Non-State Entity Application: VHCURES Limited Use Health Care Claims Research Data Set

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APPLICATION INSTRUCTIONS

Introduction

The Vermont Health Care Uniform Reporting and Evaluation System (VHCURES)

The Vermont legislature authorized the collection of eligibility and claims data for Vermont residents to enable the Green Mountain Care Board (GMCB) to carry out its statutory duties that include determining the capacity and distribution of existing resources; identifying health care needs and informing health care policy; evaluating the effectiveness of intervention programs on improving patient outcomes; comparing costs between various treatment settings and approaches; providing information to consumers and purchasers of health care; and improving the quality and affordability of patient health care and health care coverage. (18 V.S.A. § 9410)

The GMCB is required to make the VHCURES data and information available as a resource for individuals and entities to continuously review health care utilization, expenditures, and performance in Vermont to the extent permitted by the Health Information Portability and Accountability Act (HIPAA) and other pertinent state and federal laws.

The claims and eligibility data available under a data use agreement can be broadly grouped into three lines of business including commercial, Medicaid, and Medicare. The GMCB has independent discretion to make decisions regarding the use and disclosure of commercial insurer data. The Department of Vermont Health Access (DVHA) and the GMCB share discretion with respect to the Medicaid data subset. DVHA must approve the use and disclosure of Medicaid data and must sign the Data Use Agreement (DUA) for authorized users of the Medicaid data subset. Per an agreement with the federal Centers for Medicare and Medicaid Services (CMS), the Medicare data subset is available only to Vermont State Agencies and entities performing research that is directed and partially funded by the State of Vermont. Under a DUA between GMCB and CMS, GMCB has independent discretion to make decisions regarding the use and disclosure of the Medicare data subset by Vermont state agencies.

Vermont state agencies may apply for a standard comprehensive research data set that includes all unrestricted and restricted data elements for broad use internally and by state contractors. Non-state entities may apply for a DUA for a limited use health care claims research data set using a different application form. This type of data set excludes the Medicare data subset and is tailored to specific research purposes as approved by GMCB and DVHA if the Medicaid data subset is requested. Applicants who are non-state entities must justify requests for individual restricted data elements and explain how the requested restricted data elements are applicable to the intended research purpose.

Data Governance Council

The GMCB chartered the Data Governance Council (DGC) to oversee the stewardship of VHCURES including the development and revision of principles and policies to guide decisions on data use and

disclosure. The DCG supports the GMCB decision-making process for applications requesting use and disclosure of VHCURES data sets by non-state entities as addressed in this application form.

Application Review Process

This application is required of non-state entities requesting a DUA for a VHCURES limited use health care claims research data set (hereafter referred to as a limited use research data set) with the option of including the commercial and Medicaid data subsets to support a project focused on a specific research purpose or study.

GMCB staff must deem this application complete before initiating the full review process. **This includes submission of all required and applicable optional attachments as listed in the Application Checklist in this application.** Applicants must include a full list of individuals who will have access to the data set upon the effective date of the DUA with this application. Applicants must file Individual User Affidavits (IUA) signed by the Authorized User (AU) or Principal Investigator (PI) for all data users listed on this application. AUs or PIs must ensure that IUAs are filed with GMCB for future data users prior to their access to the data set or risk forfeiture of the DUA and the data set.

After an application is deemed complete, GMCB will start the application review process that may include a public discussion of the application by the DGC. The GMCB has the discretion to approve or disapprove applications for a DUA. All requests for the Medicaid data subset must also be approved by the Department of Vermont Health Access (DVHA). The GMCB will provide DVHA with a copy of the complete application, following a review of the application by the GMCB. Applicants may also be required to obtain approval of the AHS Institutional Review Board (IRB) Committee. (See http://humanservices.vermont.gov/boards-committees/irb)

The Agency of Administration (AOA) under "Procurement and Contracting Procedures" of Bulletin 3.5 is required to review and approve the DUA after the GMCB and DVHA, if applicable, have approved the application for a DUA.

The GMCB must review and approve requests by non-state entities to redisclose data including custom extracts to contractors, subcontractors, or other external agents. Non-state entities must file data redisclosure request form(s) (DRRF) with the GMCB prior to redisclosing the data set or any extracts generated from the data set to any external agents. This ensures continued compliance with provisions of state and federal laws and regulations regarding the data. The GMCB must also review any proposal to change the use or research purpose of the data after the DUA has been issued for a specific research purpose. The GMCB may require the filing of a new application for a DUA after reviewing requests for change in data use under an existing DUA.

Final Steps in the Application Process

If approved by AOA, the GMCB and the applicant jointly enter into a DUA that is signed by the Authorized User, Principal Investigator, GMCB, and DVHA if the Medicaid data subset is included. Prior to receiving the data set approved under the DUA, all individuals accessing and using the data on behalf of the Authorized User must sign IUAs attesting to understanding the appropriate use and disclosure of the data set and agree to comply with the requirements. If GMCB declines an application, a written

statement identifying the specific basis for denial of the application will be provided to the applicant. The applicant may resubmit or supplement the application to address GMCB's concerns including those of DVHA if Medicaid data are being requested. An adverse decision regarding an application may be appealed to the GMCB.

General Instructions

Applicants must complete all required sections of the application and submit an electronic copy of the completed application, including all attachments, to gmcb.data@vermont.gov. Incomplete applications will not be reviewed until the applicant has provided all required information. An application checklist is provided to help ensure that your application is complete. For questions about the application process, gmcb.data@vermont.gov

Definitions

Agent: Means any individual or entity (e.g., a contractor, subcontractor, grantee, or subgrantee) acting on behalf of the Authorized User and subject to the Authorized User's control or accessing the Data Set on behalf of the Authorized User.

Authorized User: The Authorized User (AU) is typically an organization or agency. The AU signatory to the Application and the DUA must have the authority to sign legally binding agreements on behalf of the organization or institution.

***Custom Extract*:** A custom extract includes the minimum necessary data to support the research purpose. A custom extract is a data subset or table generated from the commercial and Medicaid data subsets. The Medicare data subset is only available to Vermont state agencies under the data use agreement between CMS and the GMCB.

This process ensures continued compliance with the requirements of the DUA and particularly supports the concept of using the minimum necessary data to support the approved research purpose. For example, if the study approved under a VHCURES DUA addresses pediatric asthma in the Medicaid population, the GMCB may approve use of a custom extract that includes Medicaid paid claims data for enrollees under the age of 19 only.

Data Custodian: The data custodian is responsible for the establishment and maintenance of physical and technical safeguards to prevent unauthorized access to and use of the data set. Agencies may designate multiple data custodians for different departments and programs. The data custodian(s) typically coordinate the receipt of the approved data set from GMCB's data consolidation vendor. The principal investigator may also be the data custodian. State contractors or other agents approved by GMCB to receive the data set or custom extracts after a review of a Data Redisclosure Request Form must identify and file contact information for their data custodian(s) with the GMCB.

Data Redisclosure: Any Vermont state agency or non-state entity with a VHCURES DUA that intends to redisclose the VHCURES data set or any custom extracts of the data set to external agents to support projects approved under the DUA must file a Data Redisclosure Request Form (DRRF) with the GMCB for review and approval prior to the redisclosure.

After the GMCB has reviewed a DRRF and approved redisclosure of data to an external agent, the GMCB may request its data consolidation vendor to generate custom data extracts for external agents or permit the external agent to access the data enclave hosted by the vendor. Use of services provided by the GMCB's data consolidation vendor may require payment of a fee to the vendor.

Institutional Review Board (IRB): An institutional review board (IRB), also known as an independent ethics committee (IEC), ethical review board (ERB), or research ethics board (REB), is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans.

Personally Identifiable Information (PII): The term PII refers to information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. The definition of PII is not anchored to any single category of information or technology. Rather, it requires a case-by-case assessment of the specific risk that an individual can be identified. It is important to recognize that non-PII can become PII whenever additional information is made publicly available when combined with other available information.
Source: https://www.gsa.gov/reference/gsa-privacy-program/rules-and-policies-protecting-pii-privacy-act

Principal Investigator (PI): The Principal Investigator means the individual designated by the Authorized User to be responsible for ensuring compliance with all the restrictions, limitations, and conditions of use and disclosure specified in the DUA. The Principal Investigator may delegate technical responsibility to other personnel for the establishment and maintenance of security arrangements to prevent unauthorized access to and use of the data.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

State Entity: Vermont state agencies, contractors, or other external agents performing work for the State of Vermont. A non-state entity is not a Vermont state agency or an agent performing work directed and funded by the State of Vermont.

Application Checklist (For use by the applicant. Applicants must include all required attachments and applicable optional attachments)

Completed Application

☐ **Section 1:** Research Summary

☐ **Section 2:** Data Management Plan

☐ **Section 3:** Project Team (*Including data users for whom signed IUAs are being filed*)

☐ **Section 4:** Data Procurement and Price

☐ **Section 5**: Data Transmission and Receipt

☐ **Section 6:** Signatures

Required Attachments

☐ **Attachment 1:** Data Use Agreement template (*Will be signed by the Authorized User and Principal Investigator after the application is approved by Agency of Digital Services for Agency of Administration, GMCB, and DVHA (if Medicaid data is to be disclosed under the DUA*)

☐**Attachment 2:** Entity's Data Governance and Protection Policies and Procedures

☐**Attachment 3:** Limited Use Research File Specification (Includes justification for requesting restricted data elements as necessary to support the specific research purpose)

Optional Attachments Applicable to Proposed Redisclosures of the Data or Extracts

☐**Attachment 4**: Copy of proposed contracts, subcontracts, or any other agreements with external agents requiring redisclosure of the data set or custom extracts

☐**Attachment 5:** Data Redisclosure Request Form(s) (DRRF) must be filed for every external agent identified under Attachment 4 to whom the data or data extracts will be re-disclosed by the entity in possession of the DUA

☐**Attachment 6:** Data Governance Policies and Procedures for every external agent identified under Attachment 4 that will be receiving and managing the data set or extracts of the data set

Miscellaneous Optional Attachments

☐**Attachment 7:** If applicable to this application, Institutional Review Board approval document

☐**Attachment 8:** Other materials requested by the GMCB for the purpose of reviewing the application

APPLICATION

Section 1: Research Summary

Section 1 summarizes the specific research purpose of the project requiring access to a limited use health claims research data set during the term of the DUA. The Authorized User must discuss any proposed changes in the research purpose that are not specified in this application with the GMCB. The GMCB may require the filing of an application for proposed changes in data use and the research purpose.

Answer every question in this section. If a question does not apply to your research project, indicate that the item is "Not Applicable." Do not leave a question blank or the application will be deemed incomplete.

1-1. Project Overview

Authorized User Signatory Name & Title: Jun Wang, Principal Data Scientist	
Organization/Entity Name: Archway Health Advisors, LLC	
Type of Organization	☐Federal or State government entity outside of Vermont ☐Contractor of Federal or State government entity outside of Vermont ☐Academic Institution ☐Non-profit research organization ☐Participant in the Vermont health care system financing, insurance, or delivery system with direct impacts on the Vermont population ☐Participant in health care financing, insurance or delivery systems outside of Vermont ☒ Health care enterprise such as manufacturers or distributors of pharmaceuticals and medical technology; designers and developers of health systems and facilities, etc. ☐Other: Please describe below
Principal Investigator Name & Title (if different from Authorized User):	
Project Name (Specify a topic or study): Identifying Best Performing Providers for Developing an Episode Payment Market in Vermont	

Brief Project Description (Summary of subsection 1-5-1): The objective of this research is to explore potential drivers attributed to the variation in the episode-of-care cost and quality outcomes among the commercial population in Vermont in order to quantify the cost reduction and quality improvement opportunities.
Project Start Date: The date Archway receive the data from GMCB
Project End Date: One year from the start date
Funding Source(s) ☐State ☐Federal ☒ If Other, please describe: Archway Health Advisors, LLC
Line of Business data subset included in data request: ☒Commercial ☐Medicaid (DVHA must approve Medicaid data use)
If you intend to rdisclose the data to contractors, subcontractors, or other external parties, identify parties (Must align with documents filed under Attachments 4, 5, and 6):

1-2. Authorized User Acknowledgements

Please initial each item indicating your agreement with conditions of use.

JW	*I agree that I have the authority to sign legally binding agreements on behalf of the organization or institution as applicable to this application and the attached Data Use Agreement (DUA).*
JW	*I have read and agree to the terms of the attached DUA. I understand the contents of the attached DUA may only be modified or amended in writing upon mutual agreement of both parties.*
JW	*I have read and agree to cooperate with the GMCB to amend the DUA from time to time to the extent necessary for the GMCB to comply with changes to 18 V.S.A. § 9410, HIPAA, or other legal requirements that may apply to the Data Set.*
JW	*I understand and agree that I am required to file signed Individual User Affidavits (IUAs) with the GMCB for every individual data user within my organization and those employed by any contractors, subcontractors or organizations outside my organization approved by the GMCB to access and use the VHCURES data set. I must file the IUAs prior to receipt of the data set and as new users join the project or risk forfeiture of the data set and the DUA.*
JW	*I understand and agree that I must obtain the express written approval of the GMCB to release the data set or any derived extracts of the data to any agents or parties outside my organization. I must*

file a Project Review Form (PRF) with the GMCB for review prior to any re-disclosure of the data set to parties outside of my organization or risk forfeiture of the data, the DUA and be subject to civil and criminal sanctions and penalties for an unauthorized disclosure of data.

1-3. Project Questions

Answer the following questions about your research project.

Yes ☐ No ☒	Is the project directed by the State of Vermont including Vermont state agencies and UVM?
Yes ☐ No ☒	Is this project partially or wholly funded by the State of Vermont?
Yes ☐ No ☒	Will products generated from the project be used for a proprietary, commercial purpose to generate revenues and income? **If yes, explain below:**
Yes ☒ No ☐	Is the project useful for determining the capacity and distribution of existing health care resources?
Yes ☐ No ☒	Is the project useful for identifying health care needs and informing health care policy?
Yes ☒ No ☐	Is the project useful for evaluating the effectiveness of intervention programs on improving patient outcomes?
Yes ☒ No ☐	Is the project useful for comparing costs between various treatment settings and approaches?
Yes ☐ No ☒	Is this project useful for providing information to consumers and purchasers of health care?
Yes ☒ No ☐	Is this project useful for improving the quality and affordability of patient health care and health care coverage?
Yes ☐No☒	Does the project directly support public health activities?
Yes ☐ No ☒	Does this project support educational purposes such as exploring the claims data for quality, potential uses, health services research training, or integration with other data sets?
Yes ☐ No ☒	Does this project propose to link VHCURES data with any other individual record-level data sets? *If yes, describe the data sets and proposed methodology for linking in Section 1-5-4.*
Yes ☐ No ☒	Does this project anticipate re-disclosure of the data set, custom extracts or analytical files generated from the data set to any identifiable external agents under contracts,

grants, and agreements for research purposes that have been specified? *If yes, file Attachment 4, 5, and 6.*

1-4. Requested Data

Indicate the data files requested in this application.

File Type	Commercial Insurers	Medicaid[1]	Medicare[2]	Data Years or Date Range[3]
Medical Eligibility-VT Residents	☒	☐	Not applicable	CY2017-2018
Medical Claims-VT Residents	☒	☐	Not applicable	CY2017-2018
Medical Eligibility- 5% National Sample	Not applicable	Not applicable	Not applicable	
Medical Claims- 5% National Sample	Not applicable	Not applicable	Not applicable	
Pharmacy Eligibility	☒	☐	Not applicable	CY2017-2018
Pharmacy Claims	☒	☐	Not applicable	CY2017-2018
Medicare Part D Event- VT Residents	Not applicable	Not applicable	Not applicable	
Medicare Part D Event- 5% National Sample	Not applicable	Not applicable	Not applicable	
Medicare MEDPAR	Not applicable	Not applicable	Not applicable	

[1] The Department of Vermont Health Access (DVHA) must approve uses and disclosure of Medicaid data.

[2] Medicare data may only be used for research directed and partially funded by the state of Vermont.

[3] VHCURES data are available on a consolidated CY quarterly or annual basis on paid claims date basis starting with CY 2007.

1-5. Project Overview

1-5-1. Summarize the purpose and objectives of the proposed research. Describe how the research will contribute to generalizable knowledge that would also be applicable to the Vermont population, health, and health care and, if applicable, to the State of Vermont supporting the development, implementation, and evaluation of programs administered by Vermont state agencies.

Vermont has one of the most progressive payment landscapes in the United States with the proliferation of value-based payments, but continues to struggle with increasing costs. Episode of care models are part of the answer to reducing cost growth without sacrificing the quality of care. It has been proven to help control specialist-driven spend which accounts for 60-70% of total healthcare spending and reduce cost variation. Medicare has developed several comprehensive episode payment initiatives, but the commercial market for episode payment is underdeveloped as no forcing mechanism exists to bring payers and providers together to develop episode payment arrangements. A key barrier to the initiation of episode payment contracts is the lack of data necessary to create payments and evaluate quality. The APCD is necessary to enable providers of Vermont to understand the opportunities and risks and promote episode payment to payer partners.

We will use APCD claims data to conduct the retrospective cohort research and identify the areas that have major impact to the cost of Vermont commercial population, including high-volume inpatient or outpatient acute medical and procedure events, chronic disorders, preventive medical cares, etc. We will evaluate the variation in spending among physicians on the major service types (e.g. inpatient hospital, outpatient facility, professional services, prescription drugs, etc.), quality performance (e.g. readmission rate, ER rate, complications, mortality, etc.), and create benchmark performances that reflect the high-quality and low-cost physicians. Potential quality-improvement and cost-saving opportunities will then be quantified by comparing provider's performance with the benchmark performance.

1-5-2. Summarize the credentials, skills, and experience of the Principal Investigator and key research staff that are evidence that the Data Set will be used to conduct and support systematic investigations guided by expertise in the subject matter and research methods, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Dr. Jun Wang is the Principal Data Scientist at Archway Health with more than a decade of expertise in the custom design, development and implementation of value based payment programs, including a suite of episode-of-care products and services for Medicare's Oncology Care Model, Comprehensive Care for Joint Replacement Model, and Bundled Payments for Care improvement programs. Dr. Wang has led the production of all versions of the original

SAS analytic packages of the PROMETHEUS bundled payment model and has designed 39 custom bundled payment arrangements for Commercial programs. She also led the CMS multi-million-dollar project Generating Medicare Physician Quality Performance Measurement Results and the Massachusetts State Medicaid P4P Quality Measure Program. The database Dr. Wang has strong experience with and were used for the product design/development includes Medicare Research Identifiable File (RIF), Medicare Limited Data Set (LDS), medical and pharmacy claims from clients (hospitals, ACOs, and payers), Massachusetts/Maine APCD data, Medicare Advantage dataset, etc.

1-5-3. If your project requires the use of Medicaid data, is the research intended to support public health activities? If yes, explain the application of the project to public health. If no, you may be required to obtain approval to use the Medicaid data from the AHS IRB Review Committee in addition to DVHA. See Optional Attachment 6.

N/A

1-5-4. Explain how you will ensure that your organization and external agents performing state-directed research will have access to the minimum necessary data to support specified research purposes and projects.

Our goals of the study include exploring potential drivers attributed to the huge variation in the episode of care cost and quality outcomes among the commercial population and to quantify the episode cost reduction opportunities from all types of services provided to the commercial beneficiaries. We want to cover all the clinical areas including rare diseases, and to cover all providers including those with relatively low volume. This requires that we must use 100% state representative dataset to define episode of care, which varies largely in volume and episode length, for outcome assessment and to set up state-wide performance benchmarks.

The episode period for study varies by clinical areas. For example, to study the acute episode, such as hip and knee replacement, we need the claim data for at least 90 days before admission and 90 days after the discharge for each procedure to obtain the complete patient risk and provider performance information. For oncology study, the episode period is much longer, usually 1 to 2 years from the initial diagnosis of cancer, to cover the majority of the relevant services. This requires that we have at least 2 years of longitudinal data to get adequate number of patients with complete episode period. We therefore propose to purchase complete commercial APCD claims from 2017 to 2018.

1-5-5. List and describe any identifiable record-level data files or other record-level data sources you are planning to use in conjunction with the requested VHCURES data. If the files will be linked, explain the methodology for linking the data; if applicable, which files include direct personal identifiers and list the personal identifiers included in the files; and how the identity of individuals and their PHI will be protected from unauthorized disclosures within and outside your agency or organization.

We don't plan to link the VHCURES data to any other data files.

1-5-6. Identify and briefly describe the funding source(s) for the proposed research including both internal and external sources that may be in the form of state and federal funding, grants, and other sources**.** Describe the relationship between the funding source(s) and your organization.

This project will be fully funded internally by Archway Health Advisors, LLC.

1-5-7. Explain whether any component of the project was review and approved by an Institutional Review Board (IRB)**.** If yes, attach the IRB review and approval under Attachment 7 to this application.

This project will not subject to IRB review since the research will be a retrospective cohort study using de-identified PHI.

Section 2: Data Management Plan

Section 2 relates to the policies and procedures your organization will use to ensure the proper management of the VHCURES limited use research data set and custom extracts derived from the data set. The GMCB recognizes the applicability of best practices for information security and privacy used in the CMS Data Privacy Safeguard Program (DPSP)[1] to the review of VHCURES DUA applications. Respond to every question about your organization's and those of approved entities external to your organization policies and procedures to ensure technical and administrative safeguards over the data.

Please answer the questions in each section with references to any attached documents including relevant page and/or section numbers. **Do not simply cite a cross-reference to the policy and procedure documents included under Attachment 2 and 6 of this application in lieu of answering each question. If questions are not answered completely, the application will be deemed incomplete.**

Any Data Redisclosure Request Forms (PRF) filed with this application for external agents under Attachment 5 may cite cross-references to this application for the same items in Section 2 below. Instructions are included on the DRRFs.

[1] "Data Privacy Safeguard Program Information Security and Privacy Best Practices" listed under Additional Resources published on https://www.resdac.org/resconnect/articles/158

2-1. Physical Possession and Storage of Data Files

Include specific references to the Data Governance and Protection policies and procedures documents filed with this application under Attachments 2 and 6 in your responses to the items below. ***Do not simply cite a cross-reference to the policy and procedure documents in lieu of answering each question.***

2-1-1. Describe how your organization will maintain an accurate and timely inventory of the VHCURES limited use research data set including original files received and any derived files used within your organization or released to external agents under state contracts and agreements.

Files are only accessible upon request and approved if part of project. Files shall not leave Amazon Web Services (AWS) cloud.

2-1-2. Describe how your organization will ensure and monitor the compliance of all members of research teams both in-house and those employed by approved external agents with privacy and security policies and procedures as described in the documentation filed under Attachments 2 and 6 to this application and as required by the DUA.

Access is only granted to those working with this project (listed in Section 3-4) by administrators upon request and approval. An Individual User Affidavit must be signed before access can be granted. Audits are done to check procedures and policies are followed.

2-1-3. Describe the procedures your organization will take to track the status and roles of the research team and notify GMCB of any project staffing changes.

The status and role of each member of the research team is based on the minimum necessary amount of data access required to carry out legitimate job responsibilities assigned to the member's job. All access requests are treated on a "least-access principle." Security team will approve access to the VHCURES data set as dictated by the employee's job title. If additional access is required outside of the minimum necessary to perform job functions, the requester must include a description of why the additional access is required as part of the access request. Staffing changes will be logged and forwarded to the GMCB upon request.

2-1-4. Describe your organization's training programs that are used to educate staff on how to protect sensitive data with personally identifiable information, protected health information, and other sensitive financial, socioeconomic, and personal information.

Security Awareness training is performed upon hire and at least once a year thereafter to all Archway employees. Employees are required to certify completion and understanding of the training.
Archway Health training programs instruct employees to follow CMS DPSP Information and Security Best Practices for protecting Personally Identifiable Information (PII), Protected Health Information (PHI), Customer Information by:

- securing personal accounts and devices used for accessing sensitive and encrypting communication including requiring 2 Factor Authentication.
- discouraging the transmission PHI data whenever possible and requiring encryption when it is necessary
- requiring access to data is granted only through formal request which must be approved by supervisor and security team and then tracked to insure compliance with data management policies.
- understanding and incorporating the concepts and requirements of Encryption at Rest and in Transit

2-1-5. Describe the protocol that would be followed by your organization or that of approved external agents, if applicable, to report and mitigate a breach in the security of the data set. Who will be responsible for notifying the GMCB (and CMS as applicable to Medicare data available only to Vermont State Agencies and agents of the State) of any suspected incidents of a breach in the security of the VHCURES data?

Protocol is to inform Archway Security Team, which will first assess, respond in some cases, and notify necessary parties. This is the same protocol we use throughout the organization for all sensitive information, regardless of origin.

2-1-6. What actions will your organization and approved external entities take to physically secure the data files? This includes files in motion, or on servers, local workstations, and hard media.

Data will be stored in Amazon Web Services (AWS) cloud using Simple Storage Service (S3) and Elastic Block Storage (EBS) volume when processing the data. Regardless of storage, data is always encrypted at rest (AES-256) and in transit (TLS1.1+ or other secure protocols, as needed, for example SSH).

2-1-7. Please explain if your organization intends to transmit, store, or transfer the data set or any derived files outside the continental United States.

No, Archway Health Advisors, LLC does not intend to transmit, store, or transfer the data set or any derived files outside the continental US.

2-2. Data Sharing, Electronic Transmission, Distribution

Include specific references to the Data Governance and Protection policies and procedures documents filed with this application under Attachments 2 and 6 in your responses to the items below. ***Do not simply cite a cross-reference to the policy documents in lieu of answering each question.***

2-2-1. Describe what your organization's policies and procedures will be for sharing, transmitting, and distributing the VHCURES data set and any derived files.

The VHCURES data set and any derived files will be transmitted and stored securely:

- AES-256 encryption is used to store objects on AWS Simple Storage Service (S3). S3 is used to store data in the long term (e.g. to provide Data Custody for Customers).
- AWS IAM Rules are in place as a deny-by-default access for S3. Only approved Archway Employees are granted access.
- AWS Elastic Block Storage (EBS) Volumes are encrypted prior to storing Sensitive Information. EBS is used to store data temporarily (e.g. to run data analysis).
- Google Drive can be used to store Sensitive information. Google Drive is HIPAA compliant and Archway signed a BAA with Google.
- Encryption (BitLocker for Windows, FileVault for Mac) is used on any computers storing Sensitive Information, even temporarily.
- HTTPS/TLS is used to transmit Sensitive Information.

Permissions to the VHCURES data set will only be granted to those working directly with projects which require access. An Individual User Affidavit must be signed before access can be granted. The VHCURES data set will NOT be shared, transmitted or distributed to:

- Employees not directly involved with projects requiring the data
- Contractors
- Third party vendors

2-2-2. The GMCB's preferred method of transmission of the data files is through a secure File Transfer Protocol (SFTP) transmission. If you anticipate requesting encrypted hard media, please explain the reasons that SFTP is not an option.

We will use SFTP for the data transmission.

2-2-3. Would your organization and approved external agents be interested in accessing a hosted data enclave or a researchers' workbench environment eliminating the transmission of data

files via SFTP or via encrypted hard media outside of the hosted enclave? If yes, would the interest hold if there are fees for this service? If not interested at all or cautious, please explain your concerns.

No.

2-2-4. Describe your organization's methods and those of approved external agents for tracking, monitoring, and auditing access and use of sensitive data such as the VHCURES data set.

Access to VHCURES data set is controlled using centralized user management and authentication. Access to Archway Platform systems and applications is controlled by requiring unique User Login IDs and passwords for each individual user and developer. The level of security assigned to a user of the organization's information systems is based on the minimum necessary amount of data access required to carry out legitimate job responsibilities assigned to a user's job classification. All access requests are treated on a "least-access" principle. All access to Archway systems and services are reviewed and updated on a regular basis to ensure proper authorizations are in place commensurate with job functions.

2-2-5. Describe the policies and procedures and procedures your organization and approved external agents use to define data access privileges for individual users of the data, including the Principal Investigator, Data Custodian, analysts and researchers, administrative support, and IT support.

Only employees assigned to specific projects and approved by supervisor will be granted access to the VHCURES data set.

2-2-6. Explain the use of technical safeguards for data access (which may include password protocols, log-on/log-off protocols, session time out protocols, and encryption for data in motion and data at rest).

Keys and/or passwords are necessary to access data. Interactive sessions time out between 20-30 minutes of idleness. Encryption is used at all times, in transit and at rest.

2-2-7. If approved external agents will have access to the data please describe how that organization's analysts will access the data file, e.g., VPN connection, travel to your organization, or house the data at other locations.

There won't be external agents access to the data for this project.

2-2-8. If additional copies of the data will be housed in separate locations, list the locations and describe how the data will be transferred to these locations.

No additional copies of the data housed in separate locations.

2-3. Data Reporting and Publication

2-3-1. Explain your process for reviewing publications prior to dissemination to ensure accurate and appropriate representation of your data sources, analytic methodology, results, caveats, and disclaimers. Describe how your publications will be reviewed to ensure compliance with requirements in the DUA addressing small n suppression, disclaimer of any GMCB endorsement of findings, and data source citation.

We won't be publicly disseminating this data on any public websites initially. We will leverage the findings to identify high value specialists and will confer with GMCB once the analysis is complete to determine the best method to share the findings.

2-4. Completion of Research Tasks and Data Destruction

2-4-1. Describe how you will complete the Certificate of Data Destruction for the data set and derived files stored by your organization or by approved external agents and how the data will be deleted, destroyed or rendered unreadable by all parties with access to the files upon completion of the project.

Data stored on AWS S3 will be deleted. Data will be deleted from EBS volumes. Cryptographic Erase (CE, NIST 800-88) or sanitization (NIST 800-88, DoD 5220.22-M) may be used if storage are being decommissioned.

2-4-2. Describe your organization's policies and procedures and those of external agents used to protect VHCURES data files when individual staff members of research teams terminate their participation in research projects (which may include staff exit interviews, return of passkeys, and immediate access termination for example).

Depending on the circumstances, access is revoked before or upon termination. Devices used by personnel are then sanitized.

2-4-3. Describe your organization's policies and procedures to ensure original or derived data files, including non-published aggregate reports, are not used following the completion of the project.

Derived data files, including non-published aggregate reports are deleted/destroyed upon completion of dependent projects.

Section 3: Project Team

In Section 3-4, list the anticipated individual users within your organization and external agents such as contractors and subcontractors, and project roles. **Signed IUAs for individual users within your organization and those employed by external entities accessing the data must be filed prior to receipt of the VHCURES data set and on an ongoing basis as project staffing may change.**

3-1. Authorized User (Can legally bind the applicant's organization to agreements)

Please provide contact information for the Authorized User's signatory.

Name and Title of Signatory for the Authorized User		
Jun Wang, Principal Data Scientist		
Organization Name		
Archway Health Advisors, LLC		
Street Address		
545 Boylston Street, 10th floor		
City	State	Zip
Boston	MA	02116
Telephone	Email	
617-209-7985	info@archwayha.com	

3-2. Principal Investigator

Please provide contact information for the PI if different person than the AU.

☒Same as Authorized User Signatory

Name and Title of Principal Investigator 1		
Organization Name		
Street Address		
City	State	Zip
Telephone	Email	

3-3. Data Custodian(s)

Provide contact information for the data custodian for your organization and the data custodians for any external agents such as state contractors, subcontractors or other organizations that will storing the VHCURES data set or derived files.

Name and Title of Data Custodian		
Luke Pezet		
Organization		
Archway Health Advisors, LLC		
Street Address		
545 Boylston Street, 10th floor		
City	State	Zip
Boston	MA	02116
Telephone	Email	
(646) 724-0548	lpezet@archwayha.com	

3-4. Individual Users

Identify all individuals within your organization and external agents who will be participating on this project. These individuals may be project managers, analysts, IT professionals, or any other person who may have access to row-level data or aggregate reports prior to the suppression of small n. You must attach a signed individual user affidavit for each of these individual users prior to the receipt of the data after the DUA is approved including any users not identified on this list when this application was submitted.

Name	Organization	Project Role or Title
Jun Wang	Archway Health Advisors, LLC	Principal Investigator
Yuze Shang	Archway Health Advisors, LLC	Data Analyst
Luke Pezet	Archway Health Advisors, LLC	Data Custodian

Section 4: Data Procurement and Price

The authorized user will receive the data from the GMCB's designated data processing vendor for a fee determined by the number of years of data and whether any complex customization is required. The authorized use may contact the vendor in advance to confirm the exact pricing that generally runs about $5,200 for an extract of paid claims data spanning five (5) years. Prices are subject to change.

In the future, the GMCB may be offering access to the data through a hosted data enclave. This would eliminate or be an additional option for accessing the data via electronic SFTP transmission of the record-level data. GMCB will notify the authorized user for the DUA when this service becomes available as an option and how it will work as to number of user seats and pricing.

There may be fees for custom extracts. Typically, custom extracts are generated to support the data stewardship principle of disclosing the minimum necessary data to support the research purpose. Data users may be authorized to access a secured data enclave hosted by the vendor. Use of services provided by the GMCB's data consolidation vendor may require payment of a fee to the vendor. Fees will be determined on a case-by-case basis. Onpoint Health Data will manage any invoicing for fees.

The GMCB's designated vendor for the VHCURES Limited Use Research Data Set is:

Onpoint Health Data

Mailing Address:
75 Washington Avenue, Suite 1E
Portland, ME 04101

Physical Address:
55 Washington Avenue
Portland, ME 04101

Main Phone: (207) 623-2555
www.onpointhealthdata.org

Section 5: Data Transmission and Receipt

Use of an electronic secure File Transfer Protocol (SFTP) is the preferred mode of release for approved data extracts. Onpoint Health Data, the GMCB's data consolidation and warehousing vendor will provide an "Electronic Data Transmission Readiness and Logistics Checklist" to assist you in determining whether you are able to receive the transmission.

Please identify your primary contact below for setting up the logistics for SFTP transmission of the approved data extract. The primary contact must either be the Authorized User or Principal Investigator or Data Custodian identified on the DUA or be designated by the AU or PI.

As noted under Section 4, the GMCB may offer access to the data via a hosted data enclave in the future. Authorized users will be notified when this service becomes available.

Primary Contact for Planning Data Transmission Logistics

Name: Luke Pezet
Title/Role in the Project: Data Custodian
If not AU, PI or DC, designated by:
Email Address: lpezet@archwayha.com
Phone Number: (646) 724-0548
Organization/Agency Affiliation: Archway Health Advisors, LLC
Street, City, ZIP Address: 545 Boylston Street, 10th floor. Boston, MA 02116

Section 6: Signatures

All statements made in this application are true, complete, and correct to the best of my knowledge.

Authorized User Name: Jun Wang

Signature:	Date: 5/31/2019

Principal Investigator 1 Name (if different from Authorized User)

Signature:	Date:

Principal Investigator 2 Name:

Signature:	Date:

GMCB Processing Section

For GMCB Use Only

Date Application Deemed Complete:

DVHA Application Approval Date:

GMCB Application Approval Date/GMCB Initials:

Date Applicant Notified of Approval:

Application Disapproval Date:

Date Applicant Notified of Disapproval/GMCB Initials

Summary of reasons for disapproval: