

Appendix A: Protocols for Access to Protected Health Information on VHIE

Protocols for Access to Protected Health Information on VHIE

Section 1 – Purpose

Upon approval by the Green Mountain Care Board, this addendum shall be incorporated into and become part of Vermont’s Health Information Technology Plan (the “Plan”). Vermont law requires that the Plan include standards and protocols for the implementation of an integrated electronic health information infrastructure for the sharing of electronic health information among health care facilities, health care professionals, public and private payers, and individuals receiving care. In particular, 18 V.S.A. § 9351(a)(3)(B) requires that:

The Plan shall provide for each patient's electronic health information that is contained in the Vermont Health Information Exchange to be accessible to health care facilities, health care professionals, and public and private payers to the extent permitted under federal law unless the patient has affirmatively elected not to have the patient's electronic health information shared in that manner.

This addendum is intended to give effect to these provisions.

As required by statute, Vermont Information Technology Leaders, Inc. (“VITL”) has been designated to operate the Vermont Health Information Exchange (“VHIE”) in accordance with standards and protocols that are consistent with those adopted under the Plan.

Notwithstanding the annual review and approval of the HIE Plan as a whole, these Protocols shall remain in effect for the existence of the VHIE until superseded or modified with approval of the Green Mountain Care Board.

Section 2 - Definitions

“Consent” means an Individual’s decision to permit access to the Individual’s Protected Health Information on the VHIE by Participating Health Care Organizations and by public or private payers for Permissible Purposes. No affirmative action is required from an individual to establish their Consent. Individuals shall be considered to have given their Consent until and unless the individual affirmatively Opts-Out.

“De-identified” means that all identifying information related to a Person as set forth in the HIPAA Privacy and Security Rules are removed from the Protected Health Information.

“Health Care Operations” means any of those activities identified by federal regulations at 45 C.F.R. § 164.501, as may be amended, including but not limited to, quality assessment and improvement, evaluations relating to the competence of treating providers or necessary administrative and management activities.

“HIPAA” means the Health Insurance Portability and Accountability Act of 1996, as may be amended, and its implementing rules promulgated in 45 C.F.R. Parts 160, 162, and 164, as may be amended.

“HIPAA Privacy Rules” means those privacy rules described in 45 C.F.R. Part 164, Subpart E, as

modified and enlarged by the Health Information Technology for Economic and Clinical Health (HITECH) Act and any other subsequent amendments to the Rules.

“HIPAA Security Rules” means those security rules described in 45 C.F.R. Part 164, Subpart C, as modified and enlarged by the HITECH Act and any other subsequent amendments to the Rules.

“HITECH Act” means the Health Information Technology for Economic and Clinical Health Act of 2009, as may be amended, and its implementing rules promulgated at 45 C.F.R. Parts 160, 162, and 164, as may be amended.

“Medicaid State Plan” means that there is an agreement between a state and the Federal government describing how that state administers its Medicaid programs. It gives an assurance that a state will abide by Federal rules and may claim Federal matching funds for its program activities.

“Medical Emergency” means a condition that poses an immediate threat to the health of any individual and which requires immediate medical intervention. The term “Medical Emergency” specifically is intended to include an “Emergency Medical Condition” which is defined as a medical condition manifesting itself by acute symptoms of sufficient severity such that the absence of medical attention could reasonably be expected to result in (1) placing the health of the individual in serious jeopardy or (2) serious impairment to bodily functions or (3) serious dysfunction of any bodily organ or part.

“Opt-Out” means a Person’s affirmative election to withhold Consent, communicated to VITL through designated process.

“Participating Health Care Organization” means the individual hospital, medical practice, physician practice, home health care agency or other health care provider who has entered into a VHIE Services Agreement. Health Care Organization is either a recipient of Data or a supplier of Data, or both, with respect to Data available through the VHIE. The term “Participating Health Care Organization” shall include all the individual providers and authorized staff employed or otherwise legally associated with the entity or organization.

“Part 2 Provider” means a Participating Health Care Organization provider that has notified VITL that the organization or a unit or staff member within its organization, meets the definition of a Program under 42 C.F.R. Part 2, presently located in 42 C.F.R. § 2.11.

“Part 2 Lawful Holder” means any entity other than a Part 2 Provider that has notified VITL that the records it has provided to VITL consist or are reasonably be expected to consist, in whole or in part, of records protected by 42 C.F.R. Part 2.

“Patient”, “Individual” or “Person” means an individual whose personal demographic information or Protected Health Information is stored or transferred by the VHIE. The term includes a personal representative who has the authority to authorize the disclosure of a Person’s Protected Health Information pursuant to 45 C.F.R. § 164.502 (g) and any other applicable state or federal laws.

“Payment” means any activity undertaken to obtain or provide reimbursement for the provision of health care items or services to a Person.

“Permissible Purposes” means Treatment, Payment, Health Care Operations, consistent with HIPAA

and Vermont law.

“Protected Health Information” and the abbreviation “PHI” shall have the same meaning as the term “protected health information” in 45 C.F.R. § 160.103, limited to the individually identifiable health information created or received by or on behalf of a Participating Health Care Organization. Such term shall also include Electronic Protected Health Information.

“Public Health Authority” means an agency or authority of the United States or a State that has been granted authority and responsibility to protect public health and to prevent or control disease, injury or disability, and, as such, that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability.

“Significant Public Health Risk” shall have the same the meaning as the term “significant public health risk as” in 18 V.S.A. § 2 (12).

“Revoke” or “Revocation” of Opt-Out means a Person’s withdrawal of a previous election to Opt-Out.

“Substance Use Disorder Identifying Records” or “SUD Identifying Records” means records obtained from a Part 2 Provider or Part 2 Lawful Holder that meet the applicability provisions for restrictions on disclosure in 42 C.F.R. Part 2, presently located in 42 C.F.R. § 2.12(a)(1).

“Treatment” means the provision, coordination, or management of health care and related services by one or more Health Care Organizations.

Section 3 –Access by Participating Health Care Organizations

A. General. Each Individual's electronic Protected Health Information that is contained in the Vermont Health Information Exchange shall be accessible to Participating Health Care Organizations to the extent permitted under law unless the Individual has affirmatively elected not to have the Individual's electronic Protected Health Information shared in that manner.

Participating Health Care Organizations shall access Protected Health Information on the VHIE only for Permissible Purposes and only with respect to Individuals with whom they have, had, or are about to commence, a Treatment relationship.

B. Responsibilities of Participating Health Care Organizations. Participating Health Care Organizations shall–

- (i) execute a VHIE Service Agreement addressing the terms of providing Patient PHI for exchange on the VHIE and the Participating Health Care Organization’s Access to Patient Records
- (ii) cooperate in good faith to execute all provider responsibilities under any processes established by VITL to collect and record Individual elections to Opt-Out, and
- (iii) have policies and procedures in place to ensure that only those individuals involved in Treatment, Payment or HealthCare Operations may access a Persons’ PHI on the VHIE.

- C. VITL Responsibilities.** In addition to the obligations provided elsewhere in this addendum, VITL, as the operator of the VHIE, shall—
- (i) enter into a Business Associate Agreement (“BAA”), including, if applicable, a Qualified Service Organization Agreement (“QSOA”), with Participating Health Care Organizations addressing the terms of VITL’s use and disclosure of Individual PHI obtained from the Participating Health Care Organization and
 - (ii) ensure mechanisms exist to ensure records of patients who have Opted Out are not available, except in the event of Medical Emergencies as in Section D.
- D. Emergency Access to PHI on the VHIE.** Notwithstanding a Persons’ choice to Opt-Out, a Participating Health Care Organization may access the Individual’s PHI through the VHIE for use in Treatment of the Individual for a Medical Emergency, but only if the Participating Health Care Organization is unable to obtain Individual consent for such access. Participating Health Care Organizations accessing PHI under such circumstances must notify the Individual of such access as soon as is reasonably possible and must obtain a Revocation of the Individual’s Opt-Out for further access to PHI of that Individual on the VHIE after the Medical Emergency has ended.

Section 4 – SUD Identifying Records

- A. Protections necessary to prevent disclosures.** The regulations set forth in 42 C.F.R. Part 2, governing records of covered substance use disorder treatment providers, require additional protections to prevent disclosure of SUD Identifying Records.
- B. VITL Responsibilities.** In addition to the obligations provided elsewhere in this addendum, including those in Section 3.C, VITL, shall—
- (i) work with AHS, Part 2 Providers, and Part 2 Lawful Holders to identify and meet all applicable technical and programmatic requirements before allowing parties to access SUD Identifying Records under Sections 3, 5, or 6,
 - (ii) take reasonable care to prevent unpermitted disclosure of SUD Identifying Records, including working with Part 2 Providers to appropriately identify, store, and manage, as required by law, SUD Identifying Records transmitted to VITL, and
 - (iii) disclose SUD Identifying Records as permitted by law and authorized by the Part 2 Provider or Part 2 Lawful Holder or as required by law.

Section 5 – Public Health Access

Patient PHI that is contained in the VHIE shall be accessible to a Public Health Authority for public health purposes to the extent that access is authorized under state and federal law. This access shall not be limited by the patient’s election not to share data with Participating Health Care Organizations and public and private payers under 18 V.S.A. § 9351(a)(3)(B). A Public Health Authority that receives PHI for a public health activity or purpose may only disclose such PHI to the extent permitted by state and federal law.

Section 6 – Payer Access

- A. General.** Each Individual's electronic Protected Health Information that is contained in the

Vermont Health Information Exchange shall be accessible to public and private payers to the extent permitted under federal and state law unless the Individual has affirmatively elected not to have the Individual's electronic Protected Health Information shared in that manner.

Public and Private Payers shall access Protected Health Information on the VHIE only for Permissible Purposes and only with respect to Individuals with whom they have or had a relationship.

B. Payer Responsibilities. Payers shall—

- (i) enter into a Data Use Agreement addressing the terms of their Access to Individual Records and
- (ii) have policies and procedures in place to ensure that only those individuals involved in Payment or Health Care Operations may access a Person's PHI on the VHIE.

C. VITL Responsibilities. In addition to the obligations provided elsewhere in this addendum, VITL, as the operator of the VHIE, shall—

- (i) if receiving PHI from the Payer entity, enter into a Business Associate Agreement (“BAA”) with payers addressing the terms of VITL's use and disclosure of Individual PHI obtained from the Payer,
- (ii) implement policies and procedures to prevent Payer Access through the VHIE to PHI of Patients who have Opted Out.

Section 7—National Exchange

A. **General.** Each Individual's electronic Protected Health Information that is contained in the Vermont Health Information Exchange shall be available for query-based exchange with national exchanges pursuant to Restatement II of the Data Use and Reciprocal Support Agreement (“DURSA”), April 13, 2019, and as amended in the future, unless a Participating Health Care Organization elects to not make their data available or the Individual has affirmatively elected not to have the Individual's electronic Protected Health Information shared in that manner.

Participants in these exchanges shall access Protected Health information for permitted purposes pursuant to and as defined by DURSA to facilitate and protect eHealth Exchange.

Additionally, an individual's PHI contained on the VHIE shall also be provided for permissible purposes to other organizations as required by federal law.

B. **VITL's Responsibilities.** VITL, in coordination with the HIE Steering Committee, shall participate in the DURSA and any successor agreements thereto and shall comply with the requirements of participation. VITL may also participate in the exchange of Protected Health Information with other state or regional health information exchanges under direct agreements so long as they are consistent with the DURSA's exchange framework and protections for the privacy, confidentiality and security of the health data.

Section 8 – Individual Rights with Respect to Access

A. Education. VITL and the Department of Vermont Health Access shall develop, maintain and administer a program of education that enables Individuals to fully understand their rights regarding the sharing of their Protected Health Information through the VHIE and provide them with ways to find answers to associated questions. Educational materials and processes shall be incorporated as appropriate with existing education obligations, such as Notice of Privacy Practices disclosure requirements under HIPAA, and shall aim to address diverse needs, abilities, and learning styles with respect to information delivery.

Education materials and processes shall clearly explain–

- (i) the purpose of the VHIE;
- (ii) the way in which Protected Health Information is collected;
- (iii) how and with whom Protected Health Information may be shared using the VHIE;
- (iv) the Permissible Purposes for which Protected Health Information may be shared using the VHIE;
- (v) how to Opt-Out and how to Revoke the Opt-Out; and
- (vi) how to contact the Office of the Health Care Advocate.

B. Patient Opt-Out. With the exception of access by Public Health Authorities and access in a Medical Emergency, Patients shall be free to Opt-Out of participation in the VHIE at any time, which election shall remain in effect with respect to information requested by Participating Health Care Organizations or Payers, unless and until the Patient Revokes such election in writing.

C. Patient Access to PHI. All patients shall be provided the right of access to their PHI contained in the VHIE to the extent permitted under applicable HIPAA rules.

D. Patient Request for Audit Report. A Patient may request and receive an audit report of access to their PHI on the VHIE by contacting VITL’s Privacy Officer. VITL shall provide the requested audit report as soon as reasonably possible, but in no event longer than 30 days after request.

E. Revocation. A Patient who has Opted-Out shall be entitled to Revoke such Opt-Out at any time. VITL shall develop and administer one or more Revocation mechanisms for this purpose, including a mechanism by which the Patient’s Opt-Out revocation may be documented by the Payer entity. It is the obligation of VITL to update records of the Patient’s Consent status for the VHIE. A Revocation shall remain effective unless the Patient subsequently Opts Out.

F. Deidentified Data. De-identified patient information may be used for research, quality review, population health management and public health purposes, as permitted by HIPAA. No commercial use or sale of de- identified patient information is permitted.

G. VITL Responsibilities.

- (i) establish one or more user-friendly mechanisms through which Patients may Opt-Out,
- (ii) maintain updated Consent-status records of all Patients who have Opted-Out, and
- (iii) ensure the ability to audit access to patient records to facilitate compliance by Participating Health Care Organizations and participating payers with Accounting of Disclosure regulations under HIPAA.