

Data Submission and Data Release Rules

April 21, 2021



Data Governance Council



The GMCB is the steward of VHCURES and several other data resources. In this role, the GMCB is responsible for a broad set of data management concerns. While not intended as an all-encompassing inventory, these concerns can generally be attributed to the following four categories:



The [Data Governance Council](#) is composed of seven voting members. The Council meets approximately every other month in an open, public meeting. Meetings are announced on the [Board's calendar of events](#) and meeting information for the Data Governance Council is publicly available.

Current Council Membership:

- Susan Barrett, GMCB, Chair
- Tom Pelham, GMCB
- Alena Berube, GMCB
- Cathy Fulton, VPQHC
- Lauri Scharf, Bi-State Primary Care
- Mary-Kate Mohlman, Blueprint For Health, DVHA
- Helen Reid, VDH

Proposed Draft Data Submission and Release Rules



- GMCB stewards two data sets – VHCURES and VUHDDS – and currently operates under BISHCA rule H-2008-01, which is more than 10 years old.
 - To provide flexibility to account for changing technology and research needs, two new rules governing data submission and data release are being proposed.
- GMCB staff have been engaged in an informal rule drafting process for new Rule 8.000 and new Rule 9.000.

Proposed Draft Data Submission and Release Rules



- The Data Governance Council voted in support of presenting the draft proposed Rules to the GMCB following a review at a public Council meeting on February 2, 2021.
- Draft Rules posted to GMCB website, and targeted stakeholder outreach (VUHDDS submitters, VHCURES payers/submitters, vendors, authorized VHCURES data users) in February.
 - Comments received from Onpoint

Proposed Draft Data Submission and Release Rules (continued)



- Formal rulemaking under Vermont Administrative Procedures Act:
 - *GMCB vote on proposed rules* (April 21, 2021)
 - Pre-filing with ICAR
 - Proposed rules filed with Secretary of State
 - Publication of notices by Secretary of State
 - Hearing and comment period (consideration of comment, public hearing if desired or if required based on public comments)
 - *GMCB vote on approval of final proposed rules*
 - Final proposed rules filed with Secretary of State and LCAR
 - LCAR review
 - *GMCB vote on final rules* (if needed)
 - Adopted final rules filed with Secretary of State

Draft Rule 8.000: Data Submission



Authority / Legal context

- 18 V.S.A. §9375: GMCB must collect and review data from ASCs and psychiatric hospitals.
- 18 V.S.A. §9410: Requires GMCB to establish and maintain a unified health care database and requires health insurers, health care providers, health care facilities, and governmental agencies to file reports, data, statistics, and other information specified by the GMCB.
- 18 V.S.A. §§9453 and 9454: Requires GMCB to adopt uniform formats that “hospitals” (general hospitals and psychiatric hospitals other than VPCH) must use to report financial, scope-of-services, and utilization data and information. Requires GMCB to designate an organization to collect data and requires hospitals to file information at the time and place and in the manner required by the GMCB.

Draft Rule 8.000: Data Submission



Sec. 8.200. VHCURES Registration and Submission

- Rule requires that health insurers, prior to doing business in VT and annually by Dec. 31 thereafter, register with GMCB and provide information on their organization and lines of business, including information about what data they will be submitting to VHCURES.
- Rule requires “mandatory submitters” to regularly submit medical claims data, dental claims data, pharmacy claims data, member eligibility data, provider data, and other non-claims information to VHCURES data collection vendor.
- VHCURES mandatory submitters are health insurers with average of 200 or more members in each month of last calendar year who are “VHCURES Members” (members who are VT residents).
 - No explicit exclusion for self-insured plan data; relying on statutory definitions and *Gobeille* decision.

Draft Rule 8.000: Data Submission



Sec. 8.200. VHCURES Registration and Submission

- Rule establishes basic requirements for submission, including transmission methods; file testing; rejection and resubmission of data; replacement of data; required run-out; and reporting frequency (varies based on # of VHCURES members)
- Technical requirements for VHCURES submission are set out in VHCURES Reporting Manual maintained by DGC. VHCURES Reporting Manual will address:
 - Data that VHCURES mandatory submitters must submit.
 - Technical specifications for data.
 - Reporting schedule for VHCURES mandatory submitters.
 - Other matters.
- VHCURES “voluntary submitters” are encouraged to follow data submission requirements in VHCURES Reporting Manual.
- Mandatory submitters must comply with additional guidelines or instructions of VHCURES data collection vendor.

Draft Rule 8.000: Data Submission



Sec. 8.300 VUHDDS Submission

- VUHDDS mandatory submitters are general hospitals, psychiatric hospitals, and ambulatory surgery centers.
 - “General hospital” as defined in 18 V.S.A. § 1902(1)(A) and “psychiatric hospital” as defined in 18 V.S.A. § 1902(1)(B).
 - ASCs defined as having same meaning as in licensing statute, 18 V.S.A. §2141.
- VUHDDS mandatory submitters must submit inpatient discharge data, outpatient procedure and service data, ED data, and other financial, scope of service, volume of service, and utilization data to data collection vendor in manner and at times specified in VUHDDS Reporting Manual created and maintained by DGC.
- VUHDDS voluntary submitters are encouraged to follow VUHDDS Data Reporting Manual.

Draft Rule 8.000: Data Submission



Sec. 8.400 Changes to a Reporting Manual

- DGC may revise or modify reporting manuals after sending each affected submitter a copy of proposed revisions or modifications and considering public comments submitted during 30-day public comment period.
- DGC may hold public meetings to discuss and receive comments on proposed revisions or modifications to reporting manuals.
- Revisions or modifications to reporting manuals become effective 90 days after approval by DGC. For “good cause,” submitters may request reasonable extension to comply.
 - Does not allow DGC to grant waiver of need to comply, but under different provision, Board may grant waiver to prevent unnecessary hardship, delay, or injustice.
 - “Good cause” not defined, each request would need to be reviewed and considered; guidance could be provided (e.g., inability to comply due to no fault of submitter).
- If DGC denies a request for an extension, submitter can appeal to Board.

Draft Rule 9.000: Data Release



Authority / Legal Context

- 18 V.S.A. § 9410 directs the GMCB to maintain a “unified health care database” to carry out its statutory duties and to make data in the database available to support analyses of health care utilization, expenditures, and performance in VT.
- The GMCB is not a “covered entity” that is subject to HIPAA, but it complies with HIPAA on issues of data release.
 - “To the extent allowed by HIPAA, the data shall be available as a resource . . . to continuously review . . .”
 - The release of health care data and statistical information that are subject to HIPAA “shall be governed exclusively by the regulations adopted thereunder in parts 45 C.F.R. Parts 160 and 164.”
- Notwithstanding HIPAA, 18 V.S.A. § 9410 prohibits the GMCB from releasing “direct personal identifiers,” including names, street addresses, email addresses, phone numbers, and SSNs.

Draft Rule 9.000: Data Release



Authority / Legal Context (continued)

- Besides HIPAA, other laws may prevent or caution against release of data (e.g., detailed pricing information may be proprietary, and release may cause antitrust concerns).
- Under 18 V.S.A. § 9410, the GMCB must adopt a “confidentiality code” to ensure that the information submitted is handled in an ethical way.
- The GMCB has data use agreements (DUAs) with the Centers for Medicare and Medicaid Services and the Department of Vermont Health Access to incorporate Medicare and Medicaid claims data into the database.
 - The GMCB must comply with the terms of these DUAs.

Draft Rule 9.000: Data Release



Sec. 9.201 Availability of Data

- The GMCB will maintain data release schedules that classify data elements as “unrestricted,” “restricted,” or “unavailable” based on the level of risk that release of the data would pose for identification of individuals and disclosure of proprietary or other sensitive information.
 - Unrestricted: may be available for public release.
 - Restricted: not available for use or release outside the GMCB unless permitted under a DUA.
 - Unavailable: not available for use or release outside the GMCB in any circumstance.
- Approach reflects current framework.
 - VHCURES: Data elements classified as unrestricted, restricted, or unavailable under BISHCA rule (sec. 8 and App. J-1 through J-14).
 - VUHDDS: Data elements classified in BISHCA policy as available in a public use file or a research file.

Draft Rule 9.000: Data Release



Sec. 9.201 Availability of Data (continued)

- The GMCB may specify additional restrictions or limitations on the availability of data in Data Use and Disclosure Manuals.
 - Examples of additional restrictions or limitations include those required by agreements under which the GMCB obtains the data and laws that apply to the data.
 - For instance, the GMCB's DUA with CMS says that the GMCB may only redisclose the data to agencies of the State of Vermont or an entity performing research directed and funded by the State.

Draft Rule 9.000: Data Release



- **Sec. 9.202 Modes of Access; Secure Analytic Environment**
 - People that are permitted to access data may receive data extracts or permission to access the data through a Secure Analytic Environment.
 - Secure Analytic Environment = secure means of accessing restricted data virtually.
 - Currently only available for state users with respect to VHCURES data.

Draft Rule 9.000: Data Release



Sec. 9.203 Release of Public Use Data, Analytic Tables, and Standard Reports

- If beneficial to the public, usable, and technically feasible, the GMCB may from time to time publish unrestricted data elements and information derived from unrestricted data elements in public use data files, analytic tables, or standard reports.
 - Analytic tables = files developed to answer specialized questions with detailed information relating to claims, patients, health insurers, or health care providers.
 - Standard report = a recurring report derived from the VHCURES or VUHDDS data sets that is intended to provide information pertaining to claims, members, patients, health insurers, health insurance, health care providers, and/or health care services.

Draft Rule 9.000: Data Release



Sec. 9.203 Release of Public Use Data, Analytic Tables, and Standard Reports (continued)

- Public use files, analytic tables, and standard reports shall
 - be made available upon request for no or minimal cost by Web-based electronic data download; and
 - contain clear and conspicuous explanations of the characteristics of the data (e.g., dates of data, absence of data on uninsured patients or non-residents, underlying methodology of report).

Draft Rule 9.000: Data Release



Sec. 9.301 Application

- A person may request access to the Secure Analytic Environment or data sets or analytic tables that include restricted data elements by applying for a limited data set on forms maintained by the GMCB and agreeing to terms in the GMCB Data Use Agreement.
 - Limited data set defined by reference to HIPAA, 45 C.F.R. § 164.514(e)(2) (protected health information that excludes direct identifiers, such as names, telephone and fax numbers, email addresses, SSNs, medical record numbers, and health plan beneficiary numbers).
- The GMCB may require submission of a pre-application review form
 - Current practice for non-state entities.

Draft Rule 9.000: Data Release



Sec. 9.301 Application (continued)

- The GMCB will create and maintain one or more Data Use and Disclosure Manuals that specify procedures for the submission and review of applications.
- The GMCB's procedures may
 - require review and approval of applications by agencies other than the GMCB
 - For example, DVHA must approve application where Medicaid data is involved (unique restrictions apply to Medicaid data).
 - specify different procedures for different types of requests and requestors
 - For example, State agencies may access data under "broad use" DUAs, whereas non-state entities may only access data under "limited use" DUAs that are specific to a research project.

Draft Rule 9.000: Data Release



Sec. 9.302 Review of Applications

- The DGC shall approve or deny applications on behalf of the Board (not on behalf of DVHA). DGC shall solicit and consider public comment relating to applications.
- The DGC may approve an application only when satisfied:
 - The application is complete and signed by the PI and a person with authority to bind the applicant.
 - Procedures to ensure the confidentiality of any patient data or other confidential data are documented.
 - Qualifications of the investigators and staff.
 - Release is not prohibited by state or federal law or regulation.
 - The data will be used in a way that aligns with the GMCB's statutory responsibilities, federal and state data protection and privacy requirements, and data stewardship policies adopted by DGC.

Draft Rule 9.000: Data Release



Sec. 9.302 Review of Applications (continued)

- If the DGC denies an application, it must provide a written explanation for the denial and give the applicant an opportunity to resubmit or supplement the application.
- Adverse decisions of the DGC may be appealed to the GMCB within 30 days by filing a notice of appeal.
- Board decisions denying an appeal are final decisions that may be appealed (to the Supreme Court).

Draft Rule 9.000: Data Release



Sec. 9.303 Data Use Agreements

- An Authorized User and Principal Investigator (PI) must execute a DUA with the GMCB in order to access the Secure Analytic Environment or data sets or analytic tables that include restricted data elements.
- GMCB will create and maintain standard DUAs that set forth the restrictions, limitations, and conditions on the use and disclosure of data from the database.
- The PI and any individual who will have access to the data under a DUA must sign an individual user affidavit (IUA).
 - An IUA is a form people must sign acknowledging and affirming that they have read, understand, and agree to abide by the terms and conditions in the DUA.

Draft Rule 9.000: Data Release



Sec. 9.401 Analytic and Information Services

- Upon request, Board or vendor may provide analytic and information services for members of the public.

Draft Rule 9.000: Data Release



Sec. 9.402 Costs and Fees

- Data sets containing restricted data elements will be made available at the cost charged by the Board's vendor to program and process the requested data set.
 - Paid directly to vendor (not revenue generating).
- Access to the Secure Analytic Enclave will be provided at the cost charged by the Board's vendor.
 - Paid directly to vendor (not revenue generating).
- Analytic tables and information services will be made available at the maximum allowable rate under law for time spent extracting data and performing similar tasks necessary to create the table or provide the services.

Draft Rule 9.000: Data Release



Sec. 9.402 Costs and Fee Waivers

- Subject to budgetary limitations of the GMCB, the DGC may grant full or partial cost or fee waivers or enter into alternative payment arrangements with applicants.
- Applicant must demonstrate that
 - Requested data will be used to fulfill a public purpose;
 - Payment of the costs would constitute an undue hardship.
- State departments, agencies, etc. do not have to pay fees.

Draft Rule 9.000: Data Release



Sec. 9.501 Data Linkage

- Incorporates themes from data linkage policy.
- Prohibits linking VHCURES or VUHDDS data, including public use data, with data sources containing personally identifiable information or other data sources that could result in the identification of individuals in the data set without the express consent of the GMCB.
- If necessary to conduct research that would otherwise not be practicable, a person may request authorization to link VHCURES or VUHDDS data using GMCB forms.
- Any data set linked to VHCURES or VUHDDS data must, at a minimum, adhere to protections, constraints and requirements set forth in our DUA.
 - Linked data can't be subject to less stringent protections.

Draft Rule 9.000: Data Release



Sec. 9.502 Data Redisclosure

- Prohibits Authorized User from redisclosing VHCURES or VUHDDS data or extracts generated from the data to third parties or external agents (e.g., contractors) without express written approval of GMCB or DGC.
- PI must ensure that individual user affidavits are submitted for all data users prior to granting access to data under a redisclosure.
- These are also requirements of our DUA.

Draft Rule 9.000: Data Release



Sec. 9.601 Enforcement

- A person who knowingly fails to comply with the requirements of 18 V.S.A. § 9410, or the rule (including the terms of a DUA) may be subject to sanctions.
- The GMCB's authority to sanction individuals is in addition to other powers it has to seek legal or equitable remedies, including the power to enforce the terms of a DUA.
 - Meaning the GMCB can act under the contract (e.g., revoke access) without pursuing sanctions.

Questions, Comments, Potential Vote



- Questions or comments?
- Proposed motion language:

The Green Mountain Care Board approves the draft proposed Rule 8.000 (Data Submission) and Rule 9.000 (Data Release) as presented as replacements for BISHCA rule H-2008-01, and the Board instructs its staff and legal teams to proceed with the formal rulemaking under the Vermont APA for both rules.