



Green Mountain Care Board

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GMCB USE ONLY

DUA #: RTI 2018_2 Opioid_DUA
Authorized User: State Entity []; Non-State Entity [X]
Data: Commercial [X]; Medicare []; Medicaid [X]
DUA Start Date:
DUA End Date: 9/30/18
AOA Approval Date:
AGO Approval Date:

Data Use Agreement for Release of a VHCURES Limited Use Health Care Claims Research Data Set

1. Parties

This agreement is made and entered into by and between the GMCB and RTI International, hereinafter referred to as “the Authorized User,” for the Project Title¹: Treatment and Outcomes for Patients with Opioid Use Disorder after Cessation of Opioid Prescriptions.

2. Definitions

For purposes of this Agreement,

- A. “Agent” means those persons who are agents of the Authorized User, in accordance with the federal common law of agency.
- B. “Agreement” means this data use agreement detailing the Authorized User’s commitment to data privacy and security and setting forth restrictions, limitations, and conditions on the use and disclosure of the Data Set. The Agreement includes the following attachments:
 - 1. the Application, including the Authorized User’s Data Governance Policies and Procedures and all other attachments to the Application (Attachment A);
 - 2. if the Data Set includes Medicare data, the GMCB’s data use agreement with CMS (Attachment B);
 - 3. if the Data Set includes Medicaid data, the GMCB’s data use agreement with DVHA (Attachment C); and
 - 4. for Vermont agencies, the Vermont Agency Addendum (Attachment D).
- C. “Application” means the Authorized User’s Application for Access to VHCURES Limited Use Health Care Claims Research Data Set, as filed with and approved by the GMCB and, if applicable, DVHA.

¹ The Project Title will be provided by the GMCB based on the Application.

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- D. “Authorized User” means the individual or entity being given access by GMCB, and in the case of the Medicaid data subset, by DVHA, to the Data Set pursuant to this Agreement.
- E. “CMS” means the Centers for Medicare & Medicaid Services.
- F. “Data Set” means the VHCURES Limited Use Health Care Claims Research Data Set being released to the Authorized User, and all data therein.
- G. “Disclose” means to release, transfer, provide access to, or divulge in any manner information outside of the entity holding the information.
- H. “DVHA” means the Department of Vermont Health Access.
- I. “GMCB” means the Green Mountain Care Board established in Title 18, chapter 220 of the Vermont Statutes Annotated.
- J. “HIPAA” means the Health Insurance Portability and Accountability Act of 1996, including the Standards for the Privacy of Individually Identifiable Health Information at 45 CFR Parts 160 and 164 (“Privacy Rule”) and the Security Standards at 45 CFR Parts 160 and 164 (“Security Rule”), as amended by subtitle D of the Health Information Technology for Economic and Clinical Health Act.
- K. “IUA” means an Individual User Affidavit, a form maintained by the GMCB.
- L. “Non-State Entity” means an individual or entity that is not a Vermont State Entity.
- M. “Principal Investigator” means the individual designated by the Authorized User to be responsible for ensuring compliance with the requirements in this Agreement. The Authorized User may also be the Principal Investigator.
- N. “Research” means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- O. “State” means the State of Vermont, including the GMCB.
- P. “Sub-User” means any person or entity (e.g., contractor, subcontractor, grantee, or subgrantee) that is given access to the Data Set by the Authorized User, other than as a member of the Authorized User’s workforce.
- Q. “Vermont State Entity” means an agency of the State of Vermont (a “Vermont agency”) or a contractor or other organization performing research that is directed and partially funded by the State of Vermont.
- R. “VHCURES” means the Vermont Health Care Uniform Reporting & Evaluation System, a health care database maintained by the GMCB pursuant to 18 V.S.A. § 9410.

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3. Authority and Purpose

Pursuant to 18 V.S.A. § 9410, the GMCB maintains certain health care claims and eligibility data within VHCURES to enable it to carry out its statutory duties, including

- A. determining the capacity and distribution of existing resources; identifying health care needs and informing health care policy;
- B. evaluating the effectiveness of intervention programs on improving patient outcomes;
- C. comparing costs between various treatment settings and approaches;
- D. providing information to consumers and purchasers of health care; and
- E. improving the quality and affordability of patient health care and health care coverage.

To the extent allowed by HIPAA, the GMCB seeks to make some of this data available as a resource for individuals and entities to continuously review health care utilization, expenditures, and performance in Vermont. The purpose of this Agreement is to specify the conditions under which the GMCB will release VHCURES data, and to ensure that the data is accessed, maintained, used, and disclosed in compliance with all applicable statutory, regulatory, and contractual requirements.

4. Data Referenced by this Agreement

Claims and eligibility data within VHCURES that may be available under a data use agreement can be broadly grouped into three lines of business: commercial, Medicaid, and Medicare. The GMCB has independent discretion to manage data for the commercial line of business, while DVHA and the GMCB share discretion with respect to the Medicaid line of business. DVHA must approve the use and disclosure of Medicaid data and, if the Authorized User will be receiving Medicaid data, DVHA must sign this Agreement. Recipients of Medicaid data must comply, and, by signing this Agreement, agree to comply, with the requirements of the data use agreement between the GMCB and DVHA (Attachment C). Pursuant to a data use agreement between the GMCB and CMS, Medicare data is available only to Vermont State Entities for purposes of Research. Recipients of Medicare data must comply, and by signing this Agreement, agree to comply, with the requirements of the data use agreement between the GMCB and CMS (Attachment B).

The table below identifies the types of data that will be disclosed to the Authorized User under this Agreement.

FOR GMCB USE ONLY

| File Type | Commercial Insurers | Medicaid | Medicare |
|--|-------------------------------------|-------------------------------------|--------------------------|
| Medical Eligibility | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Medical Claims | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Pharmacy Eligibility | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | Not applicable |
| Pharmacy Claims | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | Not applicable |
| Medical Eligibility- 5% Medicare National Sample | Not applicable | Not applicable | <input type="checkbox"/> |

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| | | | |
|--|----------------|----------------|--------------------------|
| Medical Claims- 5% Medicare National Sample | Not applicable | Not applicable | <input type="checkbox"/> |
| Medicare Part D Event - VT Residents | Not applicable | Not applicable | <input type="checkbox"/> |
| Medicare Part D Event - 5% National Sample | Not applicable | Not applicable | <input type="checkbox"/> |
| Medicare MEDPAR | Not applicable | Not applicable | <input type="checkbox"/> |

5. Responsibilities of the Principal Investigator

The Principal Investigator will act as the steward of the Data Set, including, but not limited to,

- A. ensuring that the GMCB has an IUA on file for each person that will be given access to the Data Set and that each such person understands and observes all the restrictions, limitations, and conditions specified in this Agreement;
- B. ensuring appropriate safeguards are implemented to protect the confidentiality of the Data Set and prevent its unauthorized use or disclosure;
- C. tracking and reporting to the GMCB on the uses and disclosures of the Data Set, including notifying the GMCB and, if appropriate, CMS, of any unauthorized uses or disclosures;
- D. seeking and obtaining the consent of the GMCB and, when applicable, DVHA, before disclosing the Data Set to a Sub-User or to any other entity not identified in the Application as the data user; and
- E. providing the GMCB with copies of any materials that contain data from the Data Set or information derived from the Data Set prior to its publication or release.

The Principal Investigator may delegate technical responsibility to other personnel within Authorized User’s organization, as identified in Attachment A to this Agreement, for the implementation of appropriate safeguards to protect the confidentiality of the Data Set and to prevent its unauthorized disclosure or use.

6. Restrictions, Limitations, and Conditions of Use and Disclosure

The Authorized User, by and through the Principal Investigator, will ensure compliance with the following restrictions, limitations, and conditions:

- A. The Authorized User may not use, disclose, or otherwise grant access to the Data Set or any derivative data, including statistical tabulations derived from the data,
 - i. in a manner that is contrary to law; or
 - ii. for purposes other than those expressly specified in the Application and permitted by this Agreement, without the express written consent of the GMCB and, if applicable, DVHA, unless required by law.
- B. The Authorized User may not disclose the identity of enrollees, members, beneficiaries, patients, employer groups, purchaser groups, or abortion services providers from information contained in the Data Set and may not disclose any direct findings, listings, or other

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information from the Data Set that could be used to identify one or more of these individuals or groups.

- C. The Authorized User may not use the Data Set to identify or contact enrollees, members, beneficiaries, or patients, and must obtain the express written approval of the GMCB before attempting to link the Data Set in any manner with other data containing personally identifiable information that may enable the identification of one or more entities or individuals named in subsection B of this section.
- D. The Authorized User may not disclose, with or without direct physician identifiers, direct findings, listings, or information derived from Medicare data, if such findings, listings, or information can, by themselves or in combination with other data, be used to deduce a physician's total Medicare reimbursements.
- E. Prior to calculating aggregated values based on observations or elements, the Authorized User must censor any cell in a data table with a count of 10 or fewer along with another cell in the same row and another cell in the same column to prevent the identification of the cell with a count of 10 or fewer in a table.
- F. The Authorized User may not decrypt or attempt to decrypt any encrypted data for any purpose or disclose any information that has been encrypted or removed from the Data Set.
- G. The Authorized User may not produce, publish, disseminate, or make public any information that could be used to determine or ascertain information about insurers or providers that would be deemed proprietary, such as the amount paid by identified insurers or to identified providers for individual procedure codes. This prohibition on public reporting is not applicable to reporting paid amounts at aggregate service levels, such as service bundles, episodes of care, and other types of service aggregations.

7. Disclosures Required by Law

The Authorized User may not disclose the Data Set on the basis that such disclosure is required by law without notifying the GMCB so that the GMCB and, if the Data Set includes Medicaid data, DVHA, have the opportunity to object to the disclosure and seek appropriate relief. If the GMCB or DVHA objects to the disclosure, the Authorized User shall refrain from disclosing the Data Set until the GMCB or DVHA have exhausted all alternatives for relief.

8. Safeguards

The Authorized User shall implement appropriate administrative, technical, and physical safeguards to protect the confidentiality of the Data Set and prevent its unauthorized use or disclosure. Such safeguards must comply with HIPAA and, if the Data Set includes Medicare data, with section 7 of Attachment B.

9. Review of Publications

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Unless a different time period is specified by the GMCB, the Authorized User must provide the GMCB a preview copy of any materials proposed to be published or otherwise disclosed at least fifteen (15) business days prior to publication or disclosure, if the materials contain data from the Data Set or information derived from the Data Set (this includes materials understood by the Authorized User to be consistent with the uses stated in the Application). The GMCB will review the proposed materials and determine whether they comply with all pertinent provisions of this Agreement. When multiple reports of a similar nature will be created from the Data Set, the GMCB may, on request, waive the requirement that any subsequent reports or publications be provided to the GMCB prior to release.

10. Reporting

While this DUA is in effect, the Authorized User must file periodic reports, at times specified by the GMCB, with updated information on

- A. the status of each individual data user for whom an IUA has been filed;
- B. proposed new users that will require access to the Data Set and who will be filing IUAs prior to gaining access to the Data Set; and
- C. details about data disposition and location, as required by the GMCB.

11. Attribution

The Authorized User must prominently state in written materials, publications, and presentations that the analyses, conclusions, and recommendations drawn from the Data Set are solely those of the Authorized User or the Principal Investigator and are not necessarily those of the GMCB.

12. Minimum Necessary

The Authorized User will limit, and will ensure that any Sub-User limits, access to the Data Set to the minimum number of individuals, data elements, and records necessary to achieve the purposes described in the Application or in a sub-agreement approved by GMCB under section 18 of this Agreement.

13. Notification of Unauthorized Access, Uses and Disclosures; Mitigation

- A. The Authorized User must immediately report to the GMCB whenever it (or any of its employees or Agents) becomes aware that the Data Set has been accessed, used, or disclosed in a way that is not permitted by state or federal law or that otherwise violates the terms of this Agreement. The Authorized User must require each Sub-User to immediately report to the Authorized User whenever it becomes aware that the Data Set has been accessed, used, or disclosed in a way that is not permitted by state or federal law or that otherwise violates the terms of this Agreement.
- B. In addition to the requirements of subsection A of this section, the Authorized User 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

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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 by any individual data user, including the Principal Investigator and must cooperate fully in the federal security incident process.

- C. The Authorized User must mitigate, to the extent practicable, any harmful effect that is known to it of an impermissible use or disclosure of the Data Set. Mitigation may include providing notices to affected individuals. The Authorized User shall draft and carry out a plan of corrective action to address any incident of impermissible use or disclosure of the Data Set. If requested by the GMCB, the Authorized User shall make its mitigation and corrective action plans available to the GMCB. The Authorized User shall require each Sub-User to agree to these same terms and conditions.

14. Ownership

The Authorized User agrees that it has a license to use the Data Set pursuant to this Agreement only for the term established herein and does not obtain any right, title, or interest in the Data Set.

The Authorized User must acknowledge the GMCB as the owner and VHCURES as the source of the data in any public reports, publications, presentations, or other materials generated from the Data Set.

15. Reliance on Representations

The Authorized User represents that it is authorized to bind all individuals who may have access to the Data Set to the terms of this Agreement.

The Authorized User represents that the facts and statements made in the Application are complete and accurate and represent the total uses to which the Data Set will be put. The Authorized User further represents that the Data Set is the minimum amount of data necessary to achieve the purposes described in the Application.

The disclosure of the Data Set to the Authorized User is being made in reliance upon the accuracy of all representations made by the Authorized User, including the representations made by the Authorized User in the Application.

16. Termination of Individual Users' Access; Certificates of Destruction

The Authorized User must notify the GMCB at least fifteen (15) days prior to the date an individual user will no longer need access to the Data Set and follow procedures to ensure that the individual user's access has been terminated by this date.

The Authorized User must file certificates of data destruction with the GMCB for terminated users with data or data tables that were generated using the Data Set and were stored in distributed data systems external to the Authorized User.

17. Disclaimer of Warranties

The GMCB makes no warranty concerning the accuracy of the Data Set or its fitness for any particular purpose.

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18. Sub-Agreements

The Authorized User may not assign any of its rights or obligations under this Agreement or disclose the Data Set to a Sub-User without the prior written approval of GMCB, and where applicable, DVHA. The Authorized User must notify the GMCB at least thirty (30) days prior to disclosing the Data Set to a Sub-User and must provide the GMCB with the following information:

- A. an electronic copy of the agreement between the Authorized User and the Sub-User;
- B. an IUA for each proposed individual data user; and
- C. any other information requested by the GMCB.

The Authorized User must ensure that any Sub-User to whom the Authorized User or Principal Investigator provides the Data Set is bound by a written agreement to the same restrictions and conditions that apply to the Authorized User and Principal Investigator under this Agreement. The written agreement must identify the GMCB and, if applicable, DVHA, as direct and intended third-party beneficiaries with the right to enforce any breach of the agreement upon request.

The Authorized User shall be responsible and liable for any use, publication, or other disclosure or release of the Data Set by any of its Sub-Users.

19. Insurance

Before receiving the Data Set, the Authorized User must provide certificates of insurance to show that the following minimum coverages are in effect: IT Professional Liability or Technology Professional Liability insurance with minimum third-party coverage of \$1,000,000.00 per claim, \$2,000,000.00 aggregate; and first party Breach Notification Coverage of not less than \$2,000,000.00. With respect to the first party Breach Notification Coverage, the Authorized User shall name the State of Vermont and its officers and employees as additional insureds for liability arising out of this Agreement.

20. Defense and Indemnity

The Authorized User shall defend the State and its officers and employees against all third-party claims or suits arising in whole or in part from any act or omission of the Authorized User or of any Agent or Sub-User in connection with their receipt, use, disclosure, or other involvement with the Data Set. The State shall notify the Authorized User in the event of any such claim or suit, and the Authorized User shall immediately retain counsel and otherwise provide a complete defense against the entire claim or suit. The State retains the right to participate at its own expense in the defense of any claim. The State shall have the right to approve all proposed settlements of such claims or suits.

After a final judgment or settlement, the Authorized User may request recoupment of specific defense costs and may file suit requesting recoupment in the Superior Court of the State of Vermont, Civil Division, Washington Unit. The Authorized User shall be entitled to recoup costs only upon a showing that such costs were entirely unrelated to the defense of any claim arising from an act or omission of the Authorized User or of the Authorized User's Agent or Sub-User in connection with their receipt, use, disclosure, or other involvement with the Data Set.

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The Authorized User shall indemnify the State and its officers and employees if the State, its officers or employees become legally obligated to pay any damages or losses arising from any act or omission of the Authorized User or of an Agent or Sub-User in connection with their receipt, use, disclosure, or other involvement with the Data Set.

The Authorized User agrees that in no event shall the State be obligated to defend or indemnify the Authorized User or any third party, or otherwise be liable for the expenses or reimbursement, including attorneys' fees, collection costs or other costs of the Authorized User or third party.

21. Antitrust Violations

The Authorized User agrees to not bring suit for alleged antitrust violations on the basis of this DUA.

22. Sovereign Immunity

The State reserves all immunities, defenses, rights or actions arising out of the State's sovereign status or under the Eleventh Amendment to the United States Constitution. No waiver of the State's immunities, defenses, rights or actions shall be implied or otherwise deemed to exist by reason of the State's entry into this Agreement.

23. Bankruptcy

The Authorized User agrees that, upon the filing of any petition in bankruptcy by the Authorized User or the initiation of any bankruptcy proceedings against the Authorized User or reorganization proceedings affecting the Authorized User or the claims of creditors of the Authorized User that the GMCB determines might affect the data, the data in whatever form shall automatically revert to GMCB free of all liens and encumbrances. To the extent allowed by federal law, the Authorized User hereby waives all rights to interpose any objections to the reversion or to aid or support the claims of any third party that are adverse to the rights of the GMCB under this provision.

24. Term; Survival

This Agreement shall expire at 12:00 a.m. on 3/31/2019 ("Expiration Date"), unless, prior to the Expiration Date, the GMCB approves an extension or the Agreement is terminated. The provisions of this Agreement that by their terms encompass continuing rights or responsibilities shall survive the Agreement's expiration or termination.

If the Authorized User is a Vermont agency, the Expiration Date will be two (2) years from the date the Agreement is executed. A Vermont agency must reapply at least sixty (60) days prior to the Expiration Date to ensure continuous access to data. Failure to submit new DUA applications to the GMCB in a timely and complete manner may result in gaps in access to data while the application is under review.

Authorized Users that are not Vermont agencies shall notify the GMCB at least sixty (60) days prior to the Expiration Date and request an extension. The Authorized User shall file any information required by GMCB pertaining to a request for an extension in a timely and complete manner. The term of any extension is wholly at the discretion of GMCB, which may also deny the request and require the Authorized User to file an application for a new DUA. A DUA may not be extended more than once.

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25. Enforcement; Penalties

In the event the GMCB's data use agreement with CMS or DVHA is not renewed or is terminated, or in the event the Authorized User, the Principal Investigator, a Sub-User, or an individual data user fails to adhere to the terms of this Agreement, the GMCB and, when applicable, DVHA and/or CMS, may take any or all of the following actions: (i) terminate the Agreement and recall the data or require that the data be destroyed; (ii) revoke the permission of an individual or entity to use the data; (iii) require corrective actions; and (iv) pursue civil and criminal sanctions under applicable state and federal laws and regulations.

The following are examples of civil and criminal sanctions that may apply, depending on the types of data included in the Data Set:

- A. 18 V.S.A. § 9410, providing for the assessment of administrative penalties of up to \$1,000 per violation for knowing violations of the statute; up to \$10,000 per violation for willful violations of the statute; and up to \$50,000 per violation for knowing failures to comply with the confidentiality requirements of the statute or confidentiality rules adopted pursuant to the statute through use, sale, or transfer of the data or information for commercial advantage, pecuniary gain, personal gain, or malicious harm.
- B. 33 V.S.A. § 1902a, providing for assessment of an administrative penalty of up to \$1,000 for a first violation and up to \$2,000 for any subsequent violation.
- C. Those described in section 14 of Attachment B.

26. Location of Data Set

The Data Set may not be transmitted, stored, or transferred by any means outside the continental United States without the express written permission of the GMCB and, if applicable, DVHA.

27. Destruction of the Data Set; Certificates of Destruction

The Authorized User must ensure that the Data Set is deleted, destroyed, or otherwise rendered unreadable, as directed by the GMCB, within thirty (30) days of the Expiration Date or the termination of this Agreement, or by the date the Data Set is no longer needed for the purposes described in the Application, whichever comes first. The Principal Investigator shall certify that the Data Set has been deleted, destroyed, or otherwise rendered unreadable by submitting a written certificate of destruction to the GMCB, and when applicable, DVHA.

28. Amendment

This Agreement may only be modified or amended in writing upon mutual agreement of both parties. The Authorized User shall cooperate with GMCB to amend this Agreement from time to time to the extent necessary for the GMCB to comply with changes to 18 V.S.A. § 9410, HIPAA, or other legal requirements that may apply to the Data Set.

29. Interpretation

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Any ambiguity, conflict, or inconsistency in the Agreement shall be resolved to require compliance with 18 V.S.A. § 9410, HIPAA, and other requirements that may apply to the Data Set, including the GMCB's data use agreements with CMS and DVHA.

30. Governing Law, Jurisdiction, and Venue

This Agreement will be governed by the laws of the State of Vermont. Any action or proceeding brought in connection with this Agreement shall be brought and enforced in the Superior Court of the State of Vermont, Civil Division, Washington Unit. The Authorized User irrevocably submits to the jurisdiction of this court for any action or proceeding regarding this Agreement.

31. Counterparts; Execution

This Agreement may be executed in counterparts and the exchange of signature pages to this Agreement (in counterparts or otherwise) by facsimile transmission or other electronic transmission (including in the form of a .PDF file) shall be sufficient to bind the parties to the terms and conditions of this Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement effective upon the Effective Date set forth above. Each person signing this agreement hereby represents that he or she is authorized by the organization on whose behalf he or she is signing to enter into the Agreement.

Green Mountain Care Board

Signature: _____
Name: Susan Barrett
Date: _____
Title: Executive Director

Authorized User

Signature: _____
Name: Tony Dawson
Date: _____
Title: Supply Chain Specialist
Organization: RTI International

Department of VT Health Access

Signature: _____
Name: Cory Gustafson
Date: _____
Title: Commissioner

Principal Investigator (if different than Authorized User)

Signature: _____
Name: Susan Haber
Date: _____
Title: Director, Health Coverage
Organization: RTI International

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Principal Investigator (Additional)

Signature: _____

Name: _____

Date: _____

Title: _____