

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
- <u>Data Request Process</u>

After reviewing the information on the website and this Application, please contact CHIA at <u>apcd.data@state.ma.us</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@state.ma.us.
- 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.
- 5. Data for approved Applications will not be released until the payment for the Data is received.

III.	ORGANIZATION &	Z INVESTIGATOR	INFORMATION

Project Title:	Use of GLP-1RA Medications on Total Medicare
	and MassHealth Costs.
IRBNet Number:	2278761
Organization Requesting Data (Recipient):	Valmeek Kudesia, M.D.
Organization Website:	
Authorized Signatory for Organization:	Valmeek Kudesia, M.D.
Title:	Medical Doctor
E-Mail Address:	vmkudesia@gmail.com
Telephone Number:	617-549-9984
Address, City/Town, State, Zip Code:	14 Owatonna St. Auburndale, MA 02466
Data Custodian:	Valmeek Kudesia, M.D.
(individual responsible for organizing, storing, and archiving	
Data)	
Title:	same
E-Mail Address:	same
Telephone Number:	same
Address, City/Town, State, Zip Code:	same
Primary Investigator (Applicant):	Valmeek Kudesia, M.D.
(individual responsible for the research team using the Data)	
Title:	same
E-Mail Address:	same
Telephone Number:	same
Address, City/Town, State, Zip Code:	same
Names of Co-Investigators:	none
E-Mail Addresses of Co-Investigators:	none

IV. PROJECT INFORMATION

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 ☐ Inclusion in a product	☐ Student research ☐ Other (describe in box below)	☐ Utilization review of resources			

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.

Determine the effect of GLP-1RA medications on the total costs combined from acute and chronic care (see attachment)

3 Has an Institutional Review Roard (IRR) reviewed your Project?

٦.	This air institutional review Board (IRB) reviewed your Project.
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	Yes [If yes, a copy of the approval letter and protocol <u>must</u> be included with the Application package on IRBNet.]
\times	No, this Project is not human subject research and does not require IRB review.

4. **Research Methodology**: 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.

This project studies a potentially novel option to decrease acute care and chronic care utilization and healthcare costs in the Commonwealth of Massachusetts. This project specifically addresses MassHealth LTSS/HCBS costs which are significant public expense at \$3.4B with 10% YoY increase. The results of this study may inform public policy that governs MassHealth, which covers the health of greater than 25% of Massachusetts residents, resulting in changes to access of treatments and increase in quality of life for Massachusetts residents covered by MassHealth. See attachment for sources.

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 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.

apj	proved Project.		
1.	Please indicate below whether this is a one-time request, or if the described Project will require subscription.		
	☑ One-Time Request	OR	□ Subscription

	□ Release Version 7.0	☐ Release Version 8.0			
	□ 2013	□ 2014			
	□ 2014	□ 2015			
	□ 2015	□ 2016			
	□ 2016 □ 2017				
	□ 2017	⊠ 2018-2023			
	Specify below the data files requested for this file.	s Project, and provide your justification for requesting <i>each</i>			
X	Medical Claims				
	scribe how your research objectives require Medical edical claims data are required for the analysis of acute	Claims data: and outpatient utilization in context of GLP-1RA medications			
\boxtimes	Pharmacy Claims				
De	Describe how your research objectives require Pharmacy Claims data: Pharmacy claims are required for the analysis of pharmacy utilization in the context of GLP-1RA medications				
	Dental Claims				
De	scribe how your research objectives require Dental C	laims data:			
Cl	Click here to enter text.				
	Member Eligibility				
Describe how your research objectives require Member Eligibility data:					
Click here to enter text.					
□ Provider					
Describe how your research objectives require Provider data:					
Cl	Click here to enter text.				
	□ Product				
Describe how your research objectives require Product data:					
Cl	Click here to enter text.				

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

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</u> <u>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

The geographic subdivisions listed below are available for Massachusetts residents and providers only. 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:						
Click here to enter text.						
b. Date Resolution						
Select <u>one</u> 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:						
Month is required to assess temporal sub-ac	cute effects of GLP-1RA medications					
c. National Provider Identifier (NPI)						
Select <i>one</i> of the following options.						

*** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your

☐ Decrypted National Provider Identifiers***

VIII. MEDICAID (MASSHEALTH) DATA

1. Please indicate whether you are seeking Medicaid Data:

☑ Encrypted National Provider Identifiers (standard)

⊠ Yes

methodology:

Click here to enter text.

□ 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.

This project directly addresses long-term support services (LTSS) and home and community-based services (HCBS) which are both administered by MassHealth. The analyses and theoretical model derived this project directly relate to reducing cost of the Medicaid program, improving access for recipients, and/or increasing quality of care to recipients.

3. Organizations approved to receive Medicaid Data will be required to execute a <u>Medicaid Aknowlegment 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 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.

Click here to enter text.

⊠ No

 \square Yes

5. Will you be selling standard report products using CHIA 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.
Click here to enter text.
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.
Click here to enter text.
6. If yes, please identify the specific steps you will take to prevent the identification of individual patients in the linked dataset.
Click here to enter text.
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 <i>will not disclose a cell less than 11</i> , and percentages or other mathematical formulas that result in the display of a cell less than 11.
Published in professional journal or poster presentation. Results of <11 will be censored from any publication.
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.
None
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
4. Will you be using CHIA Data for consulting purposes? ☐ 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.
- >10 yrs experience analyzing medical and pharmacy claims for care management and research purposes
- 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	Click here to enter text.			
Code:				
Telephone Number:	Click here to enter text.			
Term of Contract:	Click here to enter text.			

1. Describe the tasks and pro	oducts assigned to the agen	t or contractor for this	s 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 cont	ractor have acc	cess to and	store the	CHIA 1	Data at a	location	other	than the
Oı	ganization's location,	off-site server	and/or data	abase?					

 \square Yes

 \square No

4. If yes, a separate Data Management Plan $\underline{\textbf{must}}$ 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	Click here to enter text.		
Code:			
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)	26miles
Printed Name:	Valmeek Kudesia, M.D.
Title:	Medical Doctor
Date:	01/17/2025

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.