

GMCB VUHDDS Data Use and Disclosure Manual

This Manual specifies the procedures for the submission and review of applications for data from the Vermont Uniform Hospital Discharge Data System (VUHDDS), 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.

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 Uniform Hospital Discharge Data System (VUHDDS) which is Vermont’s hospital discharge data set. This manual also addresses policies and procedures that are in place to ensure that data uses are in alignment with GMCB’s statutory responsibilities and with the data stewardship principles and policies of the GMCB Data Governance Council. This manual will be updated as needed to address future changes in the VUHDDS program and in state and federal laws and regulations pertaining to protected health information (PHI) and personally identifiable information (PII).

GMCB Health Data Statutory Requirements

Under the statutory authority to collect hospital discharge data (18 V.S.A. § 9410), 9456 and 9457, the Vermont Green Mountain Care Board (GMCB) administers the program, and the Vermont Department of Health (VDH) Division of Health Surveillance manages the data set under an agreement with the GMCB. VDH uses the Vermont Uniform Hospital Discharge Data System (VUHDDS) for analyses on utilization for the Vermont Hospitals Report.

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, VUHDDS 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.

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.¹ 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.

GMCB is the steward of the VUHDDS data system. 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.

Categories of Data and Information

This section provides a description of the categories of data available. 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.

¹ http://gmcbboard.vermont.gov/sites/gmcb/files/files/data-governance/GMCB%20Data%20Governance%20Charter%20-%20v1.4.3_APPROVED03.14.2018.pdf

Public Use Data Files

Public use data files 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, analytic tables, and reports include only “publicly available” data and information. See the GMCB website² for a schedule of available data elements designated as either “publicly available” or as “restricted.”

Limited Use Data

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 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.

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 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 inpatient, outpatient, and revenue data, including all restricted data elements. Under a State Agency DUA, the data are available to individual agencies and approved

² <http://gmcbboard.vermont.gov/health-data-resources/data-governance>

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.

State agencies may be able to receive access New York State hospital discharge data through an official New York Statewide Planning and Research Cooperative System (SPARCS) affidavit which must be completed and approved by the State of New York. Only Vermont state agencies are permitted access to out-of-state data.

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. 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 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.

Public at Large

GMCB develops and publishes a VUHDDS public use file. VUHDDS Public Use Files (VUHDDS-PUFs) are intended to support the study of health and health services in manners that serve the public interest and benefit Vermonters. As the steward of the VUHDDS database and the VUHDDS-PUFs, GMCB maintains data release requirements for data use and disclosure that are designed to balance data protection and privacy with data access. The VUHDDS-PUFs should be used to aid in evidence-based decision-making to plan and improve health service delivery, evaluate health care interventions and systems, and inform health policy decisions. Any uses that are inconsistent with these objectives are prohibited. VUHDDS-PUFs are available upon request. Prior to approval, requestors must agree to use the data only for statistical analysis and reporting, and to implement and maintain data security and privacy policies, procedures and associated physical, technical and administrative safeguards to prevent the inappropriate use or disclosure of individual(s) represented in the data, including when sharing information from and derivative works based on the VUHDDS-PUF with others. Requestors must also agree that they will not:

- a. Attempt to identify an individual patient or provider in the VUHDDS-PUFs;
- b. Disclose the identity of any individual(s) discovered inadvertently;
- c. Allow anyone other than the Requestor identified in this Agreement to access the VUHDDS-PUFs or the data contained therein;
- d. Use the data in the VUHDDS-PUFs for any purpose other than the purpose I identified in my request;
- e. Use the VUHDDS-PUFs for any purposes that are inconsistent with the intended uses set forth in introductory paragraph of this Agreement;
- f. Make any effort to determine identifying information about any reported case in the VUHDDS-PUFs;
- g. Link the VUHDDS-PUFs with any other data sets or databases;

- h. Use the VUHDDS-PUFs at any other location than that specified in the Organization Name and Address field in this agreement;
- i. Rent, lease, lend, sell, transmit, or otherwise distribute or dispose of the VUHDDS-PUFs temporarily or permanently without written consent of GMCB;
- j. Create or permit third parties to create derivative works based on the VUHDDS-PUFs;
or
- k. Sell derivative works based on the VUHDDS-PUFs.

Modes and Cost for Data and Information Access

Public use data analytic tables, and reports are generated by the Vermont Department of Health under a Memorandum of Understanding (MOU) with the GMCB. Upon approval of a VUHDDS data request, whether it is a public use file, or a restricted non-public data set approved for release under a DUA, the Vermont Department of Health prepares the requested VUHDDS file(s) and transfer the data via a secure Globalscape Workspace.

VDH may charge a processing fee to non-state entities for the cost associated with processing the approved data release, and the total fee will be determined by VDH. Vermont State Agencies with DUAs are not charged any fees for approved data files.

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 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 has approved the application. If approved by AOA, the GMCB and the applicant jointly enter into a DUA that is signed by the Authorized User, Principal Investigator, and GMCB. 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. An adverse decision regarding an application may be appealed to the GMCB.

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.
- 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 VUHDDS 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 VUHDDS 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 VUHDDS 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 GMCB's data assets must be consistent with the DGC's and GMCB's existing principles and policies that guide data use and disclosure decisions and must be consistent with the GMCB's legal authority. If a data linkage is desired, the PI must file a Data Linkage Request Form with GMCB for prior approval before attempting to link the VUHDDS 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 VUHDDS data set. Unauthorized linking of VUHDDS data with other external data sources without prior approval of GMCB could result in forfeiture of the DUA. In considering data linkage requests the GMCB will apply equivalent review protocols as established for GMCB'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 VUHDDS in the form of a Memorandum of Understanding (MOU), IRB approval, or other written agreement. GMCB reviews all requests—regardless of origin—to link GMCB 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 GMCB prior to any redisclosure to external agents (contractors, subcontractors, grantees, and sub-grantees) of VUHDDS limited use data or analytic files that include limited use or restricted data. GMCB 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 GMCB reports. An unauthorized data redisclosure to external agents without prior approval by GMCB 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 GMCB. PIs must submit a request for review of the publication to GMCB at least fifteen (15) days prior to the intended date of public disclosure for the publication. GMCB 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. 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 gmc.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.

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 VUHDDS 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 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).

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.

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 Rediscovery: Any Vermont state agency or non-state entity with a VUHDDS DUA that intends to redisclose the VUHDDS data set or any custom extracts of the data set to external agents to support projects approved under the DUA must file a Data Rediscovery 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.

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.

VUHDDS: Vermont collects and reports hospital discharge data in the Vermont Uniform Hospital Discharge Data System (VUHDDS) from all of Vermont's general acute care hospitals for Vermont residents and non-residents.