine the impact of MassHealth's sub-capitation policy on monthly rates of provision of all contraceptive services among reproductive-age women attributed to MassHealth ACOs relative to patients attributed to control practices, overall, within primary care settings specifically, and by insurer type.

We hope that the results of this study will provide evidence critical to inform further rollout of this initiative and share lessons with other states. Through examining whether and how value-based contracting through tiered subcapitation can impact contraceptive access, delivery, and quality in primary care, this study will be relevant and beneficial to informing primary care policy throughout the country. Specifically, we will provide MassHealth with a summary of the study findings and a policy memo that describes transitions between impact of the sub-capitation policy on LARC provision. We will also share any conference abstracts and publications from this project.

3. Organizations approved to receive Medicaid Data will be required to execute a <u>Medicaid Acknowlegment of Conditions</u>. 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 y	ou intend to link or merge CHIA Data to other data?
	⊠ Yes
	☐ No linkage or merger with any other data will occur
2 If you	s, please indicate below the types of data to which CHIA Data will be linked. [Check all that apply]
2. II yes	s, 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 will use member zip codes to link to: (1) the American Community Survey to get data on zip-code level race/ethnicity, income, and education level, and (2) the Rural Urban Commuting Area codes to get data on rurality. We will also work with MassHealth collaborators to identify a list of tax IDs for practices enrolled in MassHealth ACOs and use this list to classify practices in the dataset.

We will use the decrypted NPIs to link to the MHQP MPD. The Aim 1 analyses are at the practice level. The linkage to the MPD will allow us to link providers with practices which in turn will allow us to determine whether a practice is in a MassHealth ACO (i.e., our intervention group). MPD data will also help us determine other practice characteristics (i.e., covariates that we will stratify by or control for in our statistical models).

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 use 5-digit zip codes as the unique identifier to link the APCD to the U.S. Census Bureau's American Community Survey and Rural Urban Commuting Areas Codes.

We will use the decrypted NPIs to link to the MHQP MPD.

5. If yes, attach or provide below a complete listing of the variables from <u>all sources</u> to be included in the final linked analytic file.

We will use data from the American Community Survey to assign each member of the following neighborhood socioeconomic characteristics as defined by their zip code-level or residence: lower and higher income (based on % of residents below poverty level in the zip code); lower and higher education (based on % of residents with less than or equal to a high school diploma in the zip code); predominantly white, Black, or Hispanic (based on % of residents of each race/ethnicity in the zip code) (https://www.census.gov/programs-surveys/acs).

We will use data from the Rural Urban Commuting Areas Codes to assign each member as living in an urban or rural area as defined by their zip-code level of residence. (https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes/)

Finally, we will use provider and practice level data from the MHQP MPD.

(https://www.mhqp.org/resources/massachusetts-provider-directory-mpd/)

APCD Linkage variable: decrypted NPI

MPD variables:

Variable Name	Description
T WEI I WOIL I TWILL	Description

NetworkName Name of provider network

NetworkID MHQP unique ID of provider network

NetworkWebsite Provider network's website URL
NetworkAddress1 Provider network's address line 1
NetworkAddress2 Provider network's address line 2

NetworkCity Provider network's city
NetworkState Provider network's state
NetworkZip Provider network's zip code
MedicalGroupName Name of medical group

MedicalGroupID MHQP unique ID of medical group
MedicalGroupWebsite Medical group's website URL
MedicalGroupAddress1 Medical group's address line 1
MedicalGroupAddress2 Medical group's address line 2

MedicalGroupCityMedical group's cityMedicalGroupStateMedical group's stateMedicalGroupZipMedical group's zip codePracticeNameName of practice site

PracticeID MHQP unique ID of practice site

PracticeWebsite Practice's website URL

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PracticeAddress1 Practice's address line 1
PracticeAddress2 Practice's address line 2

PracticeCity
Practice's city
PracticeState
PracticeZip
Practice's zip code
LastName
Provider's last name
FirstName
Provider's first name
MI
Provider's middle initial
ProviderID
MHOP unique ID of provider

ProviderTypeName Provider's type (e.g. Physician or Nurse Practitioner)

DOBdate Provider's date of birth

MALICNUM Provider's MA license number

NPI Provider's NPI
UPIN Provider's UPIN
Specialty1Desc Provider's specialty #1
Specialty2Desc Provider's specialty #2

RoleAtPractice Provider's role at the practice site

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

The American Community Survey and Rural Urban Commuting Areas Codes datasets are linked at the zip-code level and do not facilitate the identification of individual patients (rather they describe the population living in the same zip code as the patient). The MHQP MPD is linked using NPIs and will not facilitate the identification of individual patients.

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 will disseminate results of this project via conferences presentations, academic seminars, and manuscripts in peer-review journals. We also plan to create a memo for policymakers that summarizes our results.

We will report sample sizes for each cell. If the sample size in a cell is <11, we will not report the results for that cell and will include a note that that the sample size was insufficient for reporting.

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.

We have no plans to use or otherwise disclose CHIA Data outside of the dissemination plans described above.

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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?

State-level, no maps
, <u> </u>
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.

Drs. Garabedian and Fang have extensive experience working with Harvard Pilgrim Health Care claims data, and claims data from other commercial insurers (e.g., Optum, Marketscan). Drs. Pace and Keating have experience working with APCD data, 17-20 and Dr. Pace has used APCD data to examine contraceptive care delivery in MA. 18

Note that the MA APCD data will be stored at Harvard Pilgrim Health Care Institute and will only be accessible to the investigators based at that site (i.e., Dr. Garabedian). Co-investigators at other institutions (i.e., Drs. Pace, Keating, Schwarz) will not be able to access the MA APCD data for this project and will only see aggregate results; their institutions' IRBs have determined that they are not engaged in human subjects research.

2. <u>Resumes/CVs</u>: 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 <u>all</u> 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.

Exhibit A: CHIA Non-Government All-Payer Claims Data Application	December 2023
3. Will the agent or contractor have access to and store the CHIA Data at a location other than the off-site server and/or database?	Organization's location,
□ Yes	
\square 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)	Docusigned by: Stuila Fireman Drag signature image here or delete and physically sign
Printed Name:	Sheila Fireman
Title:	VP Administration and Finance, Harvard Pilgrim Health Care Institute
Date:	07/29/2024

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.