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

I. INSTRUCTIONS

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

All attachments must be uploaded to IRBNet with your Application. All Application documents can be found on the CHIA website in Word and in PDF format or on IRBNet in Word format. If you submit a PDF document, please also include a Word version in order to facilitate edits that may be needed.

Applications will not be reviewed until the Application and all supporting documents are complete and the required application fee is submitted. A Fee Remittance Form with instructions for submitting the application fee is available on the CHIA website and IRBNet. A copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet.

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

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

III. ORGANIZATION AND INVESTIGATOR INFORMATION

Project Title:	Evaluating Medicaid Accountable Care Models
IRBNet Number:	1628804-1
Organization Name:	Trustees of Boston University
Organization Website:	http://www.bumc.bu.edu/
Authorized Signatory for Organization	William P. Segarra, JD, MPH
Title:	Director, Industry Contracts & Agreements
E-mail Address:	industry@bu.edu
Address, City/Town, State, Zip Code	25 Buick Street, Suite #200, Boston, MA 02215
Primary Investigator:	Megan B. Cole, PhD, MPH
Title:	Assistant Professor
E-mail Address:	mbcole@bu.edu
Telephone Number:	617-358-1901
Names of Co-Investigators:	Kathleen Carey, PhD
E-mail Address of Co-Investigators:	kcarey@bu.edu

IV. FEE INFORMATION

1. Consult the Fee Schedule for All-Payer Claims Database data and select from the following options:

☒ Researcher
☐ Other
☐ Reseller

2. Are you requesting a fee waiver?

☒ Yes
☐ No

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

V. PROJECT INFORMATION

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

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

> The work to be conducted will be an academic research study, which will assess longitudinal changes in quality of care and health care utilization for Medicaid enrolled members who are attributed to Medicaid ACOs providers vs. similar enrolled members who are not.

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

> The objective of this project is to estimate how the Massachusetts MassHealth ACO program has affected quality of care. The first aim is to evaluate the effect of MA's Medicaid ACO program on financially incentivized quality of care measures, including preventive care, chronic disease management, behavioral health, and avoidable utilization measures. The second aim is to evaluate the effect of MA's Medicaid ACO program on quality of care measures that are not included as part of the MassHealth ACO contract and thus, not financially incentivized. The third aim is to evaluate the effect of MA's Medicaid ACO program on quality of care for select clinical subpopulations: patients with cardiovascular disease, patients with diabetes, and patients with mental health disorders. Across all aims, we will assess how effects vary by ACO model type.
> Although not part of this APCD application, other analyses that use BMC EHR data (not linked to APCD) and qualitative interview data with ACO leadership will help to contextualize the results, particularly as related to how

efforts to address unmet social needs may affect quality of care (although this particular question is not measurable in the APCD and thus is not described in this proposal).

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

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

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

VI. PUBLIC INTEREST

1. Briefly explain why completing your Project is in the public interest. *Uses that serve the public interest under CHIA regulation include, but are not limited to: health cost and utilization analysis to formulate public policy; studies that promote improvement in population health, health care quality or access; and health planning tied to evaluation or improvement of Massachusetts state government initiatives.*

Completing this project is of public interest for two main reasons. First, the focus of our study is on measuring changes in health care <u>quality</u> for Medicaid enrollees as related to the MassHealth ACO; this also includes <u>utilization</u> measures (e.g. ED visits). Results in turn will inform efforts to improve health care quality for Medicaid enrollees across the state. Second, this study focuses on evaluating a Massachusetts <u>state government initiative</u>—the MassHealth ACO—which in turn may inform implementation efforts moving forward.

VII. DATASETS REQUESTED

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

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

☒ **Medical Claims**
☐2011 ☐2012 ☒2013 ☒2014 ☒2015 ☒2016 ☒2017
Describer how your research objectives require Medical Claims data:
Medical claims will be used to capture quality of care measures (e.g. cancer screenings), utilization measures (e.g. ED visits, hospitalizations), and patient diagnoses. Medical claims will also be used in conjunction with the member eligibility files and provider files to attribute members to a primary care site, based on where the patient receives the majority of their primary care services.
☒ **Pharmacy Claims**
☐2011 ☐2012 ☒2013 ☒2014 ☒2015 ☒2016 ☒2017
Describer how your research objectives require Pharmacy Claims data:

Pharmacy claims will be used to capture select disease-specific quality of care measures (e.g. receipt of ACE Inhibitor, Angiotensin Receptor Blocker (ARB), BetaBlocker Therapy for patients with heart failure).

☐ **Dental Claims**
☐2011 ☐2012 ☐2013 ☐2014 ☐2015 ☐2016 ☐2017

Describer how your research objectives require Dental Claims data:

☒ **Member Eligibility**
☐2011 ☐2012 ☒2013 ☒2014 ☒2015 ☒2016 ☒2017

Describer how your research objectives require Member Eligibility data:

Member eligibility files will be used to capture key patient demographics as well as important inclusion and exclusion criteria. This includes member age, gender, zip code, attributed PCP, the Physician Group of the Member's PCP (eg MassHealth ACO), and dates of enrollment.

☒ **Provider**
☐2011 ☐2012 ☒2013 ☒2014 ☒2015 ☒2016 ☒2017

Describer how your research objectives require Provider data:

The provide file will be used to assess the location and thus the practice of the provider if it is the attributed primary care provider. This will help us to identify intervention practices versus non-intervention practices when creating our intervention and control groups. This will be used in conjuction with the MA RPOs.

☒ **Product**
☐2011 ☐2012 ☒2013 ☒2014 ☒2015 ☒2016 ☒2017

Describer how your research objectives require Product data:

The product file will give us information about the product type, which will inform assignment to our treatment vs control group. This is critical, as for many MassHealth members, the product details are indicative as to whether they are in a MassHealth ACO or not.

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

☐ Medical Claims   ☐ Pharmacy Claims   ☐ Dental Claims   ☐ Member Eligibility
☐ Provider   ☐ Product

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

N/A – all datasets are required for this project.

VIII. DATA ELEMENTS REQUESTED

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

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

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

Applicant note: Please note that the elements that I am requesting for the re-use application are the same elements in the original application. In other words, there are no "new" elements being requested. Justification of continued use of each element is included below.

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

☐ 3-Digit Zip Code (standard)	☒ 5-Digit Zip Code***
***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology: Our study will require 5 digit zip code for two reasons. First, understanding each enrollee's zip code will allow us to more accurately assign enrollees to intervention sites. Second, it is critical that the intervention and control groups have similar demographic make-up, including zip code of residence. For example, when creating our propensity weighted control group, we will include zip code-linked sociodemographic data such that we are comparing patients from similar neighborhoods and towns. It is important that the zip codes are as precise as possible given that sociodemographics vary widely across zip codes. We also require zip codes for providers, as this will allow us to validate practice designations.	

Dates

Choose _one_ option from the following options for dates:

☐ 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: Knowing specific dates is necessary for capturing several outcomes. For example, all claim dates, inclusive of day, are needed to identify number of days from hospital discharge to follow-up visit; to identify the length of stay for hospital visit; and to ensure the sequence of claims is understood for claims occuring in the same month. When collapsing claim lines down to the visit-level, it's also critical to know if different claims occurred on the same day; in many instances, they are part of the same visit, but this would be unknown without an indicator of DD. Product start and end dates are also necessary to determine specific number of eligible days in a given time period (month, quarter).		

National Provider Identifier (NPI)

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

☐ Encrypted National Provider Identifier(s) (standard)	☒ Decrypted National Provider Identifier(s)***
*** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your methodology: In order to attribute enrollees to primary care practices, and thus to the intervention vs control group, we will need NPIs. NPIs will be linked to the Massachusetts Registration of Provider Organizations (MA-RPO) data files in order to assign each patient to a practice.	

2. If there are data elements that are included in the Extract that **_are not_** required for this Project indicate below.

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

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

N/A – all data elements are required

IX. MEDICAID DATA

1. Is Medicaid Data included in the Extract?

☒ Yes
☐ No

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

☒ Yes

☐ No

3. Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are directly connected to the administration of the Medicaid program. If you are requesting Medicaid Data, please describe, in the space below, why your use of the data meets this requirement. Requests for Medicaid data will be forwarded to MassHealth for a determination as to whether the proposed use of the data is directly connected to the administration of the Medicaid program. This may introduce significant delays in the receipt of Medicaid Data. ***Recipient may not use the Medicaid data for the new Project until Recipient is notified of MassHealth approval.***

> MassHealth data are central to our research study, which specifically focuses on how the MassHealth ACO program has affected quality of care. Our project has the support of MassHealth, which instructed us to obtain MassHealth data via the APCD. Our designated point of contact at MassHealth is Sarah Qin: Senior Manager of Delivery System Investment, Policy, and Evaluation.
>
> The public benefits described in Section V apply almost entirely to the MassHealth program and its enrollees. Findings from our study will help to inform how the MassHealth ACO models has affected quality of care, how these effects vary across model types, and how these effects vary across clinical subpopulations. Results may be used to inform ongoing and future implementation efforts as related to the MassHealth ACO, which will ultimately serve to maximize quality of care and health outcomes for Medicaid enrollees.

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

> N/A

X. DATA LINKAGE AND FURTHER DATA ABSTRACTION

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

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

2. If yes, please indicate below the types of data to which CHIA Data will be linked. [Check all that apply]
    ☐ Individual Patient Level Data (e.g., disease registries, death data)
    ☒ Individual Provider Level Data (e.g., American Medical Association Physician Masterfile)
    ☐ Individual Facility Level Data (e.g., American Hospital Association data)
    ☒ Aggregate Data (e.g., Census data)
    ☐ Other (please describe):

3. If yes, describe the dataset(s) to which the CHIA Data will be linked, indicate which CHIA data elements will be linked and the purpose for each linkage.

We will link the APCD data with two data sources. First, using <u>NPI</u> as the unique identifier, we will link the APCD to the Massachusetts Registration of Provider Organizations (MA-RPO) files. This will allow us to assign PCPs to practices and thus patients to practices, which is critical to our ability to carry out this study.

Second, we will link <u>5 digit member zip codes</u> to US Census Bureau's American Community Survey (ACS) data as to include important sociodemographic information about patients' neighborhoods (eg percent residents under poverty level, percent residents from racial/ethnic minority groups). These ACS covariates will be used when generating propensity scores, as to balance on neighborhood sociodemographic characteristics in our treatment vs control groups. This is especially important given that the APCD does not include any member-level sociodemographic information related to race/ethnicity, income, or education.

Both of the linkage datasets are <u>publicly available</u> and contain no patient-level information.

Please note that <u>we will not</u> link, stack, merge, or otherwise combine CHIA Data with claims data that the study team has from the RI APCD, BMC HealthNet, BMC EHR data, or any other data sources.

4. If yes, for each proposed linkage above, please describe your method or selected algorithm (e.g., deterministic or probabilistic) for linking each dataset. If you intend to develop a unique algorithm, please describe how it will link each dataset.

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

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

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

XI. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from CHIA Data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting. Any and all publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications will not disclose a cell less than 11, and percentages or other mathematical formulas that will result in the display of a cell less than 11.

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

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

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

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

3. Will you use CHIA Data for consulting purposes?
   ☐ Yes
   ☒ No

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

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

6. Will you be reselling CHIA Data in any format?
   ☐ Yes
   ☒ No

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

N/A

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

N/A

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

N/A

XII. APPLICANT QUALIFICATIONS

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

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

- Since 2014, Dr. Cole has used CMS Medicaid Analytic eXtract (MAX) Data. This includes twelve years of complete claims from 14 states, including inpatient, long-term care, prescription, or "other therapy" claims. For example, using these data, Cole has served as lead analyst and lead author in assessing to comorbidities in the HIV Medicaid population. This has included extensive data cleaning, quality checking, variable creation, analytic file creation, and statistical analyses.
- Since 2014, Dr. Cole has used multi-payer claims data from all payers in Rhode Island. Using these data, she has served as lead analyst and lead author in assessing the impact of Rhode Island's multi-payer patient centered medical home program on utilization and total cost of care. This has included quality checking, variable creation, analytic file creation, and statistical analyses.
- Since 2018, Dr. Cole is using the All-Payer Claims Database in RI to assess statewide cost trends and drivers of cost.
- Since 2017, Dr. Cole has led the economic impact evaluation of the TEAM UP intervention. This evaluation uses BMCHealth Net claims data to assess ED visits and inpatient admissions for children receiving care at a TEAM UP intervention site. These claims data are submitted to our study team in APCD format.
- Since 2018, Dr. Cole has used the MA APCD to evaluate how pediatric behavioral health integration into primary care has affected cost of care and utilization of care for low-income children. She serves as the PI of these analyses.

In addition, Dr. Cole has experience with HCUP State Inpatient Databases (SID) and State Emergency Department Databases (SEDD). Previously, while at The Lewin Group, she also served as a data manager on a long-term CMS contract that required extensive cleaning, review, and analysis of raw claims data submitted by every state Medicaid program. At any given time, Cole oversaw the data for a portfolio of claims data for 4-7 states.

Kathleen Carey, PhD: Dr. Carey is a Health Economist and Professor in the Dept. of Health Law, Policy, and Management at Boston University School of Public Health. Dr. Carey is currently the PI of another project using the MA APCD, which focuses on commercial ACOs in Massachusetts. Dr. Carey has decades of experience using claims data, including Medicare claims data and MarketScan commercial claims data.

A **yet-to-be-named** Senior Programmer at Boston University's Biostatistics and Epidemiology Data Analytics Center (BEDAC) will also use the APCD. BEDAC has extensive experience managing, cleaning, and analyzing claims data. They currently use the MA APCD on at least 2 projects.

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

XIII. USE OF AGENTS AND/OR CONTRACTORS

Please note: By signing this Application, the Organization assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors.

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

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	None
Company Website:	
Contact Person:	
Title:	
E-mail Address:	
Address, City/Town, State, Zip Code:	
Telephone Number:	
Term of Contract:	

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

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

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

☐ Yes
☐ No

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

AGENT/CONTRACTOR #2 INFORMATION	
Company Name:	
Company Website:	
Contact Person:	
Title:	
E-mail Address:	
Address, City/Town, State, Zip Code:	
Telephone Number:	
Term of Contract:	

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

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

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

☐ Yes
☐ No

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

XIV. ATTESTATION

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

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

By my signature below, I attest: (1) to the accuracy of the information provided herein; (2) that the requested Data is the minimum necessary to accomplish the purposes described herein; (3) that the Organization will meet the data privacy and security requirements described in this Application and supporting documents, and will ensure that any third party with access to the Data meets the data use, privacy and security requirements; and (4) to my authority to bind the Organization.

Signature: (Authorized Signatory for Organization)	*William Segarra (Aug 8, 2020 09:28 EDT)*
Printed Name :	William Segarra

Attachments
A completed Application must have the following documents attached to the Application:
☒ 1. IRB approval letter and protocol (if applicable)
☒ 2. Research Methodology (if protocol is not attached)
☒ 3. CVs of Investigators (if not submitted previously)
☒ 5. Data Use Agreement

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

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

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

Attachment #2 – Data Management Plan(s)

Non-Government-Re-Use-APCD-Application

Final Audit Report   2020-08-08

Created:	2020-08-07
By:	Julia Walter (jlwalter@bu.edu)
Status:	Signed
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"Non-Government-Re-Use-APCD-Application" History

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