

GMCB VHCURES Data Use and Disclosure Manual

This Manual specifies the procedures for the submission and review of applications for data from the VHCURES data set, limitations on the availability of such data, and requirements that persons seeking or receiving such data must comply with to ensure that the privacy and security of the data is maintained.

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Introduction

The Green Mountain Care Board (GMCB) has statutory responsibilities to collect and manage health insurance claims and other types of health data to the extent allowed by the federal Health Insurance Portability and Accountability Act (HIPAA 1996 and regulations) to support the continuous review of health care utilization, expenditures, and performance in Vermont. GMCB must protect personal health information while ensuring access to the detailed data for approved researchers to perform analyses and reporting that provide public benefits. GMCB implements policies and procedures to prevent misuse of the data and reduce any chance that the personal identity of individuals would be disclosed. GMCB established the Data Governance Council (“the Council”) to address protection of privacy and to ensure appropriate use of its health data resources. In addition, the Council focuses on the continuous improvement of data quality and utility and the financial sustainability of the GMCB’s data programs.

The GMCB executes data use agreements (DUA), which are legal agreements between data users and the GMCB, to bind data users to requirements addressing compliance with approved uses and the protection of the confidentiality of health data. This manual describes the policies and procedures designed to balance data protection with facilitating access to the data to fulfill GMCB’s statutory responsibilities and to provide public benefit.

In addition to federal and state laws and regulations addressing protected health information (PHI), the procedures in this manual recognize the applicability of the Information Security and Privacy Best Practices published by the Data Privacy Safeguard Program of the federal Centers for Medicare & Medicaid Services (CMS).¹ GMCB is bound to requirements under its DUA with CMS addressing the use and disclosure of Medicare data encompassing Vermont Medicare beneficiaries and providers of services to Vermont beneficiaries.

Scope and Applicability

GMCB is responsible for the acquisition, management, use, and disclosure of several types of health data. This manual focuses on the Vermont Health Care Uniform Reporting & Evaluation System (VHCURES) which is Vermont’s all-payer health care eligibility and claims data set. This manual will be updated as needed to address future changes in the VHCURES program and in state and federal laws and regulations pertaining to protected health information (PHI) and personally identifiable information (PII).

This manual provides information pertaining to requirements to protect individuals’ personal health information and other types of sensitive information. A flow chart of the process for requesting and obtaining data use agreements is available for reference on GMCB’s website.² This manual also addresses policies and procedures that are in place to ensure that data uses are in alignment with

¹ “CMS’s Data Privacy Safeguard Program (DPSP)” <https://resdac.org/articles/cmss-data-privacy-safeguard-program-dpsp>

² <https://gmcbboard.vermont.gov/data-and-analytics/data-governance>

GMCB's statutory responsibilities and with the data stewardship principles and policies of the GMCB Data Governance Council.

The GMCB and its designated data aggregation vendor(s) and authorized data users are responsible for compliance with the laws, regulations, principles, policies, and procedures referred to in this manual. Data users and data services vendors who fail to adhere to federal and state provisions for protection of PHI and PII who act in a manner that is willful or negligent are subject to revocation of access to VHCURES data, enforcement actions, and possible sanctions and penalties as stipulated in federal and state laws and regulations.

GMCB Health Data Statutory Requirements

Under 18 V.S.A. Sections 9405, 9410, 9453, and 9454, GMCB has broad authority and responsibilities to maintain a health care database that includes both hospital- and insurer-reported data submitted in uniform formats and has requirements to analyze health care resources, expenditures, and utilization. GMCB is the steward of several data resources for the State of Vermont, including the Vermont Health Care Uniform Reporting and Evaluation System (VHCURES) that includes eligibility and claims data for Vermont residents. This data resource support analyses and reporting pertaining to State responsibilities and activities in health care regulation, evaluation, and innovation.

Vermont law (18 V.S.A. § 9410) mandates that, to the extent allowed by the Health Insurance Portability and Accountability Act (HIPAA) – the federal privacy rule – and under state laws and regulations addressing the protection of personal and economic information, VHCURES is to be made available to the public to continuously review health care utilization, expenditures, and performance in Vermont. The data resource may be made available in the form of record-level data sets, analytical tables, or in published reports that summarize and interpret the findings derived from data analysis. The statutory mandate for the GMCB to collect commercial insurance enrollment and claims data currently includes comprehensive major medical health benefit plans that may be insured or self-insured, Medicare Supplement, and Medicare Parts C and D.

The State of Vermont cannot compel federal government programs to submit data to VHCURES. The voluntary participation of the federal Centers for Medicare and Medicaid Services (CMS) in contributing Medicare data to VHCURES occurs under a DUA between CMS and GMCB. VHCURES does not include data for Vermont veterans covered by CHAMPUS and Tricare or for Vermont residents enrolled in the Federal Employees Health Benefit Plan (FEHBP). Vermont's Medicaid program contributes data to VHCURES under a memorandum of understanding between the Department for Vermont Health Access (DVHA) and GMCB.

Based on a decision by the U.S. Supreme Court in 2016, the GMCB cannot compel self-funded ERISA health plans (Employee Retirement Income Security Act of 1974) to submit data to VHCURES for Vermont residents (See *Gobeille v. Liberty Mutual Co.*)³ ERISA plans may voluntarily contribute data and some ERISA plans have continued to contribute data to VHCURES.

³ <https://www.oyez.org/cases/2015/14-181>

GMCB Data Governance and Stewardship

GMCB's Data Governance Council, through its Data Governance and Stewardship Charter, provides guidance and leadership, and makes decisions on data use and disclosure, risk pertaining to data protection and security, data quality and utility, and financial sustainability of the GMCB's data programs.⁴ The Council has established Data Stewardship Principles and Policies to guide its decision-making.

The goal of this manual is to ensure that data use and disclosure policies and procedures are implemented to support research and analyses that benefit the public while safeguarding protected health information and other sensitive personal and economic information from unauthorized and inappropriate disclosure.

Data Use and Disclosure Requirements

Federal and State Laws and Regulations

The Green Mountain Care Board's mission is to improve the health of Vermonters through a high-quality, accessible, affordable, and sustainable health care system. GMCB is an independent five-member Board whose members are appointed by the Governor for six-year terms. The Board was created by the Vermont Legislature in 2011 through Act 48, Vermont's landmark health reform legislation. Under 45 CFR 164.512(d), as a health oversight agency, GMCB may receive disclosures of protected health information from covered entities, as defined in HIPAA, without obtaining consent, authorization, and without providing an opportunity to agree or object from the person who is the subject of the information.

Since the VHCURES data program is administered by GMCB, a government agency, some requestors may view the record-level data as public information that should be released in response to requests for disclosures under the Vermont Public Records Act. However, gaining access to certain levels of granular data may be prohibited due to federal and state requirements to safeguard the privacy of protected health information (45 C.F.R. sections 164.308 (administrative safeguards), 164.310 (physical safeguards), 164.312 (technical safeguards), and 164.316 (policies and procedures and documentation requirements)). GMCB must strike a balance between disclosing data to support research and the protection of the identity of individuals and their protected health information.

Additionally, GMCB must prevent uses of the data and public reporting that would violate federal anti-trust provisions protecting the information of health insurers and health care providers deemed proprietary in that it includes trade secrets (See 1 V.S.A. § 317(c)(9)). Within the restrictions of the disclosure requirements pertaining to protection of personal privacy and trade secrets, GMCB has broad discretion under 18 V.S.A. § 9410 to disclose the commercial insurer data but has constraints and conditions pertaining to the use and disclosure of Medicaid and Medicare data.

⁴ http://gmcbboard.vermont.gov/sites/gmcb/files/files/data-governance/GMCB%20Data%20Governance%20Charter%20-%20v1.4.3_APPROVED03.14.2018.pdf

Medicaid Data Use and Disclosure Requirements

In 2016, the Agency of Human Services (AHS) designated the Department of Vermont Health Access (DVHA) to execute a Memorandum of Understanding (DVHA MOU # 03410-01-17) with GMCB wherein DVHA provides claims and enrollment data to the GMCB to carry out its duties under 18 V.S.A. § 9410. Under the MOU, GMCB may use and disclose the Medicaid data in the performance of its statutory responsibilities addressing appropriate uses of its health data resources including health insurance claims data.

GMCB obtains prior written consent from DVHA before disclosing the Medicaid data to any Vermont state agencies or non-state entities requesting a VHCURES DUA. After a Vermont state agency or non-state entity executes a DUA with the GMCB that includes the Medicaid data subset, GMCB reviews and makes decisions on requests for redisclosures of the data to external agents including contractors, subcontractors, grantees, or sub-grantees performing work that is within the permissible scope of the DUA and is directed by the party holding the DUA.

CMS Medicare Data Disclosure Requirements Including Best Practices for Safeguarding Data Privacy

Under CMS Data Use Agreement #25534, GMCB is authorized to use Medicare data to examine health care access, utilization, expenditures, and system performance in a manner that ensures the security and confidentiality of the data through compliance with applicable law and data security standards. CMS granted GMCB the discretion to re-disclose the Medicare data to other Vermont state agencies for research projects and any entities performing research that is directed and partially funded by the state.

GMCB requires Vermont state agencies and other entities requesting to perform state-directed and funded research to provide documentation in the DUA applications describing policies and procedures for data security and protection of privacy that align with federal policies and standards. GMCB recognizes that the CMS Data Privacy Safeguard Program⁵ provides guidance on standards and best practices for security and protection of health and personally identifiable information.

Under DUA #25534, CMS requires GMCB to file quarterly reports identifying state agencies and agents to whom the Medicare data have been disclosed, for what purpose it is being used, individuals accessing the data and their roles in the research endeavor, and all locations and media being used for storage and use of the data. State agencies and authorized agents who do not comply with timely and complete filings of quarterly data tracking information as specified by GMCB risk revocation of the DUA and forfeiture of access to the CMS Medicare data.

DUA applicants are required to file documentation describing policies and procedures for data governance and protection with DUA applications and requests for data redisclosures to external agents during the term of a DUA. The GMCB advises that all applicants review the best practices published by the CMS Data Privacy Safeguard Program as an example of the minimum expectations for data security and protection for all users of GMCB's data.

⁵ <https://resdac.org/articles/cmss-data-privacy-safeguard-program-dpsp>

Categories of Data and Information

VHCURES data and information are categorized along a spectrum of risk for re-identification of individuals and disclosure of information that may be considered proprietary for insurers and providers. This section provides a description of the level of risk that release of the data would pose for identification of individuals and disclosure of proprietary or other sensitive information data. A guiding principle for use and disclosure of data and information is “minimum necessary” which is described as the minimum number of individuals, data elements, records, and derived information that is necessary to achieve the research purpose.

Unrestricted Public and General Use Data

Public use data and reports pose the lowest risk for re-identification of individuals or for disclosure of other sensitive information about insurers and providers. Data, analytic tables, and reports may be considered de-identified, meaning that enough personally identifiable information, including both direct and indirect identifiers, is removed or obscured. There is no reasonable basis to believe that the public use information can be used to identify an individual or detailed information about insurers and providers that could be deemed proprietary.

Public use data and reports include only “publicly available” data and information. See the GMCB website⁶ for a schedule of available data elements designated as either “publicly available” or as “restricted.”

Examples of Permissible Public Reporting:

- Summarized utilization and amount paid information by age groupings only, no single year ages.
- Reporting by pre-specified geographic regions with populations over 20,000 as the denominator.
- Treatment and procedures assigned to broader health services categories.
- No full dates of service but reporting by months or calendar quarters depending on volume of services and denominators.
- Primary diagnoses and conditions grouped into broad diagnostic or condition categories.
- Either paid amounts or charge amounts at the procedure level by insurer and/or provider types
- Payer type only with no reporting at the individual commercial insurer level

Restricted Data for Limited Use

Under GMCB’s Data Release Rule, selected data elements are designated as “restricted.” Restricted data elements used in combination with other data could result in the indirect or direct identification of individual patients, members, enrollees, or beneficiaries. Restricted data elements could also be used to generate information about insurers and providers that could be deemed proprietary. Public disclosure that could result in the identification of individuals or proprietary information about insurers and providers is prohibited under state and federal laws and regulations. Examples of

⁶ <https://gmcbboard.vermont.gov/data-and-analytics/data-governance>

restricted data elements include member ZIP codes, plan-specific contract numbers, and full dates of health care services and prescription fills, and combined availability of charge amount and paid amount by individual treatments and procedures, by individual insurers to individual providers.

A requestor may apply for a DUA with GMCB for access to a limited use data set that includes restricted data elements required to support a specific research purpose. Limited use data sets are available only if approved by GMCB to be in use under a DUA for a specified term with an expiration date.

A requestor may apply for a DUA with GMCB for access to analytic tables that include restricted data elements required to support a specific research purpose. As approved for internal use but not for public disclosure by GMCB, the tables can include restricted data elements and small cells that do not suppress for <11 cases or other details that may not be publicly disclosed. Upon request and approval from GMCB, analytic tables may be generated by GMCB or by the GMCB's data aggregation vendor. Decisions about whether and by whom the analytic tables would be generated are based on feasibility, complexity, and availability of GMCB staff or vendor resources. Decision making about whether to develop and publish analytic tables considers technical complexity, staffing resources, and whether the requested work provides public benefit. Fees may be required if technical support from a vendor or consultant is required to support the work.

Data Unavailable for Disclosure

Data elements categorized as unavailable for disclosure may include indirect or direct personally identifiable information (PII) that could include demographic information such as full date of birth and race/ethnicity that could be used to identify individuals in small or sparsely populated areas or names, full street addresses, social security numbers, and other information not currently collected in VHCURES. Indirect or direct PII could be used to link identified individuals to their protected health information (PHI) in the claims data or with clinical data from other sources. As permitted under State regulations, the collection of this information could be expanded in the future.

Under State regulations, the identity of individual providers of abortion-related services cannot be disclosed from the VHCURES medical or pharmacy claims data. The same prohibition applies to disclosing the identities of employers and purchasers of employment-based health benefits whose information resides in GMCB's secured data processing system. A subset of employers are sole proprietors whose names could be linked with their PHI that resides in VHCURES.

Other types of data unavailable for release include data elements solely needed for internal data processing that are of no value to researchers approved to use the VHCURES data.

Categories of Data and Information Users

To support a framework for organizing policies and procedures for data use and disclosure, there are three categories of data and information users including: 1) Vermont state agencies, 2) non-state entities, and 3) the public at large. There are multiple subtypes of users within the category of non-state entities. The subtypes of non-state entities are relevant to the process of reviewing requests and applications for DUAs.

There are common themes and requirements that cross all categories of data and information users including: data security and protection of individual privacy; alignment with GMCB's statutory

responsibilities pertaining to its data resources and services; and compliance with GMCB's principles, policies, and procedures for data governance and stewardship.

Vermont State Agencies

A Vermont state agency may request a "broad use" DUA that permits access to a comprehensive limited use data set with an initial term of two (2) years with an option to renew. A comprehensive limited use data set includes commercial, Medicaid, and Medicare data, including all restricted data elements. Under a State Agency DUA, the data are available to individual agencies and approved external agents including contractors, subcontractors, grantees, and sub-grantees performing work directed and partially funded by the State of Vermont. Vermont state agencies may use the data for multiple research purposes under the umbrella of the broad use project description as described in the DUA application.

Non-State Entities

Non-state entities are defined as agencies and organizations that do not meet the criteria to be defined as a Vermont State Agency. A non-state entity may apply for a "limited use" DUA that permits access to a limited use data set for the term of a project as approved by GMCB. Non-state entities are required to file a preliminary data request and get approval from GMCB to file a full DUA application. A non-state entity may request an extension of the term or end date for a project but must file a new DUA application for any substantive proposed change in the research purpose and use of the data.

A limited use data set available to non-state entities may include commercial and/or Medicaid data depending on the proposed research purpose. Medicare data is only available to Vermont state agencies and external agents performing work that is directed and partially funded by the state. Non-state entities with access to Medicare data must only be contractors, subcontractors, grantees, or sub-grantees performing state-directed and partially funded work under signed contracts or other formal agreements with Vermont state agencies. Formal signed agreements between Vermont state agencies and non-state entities are not always contracts. Contractors for the federal government are categorized as non-state entities.

A limited use data set may include "restricted" data elements that are relevant to the research purpose and as approved for use by GMCB in a DUA. Non-state entities must request and provide a justification for each restricted data element applying the principle of "minimum necessary data" to support the research purpose.

Organizations that are types of non-state entities include:

- Federal or state government agencies outside of the State of Vermont
- Academic institutions (except for the University of Vermont)
- Non-profit research organizations
- Participants in the Vermont health care system financing, insurance or delivery system with direct impacts on the Vermont population (except for Vermont State Agencies such as the Department of Vermont Health Access for Medicaid and other agencies providing direct benefits and services to Vermont residents)
- Participants in health care financing, insurance or delivery systems outside of Vermont

- Health care enterprises such as manufacturers or distributors of pharmaceuticals and medical technologies; designers and developers of health systems, services, and facilities.

Public at Large

GMCB develops and publishes interactive and standard reports for public disclosure. The interactive and standard reports aggregate and summarize data in order to pose no risk of disclosing the identity of individuals or information about insurers and health care providers considered proprietary. Public reports and associated data will be widely accessible via on-line postings by GMCB.

Modes and Cost for Data and Information Access

Public use data analytic tables, and reports are generated by GMCB based on feasibility, utility, and adequate availability of staff resources and will be made available to the public at large in web-based, electronic format.

Approved data users of limited use data sets and analytic tables that include restricted data elements primarily access authorized data and analytic products via a secure file transfer protocol (SFTP), or secure analytic environment, initiated by either GMCB's data aggregation vendor or directly by GMCB. Vermont State Agencies with DUAs are not charged any fees for approved data extracts generated by GMCB's data aggregation vendor. Under interagency memoranda of agreement or understanding, other Vermont state agencies may provide funding to GMCB to cover the costs associated with the GMCB's development and generation of analytical products.

Approved non-state entities receiving a raw data extract consolidated file with up to 5 years of eligibility and paid claims data for medical and prescription drug services pay fees directly to the GMCB's data aggregation vendor. Pricing is set directly by the vendor and is subject to change.

Application Process

Application Process for all Applicants

State Agencies, as well as non-state entities that are invited to apply, submit a full DUA application to the GMCB. GMCB staff must deem the 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 the 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 the application. Applicants must file Individual User Affidavits (IUA) signed by the Authorized User (AU) or Principal Investigator (PI) for all data users listed on the 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 conducts a DUA review and approval process that may involve DVHA review for Medicaid data and other Vermont state agencies involved in approving state contracts and agreements. Medicaid requests may also require IRB review through the Vermont Agency of Human Services. The application review process may include a review by the GMCB Data Governance Council at a public meeting. The GMCB has the discretion to approve or disapprove applications for a DUA.

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. 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.

Additional Application Processes for Non-State Entity Applicants

VHCURES Preliminary Data Request

Non-state entities begin the application process by completing and submitting a VHCURES Preliminary Data Request to gmc.data@vermont.gov. The purpose of this request is to determine if the intended use of the data and a few other factors make the project appropriate for an application for a DUA. GMCB reviews the request, and if it is determined that the project description may fall within appropriate use, GMCB will send the applicant the full DUA application. Commercial and Medicaid eligibility and claims data are available, however, non-state entities shall not receive access to Medicare data under any circumstances. Completion of this form does not guarantee that GMCB will permit a requestor to proceed with the application process for a VHCURES DUA. In addition to a review by GMCB data program staff, requests may also be reviewed with GMCB executives and the Council. GMCB will notify all requestors regarding decisions on requests including explanations for disapprovals to proceed with filing DUA applications. GMCB will provide an

application with full instructions to requestors approved to proceed with filing a Non-State Entity DUA Application.

Filing Data Use Agreement Applications

A non-state entity may file a DUA application after the GMCB has reviewed the Limited Use Data Preliminary Request and approved the entity to proceed with filing a Non-State Entity DUA Application. The major difference between the Vermont State Agency DUA Application and the Non-State Entity DUA Application is that the non-state entity applicant must file a Limited Use Research File Specification with their applications wherein the applicant files a request and justification for using restricted data elements, requesting only the minimum amount of data necessary to achieve the purposes described in the application.

The term limited use has a specific meaning for non-state entity DUAs in that the research purpose may not be open-ended or ambiguous but must be very specific in identifying the research purpose, objectives, and have a time-limited term that includes an end date for the agreement. However, non-state entities may request to extend the term of a DUA if only the date changes, but the research purpose does not change.

GMCB will maintain data release requirements for data use and disclosure that are designed to balance data protection with data access. Data release considerations will include the following criteria:

- the competency and expertise of requestors to conduct the proposed study;
- that requestors provide information regarding the source of funding;
- that requestors provide a compelling argument justifying access to the data set and its relationship to stated objectives; and,
- intended use, including a focused review of the potential commercial nature of the request.

Requirements for DUA Management

Authorized User Responsibilities

The Authorized User (AU) is typically a person in leadership of an organization or agency. The AU signatory on both the Application and the DUA must have the authority to sign legally binding agreements on behalf of the organization or institution. The AU must have the authority to legally bind the agency or organization to the requirements of the DUA. In the case of a change in PI, the AU must file a form that notifies GMCB of the change and includes an attestation of data destruction from the former PI.

Principal Investigator Responsibilities

GMCB requires every Vermont state agency and non-state entity granted a DUA to designate at least one Principal Investigator (PI) who is responsible for ensuring the compliance of all data users within the organization and those employed by external agents with the requirements of the DUA. The PI(s) are designated by the AU to ensure that the agency or organization stays in compliance with the DUA through assumption of responsibilities that include approving and monitoring access of individual users to the data and compliance of the individual users with DUA requirements and state and federal laws and regulations that address the protection of confidential information. PIs work with

data users to identify and clarify requirements of the DUA and consult with GMCB as needed. PI responsibilities include the following:

- PIs are required to archive signed Individual User Affidavits (IUA) for every data user participating on the project team prior to permitting access to the data set at the outset and for the duration of the DUA. This includes both data users within the PI's organization and those employed by external agents who have been approved by GMCB to use redisclosed data. In a format provided by the GMCB, PIs are required to file periodic reports with updated information identifying active and inactivated individual data users who have filed affidavits with the PIs.
- PIs are responsible for reporting any incidences of suspected or actual data breaches to GMCB and in the case of Medicare data, to CMS in cooperation with GMCB. PIs are required to cooperate with GMCB, and any other state and federal agencies involved in investigations and activities pertaining to data breaches.
- PIs review proposed reports or publications containing information derived from the limited use data prior to public disclosure. The PI determines whether the reports and publications meet the DUA requirements.
- PIs must file a Data Redisclosure Request and obtain approval from GMCB prior to redisclosing VHCURES data to external agents including contractors, subcontractors, grantees, or sub-grantees.
- PIs must file a Data Linkage Request and obtain approval from GMCB prior to permitting any linkage of VHCURES data with other external data sources that could result in the indirect or direct identification of individuals including patients, members, enrollees, or beneficiaries.
- PIs must file Certificates of Data Destruction for terminated users including both internal users and external agents during the term of the DUA and by the expiration date for a DUA. This includes all data sets and extracts derived from the tables stored in distributed data systems external to the Authorized User. PIs may consult with GMCB regarding requests to retain historic data and files beyond the expiration dates for DUAs and contracts.
- PIs are encouraged to participate in training sessions and periodic meetings organized and scheduled by GMCB to maintain a clear understanding of their responsibilities pertaining to safeguarding the use and disclosure of the data obtained under a DUA.

Individual User Affidavits (IUA)

Every individual data user working under a VHCURES DUA must sign an Individual User Affidavit (IUA) agreeing to comply with the DUA requirements. This includes individuals who work within the agencies and organizations that hold the DUA and the project teams employed by any external agents approved by GMCB to use the data to perform work directed by the holders of the DUAs. The PI obtains the signatures and archives the IUAs.

DUA applicants must initially identify all data users on the project team on the DUA application and obtain signatures and archive the IUAs. In a format and schedule provided by GMCB, the PIs will provide periodic reports that update the roster of active and inactivated data users working under a DUA. This ensures that GMCB can track all data users and locations. When a DUA expires or members of the project team either within the agencies or organization are inactivated, this information is needed to monitor that data have been destroyed as required upon filing the Certificates of Data Destruction. Failure to maintain the IUAs and file the required individual data

user reports may result in revocation of the DUA including a requirement to destroy the data disclosed to the agency or organization under a DUA.

Data Linkage Requests

All data linkage projects utilizing GCMCB's data assets must be consistent with the DGC's and GCMCB's existing principles and policies that guide data use and disclosure decisions and must be consistent with the GCMCB's legal authority. If a data linkage is desired, the PI must file a Data Linkage Request Form with GCMCB for prior approval before attempting to link the VHCURES data with any external data sources that include direct personal identifiers or with any data sources wherein the linkage could result in the identification of individuals in the VHCURES data set. Unauthorized linking of VHCURES data with other external data sources without prior approval of GCMCB could result in forfeiture of the DUA. In considering data linkage requests the GCMCB will apply equivalent review protocols as established for GCMCB's limited use research data set Data Use Agreement applications. Data linkage applicants must secure approval from stewards of the data proposed to be linked with VHCURES in the form of a Memorandum of Understanding (MOU), IRB approval, or other written agreement. GCMCB reviews all requests—regardless of origin—to link GCMCB data assets with other data sources. Review of proposed data linkage projects will include assessment of the following criteria:

- purpose of linked data and outline of proposed procedures for data linkage.
- feasibility of data linkage.
- assessment of data quality of resulting linked data set, including whether research questions are answerable, the structure is satisfactory, and data are sufficiently robust to obtain the level of granularity necessary for analysis.
- legal and ethical limitations on uses of source data sets and linked data set.
- data security and data management.
- depth and breadth of privacy interests implicated by the request.
- qualifications and technical abilities of research team.
- ownership of and terms governing the relevant datasets.

Data Redisclosure Requests

The PI must file a Data Redisclosure Request Form with GCMCB prior to any redisclosure to external agents (contractors, subcontractors, grantees, and sub-grantees) of VHCURES limited use data or analytic files that include limited use or restricted data. GCMCB must approve all requests for data redisclosures prior to the redisclosures. PIs must obtain signatures from all individual data users on the project teams of external agents and file the updated information on the required GCMCB reports. An unauthorized data redisclosure to external agents without prior approval by GCMCB may be deemed a data breach requiring the filing of a Data Breach Incident Report. A data breach may result in revocation of the DUA and possible enforcement action.

Publication Review

The PI shall review any proposed report or publication containing information derived from the limited use data prior to public disclosure to confirm that the DUA requirements have been met. The PI may refer any questions to GCMCB. PIs must submit a request for review of the publication to GCMCB at least fifteen (15) days prior to the intended date of public disclosure for the publication. GCMCB may approve public disclosure without further actions, require that the AU and PI meet certain

conditions prior to public disclosure or completely disapprove the public disclosure of a publication. GMCB will provide a written explanation of conditions or disapprovals. The GMCB may revoke the DUA if the AU publicly discloses any report that GMCB has not approved for public disclosure.

State Agency DUA Renewal Request

GMCB allows Vermont state agencies to have an initial DUA term of two years. Prior to the two-year expiration date, Vermont state agencies may request to renew the DUA. The GMCB will notify each Vermont state agency 90, 60, and 30 days prior to the expiration date with reminders to file a State Agency DUA Renewal Request. State agencies will follow this protocol rather than file a DUA Term Extension Request as discussed above. If the state agency decides to retain the broad use project summary and general research purpose, the DUA renewal process will not require the filing of a new DUA application. Essential information in the existing State Agency DUA will be updated as needed and the same requirements for managing the DUA will continue in the usual manner as described in this section of the manual that may be revised and updated periodically.

DUA Term Extension Request

The PI must file a DUA Term Extension Request with GMCB to request a revised DUA expiration date that would lengthen the term of the DUA. A DUA extension does not include approval of requests to substantively change the research purpose, objectives, or specification for the limited use data set or analytic tables that include restricted data. If interested in substantively changing the research purpose, objectives, or limited use data set, the AU or PI for a Non-State entity DUA must first file a Limited Use Data Preliminary Request Form to gain approval to submit a new DUA application. Continued use of the limited use data beyond the expiration date for the DUA without approval of GMCB may result in possible enforcement actions and a ban on filing any future DUA applications.

Reporting and Managing Suspected or Actual Data Security Breach

The Authorized User (AU) and Principal Investigator (PI) on the DUA must immediately notify the GMCB at least by email notification via gmcg.data@vermont.gov whenever it suspects, detects, or knows that the limited use data set including limited use analytic tables have been accessed, used, or disclosed by employees of the agency or organization or by external agents and other parties in any ways that are not permitted by state or federal law or that otherwise violate the terms of the DUA. This includes unauthorized access to a hosted data enclave. GMCB will advise the PI on next steps for reporting and responding to an incident if that is deemed necessary.

If the suspected or actual breach includes Medicare data, the Authorized User and Principal Investigator on the DUA must report any release, disclosure, or publication of personally identifiable information (PII) from the Medicare data, including loss of these data or disclosure to any unauthorized persons, as a potential security or privacy breach to the GMCB and to the CMS Action Desk by telephone at (410) 786-2580 and by e-mail notification at cms_it_service_desk@cms.hhs.gov within one hour of the discovery of the breach. The AU and the PI must cooperate fully in GMCB security incident reporting and mitigation process.

Tracking Data Users and Uses

PIs are required to file periodic reports tracking authorized data users and uses in a format and on a schedule as required by GMCB. Data stewardship includes keeping track of all users and uses to ensure compliance with the requirements of the DUAs between authorized users and GMCB and between GMCB and CMS for the Medicare data. CMS requires that GMCB file quarterly reports on the users and uses of Medicare data. This tracking information is crucial for monitoring data destruction after DUAs and projects have expired. Failure to comply with this requirement may result in revocation of a DUA as well as continued access to the data including the historic data already acquired.

Certification of Data Destruction

Authorized Users and/or Principal Investigators (PI) must attest to the destruction of data within 30 days of the expiration of data use agreements, contracts, subcontracts, grants and other signed agreements under which the use of VHCURES data was authorized. If requested by the AU or PI, GMCB may grant exceptions through express written permission to extend the destruction period beyond 30 days. PIs are ultimately responsible for ensuring that Certificates of Data Destruction as provided by GMCB are filed attesting to the destruction of limited use data sets used both on internal systems and by external agents on their systems. Authorized data users must employ appropriate technology to ensure secure deletion or destruction the limited use data sets including originals, copies, off-site backup copies, and archived records. PIs must consult with GMCB regarding any requests to retain historic data and derived files beyond the expiration dates for DUAs, contracts, and agreements. Failure to comply with this requirement may result in enforcement actions, sanctions, and penalties and may compromise future access of violators to GMCB data resources.

Violations and Enforcement

GMCB is responsible for implementing enforcement action for negligent or willful violations of laws and regulations including the policies and procedures detailed in this manual pertaining to maintaining data security, protecting personal privacy, and using the data for purposes as authorized under DUAs. In the event the Authorized User, the Principal Investigator, and any authorized individual user fails to adhere to the terms of the DUA, GMCB and, when applicable, CMS, may pursue civil and criminal sanctions under applicable state and federal laws and regulations. Violators shall be subject to sanction by the Board as set out in 18 V.S.A § 9410(g).

Unauthorized use and disclosure of Medicaid information in VHCURES may result in civil and criminal penalties as set out in 42 USC §§ 1320d-5 and 1320d-6. The unauthorized disclosure of Medicaid information shall also be subject to legal sanctions that are imposed under State law as required by 42 CFR 431.301.

Authorized users and external agents approved to use CMS Medicare data under a VHCURES DUA are subject to federal enforcement actions and penalties specified in section 14 of CMS DUA# 25534 between CMS and GMCB. (Attachment 3, Section 14).

Data Users Support

GMCB provides opportunities and mechanisms for data users to stay updated on policies and procedures for use and disclosure of limited use data sets and to participate in the continuous improvement of the data programs through communication and consultation with GMCB and other data users, scheduled meetings and workgroups, participation in the Data Governance Council, and through other collaborative mechanisms supported by GMCB. Improving the protection, utility, quality, and accessibility of GMCB data resources depends on the engagement of and feedback from authorized data users. Data users are invited to provide feedback and can contact GMCB via gmc.data@vermont.gov.

Glossary of Terms

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.

CMS: Means the Centers for Medicare and Medicaid Services. This is the federal agency that runs the Medicare, Medicaid, and Children's Health Insurance Programs, and the federally facilitated Marketplace.

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 Redisdisclosure Request Form must identify and file contact information for their data custodian(s) with the GMCB.

Data Governance Council: The Data Governance Council is the committee established by the Board and given responsibilities for the Board's data governance program.

Data Redisdisclosure: Any Vermont state agency or non-state entity with a VHCURES DUA that intends to redisdisclose 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 Redisdisclosure Request Form (DRRF) with the GMCB for review and approval prior to the redisdisclosure. After the GMCB has reviewed a DRRF and approved redisdisclosure 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.

DVHA: Means the Department of Vermont Health Access that is responsible for the management of Vermont's publicly funded health insurance programs.

GMCB: Means the Green Mountain Care Board established in Title 18, chapter 220 of the Vermont Statutes Annotated with responsibilities for health care regulation, evaluation, and innovation.

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.

Personal Health Information (PHI): Means protected or personal health information. The federal Privacy Rule provides protections for personal health information held by covered entities and gives patients an array of rights with respect to that information. The Privacy Rule is balanced so that it permits the disclosure of personal health information needed for patient care and other important purposes. Covered entities are defined in federal rules as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which Health and Human Services (HHS) has adopted standards.

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.

VHCURES: the Vermont Health Care Uniform Reporting and Evaluation System (VHCURES) is the data set containing information related to eligibility, health care claims, and related data submitted by health care insurers to the GMCB, pursuant to 18 V.S.A. § 9410.