VERMONT

AGENCY OF HUMAN SERVICES

Health Information Exchange

42 CFR Part 2 Data Governance Documentation

Version 1.6

Revision History

Date	Version	Description	Author(s)
6/26/2023	1.0	Initial Draft	Kristin McClure Mahesh ThopaSridharan
6/27/2023	1.1	Feedback (comments) from Part 2 DG Group added	Mahesh ThopaSridharan
7/18/23	1.1_3	VCP Group review and feedback added	Ken Gingras
7/24/2023	1.2	AHS & VITL review and feedback incorporated	Mahesh ThopaSridharan
7/25/2023	1.3	Feedback through Part 2 DG Group Meeting captured	Mahesh ThopaSridharan
8/3/2023	1.3	Updated Future goals to include specialized service agencies. Added likes to some comments.	Ken Gingras
8/3/2023	1.3	Reworded Data Output, changed patient to individual, and general edits	Simone Rueschemeyer
8/8/2023	1.4	Updated Appendix 1	Mahesh ThopaSridharan
8/15/2023	1.5	Finalized content with Part 2 DG Group feedback	Mahesh ThopaSridharan
8/23/2023	1.6	Corrected typo under Data Access section. FINAL Version to be published	Mahesh ThopaSridharan

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Purpose

This document is to serve as a reference for all involved parties, including but not limited to the ones listed below, to have a common understanding of the agreed upon approach to 42 CFR Part 2 (hereafter referred to as Part 2) Data Governance as it pertains to the Vermont Health Information Exchange (VHIE).

1. Vermont Agency of Human Services (AHS)
2. Vermont Information Technology Leaders (VITL)
3. Vermont Care Partners (VCP)
4. Designated Agencies (DA)
    a. Clara Martin Center (CMC)
    b. Counseling Service of Addison County (CSAC)
    c. Health Care & Rehabilitation Services (HCRS)
    d. Howard Center (HC)
    e. Lamoille County Mental Health Services (LCMHS)
    f. Northeast Kingdom Human Services (NKHS)
    g. Northwestern Counseling & Support Services (NCSS)
    h. Rutland Mental Health Services (RMHS)
    i. United Counseling Service of Bennington County (UCS)
    j. Washington County Mental Health Services (WCMHS)
5. Specialized Services Agencies (SSA)
    a. Northeastern Family Institute (NFI)
6. Vermont Department of Mental Health (DMH)
7. Division of Substance Use Programs (DSU) / Vermont Department of Health (VDH)

Shared Values and Goals

1. Ensuring access and minimal barriers to services for all Vermonters.
2. Clear and shared understanding of governance process.
3. We will establish data governance prior to any data being sent.
4. Patients are at the center of their health data – all individuals can make informed decisions about the use of their health data.
5. Policy makers / payers are able to assess value of programs and adapt to changing needs.
6. AHS will not share data with law enforcement or anyone else.

Part 2 Data Governance Goals

1. **Short-term goals** include conducting activities permissibly obtained consistent with CFR Part 2 § 2.33:
    a. To use the collected data for payment and healthcare operations otherwise permissible under section 2.33.b

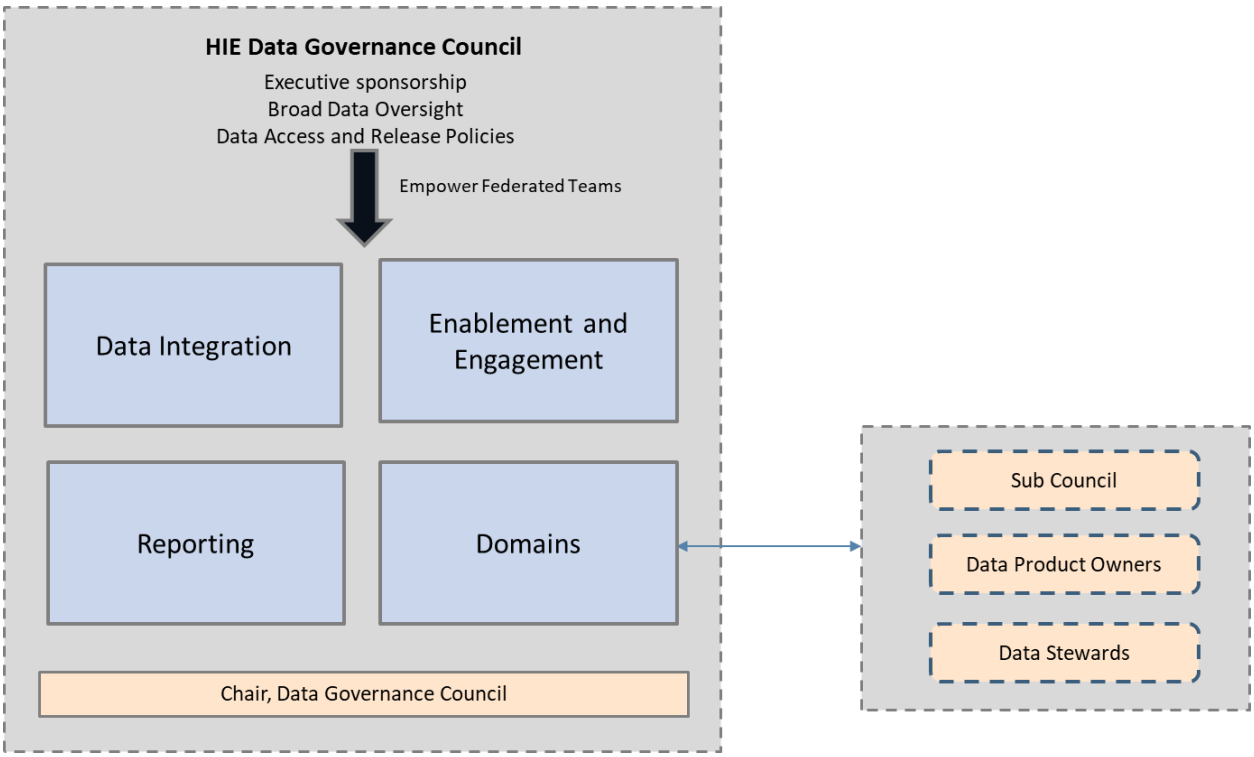
    The short-term goal applies to DA/SSA in providing required data and reporting to AHS.
2. **Long-term goals** are currently centered on effective care coordination for individuals

a. Detailed long-term goals will be dependent upon ongoing rulemaking.
b. Moving towards care coordination goals will require the right individual-level data, at the right time, delivered to the right stakeholders that can impact the care and outcomes of people served by the Designated Agencies, and Specialized Service agencies.
c. Share the information from the Designated Agencies and Specialized Service Agencies with those agencies and with the other providers across the State via the VHIE.
d. Include other substance use (SU) providers across the State in this governance model.

Data Governance Structure

The HIE Data Governance Framework takes a domain focused approach, acknowledging that different types of data require different considerations to ensure compliance with regulations and best practices. This approach creates different domains that are each accountable to the overarching Data Governance Council. 42 CFR Part 2 (substance user disorder) data is an example of a domain of data.

All domain teams, including Part 2 Data Governance Subcommittee, will share their decisions/recommendations with the HIE Data Governance Council for its approval. Once the HIE Data Governance Council approves, it will be finalized and adopted as part of data governance.



Part 2 Data Governance Subcommittee Decision Making

The Part 2 Data Governance Subcommittee is responsible for establishing data governance practices and processes for managing Part 2 data. The subcommittee is also responsible for providing their recommendations to the HIE Data Governance Council. The subcommittee is responsible for data

governance of the data that the DA/SSA send in compliance with Federal and State laws, rules, and regulations including 42 CFR part 2, HIPAA and other applicable statutes.

To ensure collaboration, it will be important that all stakeholders have equal input into key decision making. Discussions and any decisions must consider all perspectives so that final decisions are well-informed. As such, each member of this Governance Subcommittee is a voting member – 3 from AHS, 1 from VITL, 11 from DA/SSA, 1 from VCP.

Decisions will be made by a majority vote. For achieving a quorum, a minimum of 50% of this Data Governance Subcommittee members are required to vote. In that, a minimum of 6 DA/SSA subcommittee members will need to be present for the vote. The subcommittee will determine if any additional parties are needed to be included to inform data governance decision making. Alternate members will be identified by each agency for any subcommittee meetings, voting, and approvals as necessary. Decisions will be logged by the scribe for that meeting. The subcommittee will produce a decision document that describes the decisions. These notes will be made public on the healthdata.vermont.gov website within 72 hours of the meeting.
Change management – any changes to the data governance of Part 2 Data will require it be brought forward to the Part 2 Data Governance subcommittee for a discussion and vote if necessary.

Part 2 Data Governance Subcommittee Membership

Name	Organization	Role
Kristin McClure	Agency of Human Services – Central Office **(AHS-CO)**	Health Data Officer
Steve DeVoe	Department of Mental Health (**DMH**)/AHS	Director of Quality & Accountability
Anne VanDonsel	Division of Substance Use Programs (**DSU**)/VDH/AHS	Director of Performance Management and Evaluation
Beth Anderson	Vermont Information Technology Leaders (**VITL**)	President and CEO
Ken Gingras	Vermont Care Partners (**VCP**)	HIT Director
Michele Boutin	Clara Martin Center (**CMC**)	Operations
John Wurzbacher	Counseling Service of Addison County (**CSAC**)	IT Coordinator
Dave Kronoff	Howard Center (**HC**)	Compliance
Cheryl Cavanagh	Health Care & Rehabilitation Services (**HCRS**)	Compliance
Asa Kuhn	Lamoille County Mental Health Services (**LCMHS**)	IT Manager
Kim McClellan	Northwestern Counseling & Support Services (**NCSS**)	Operations
Tim Gould	Northeast Kingdom Human Services (**NKHS**)	IT Director
Jit Singh	Rutland Mental Health Services (**RMHS**)	IT Director
Eva Leonetti	United Counseling Service of Bennington County (**UCS**)	HIM Lead & Privacy Officer
Scott Adams	Washington County Mental Health Services (**WCMHS**)	IT Director
Jennifer Epstein	Northeastern Family Institute (**NFI**)	QI Coordinator

Through this collaborative decision-making process among all involved stakeholders the subcommittee has reached consensus on the following key topics:

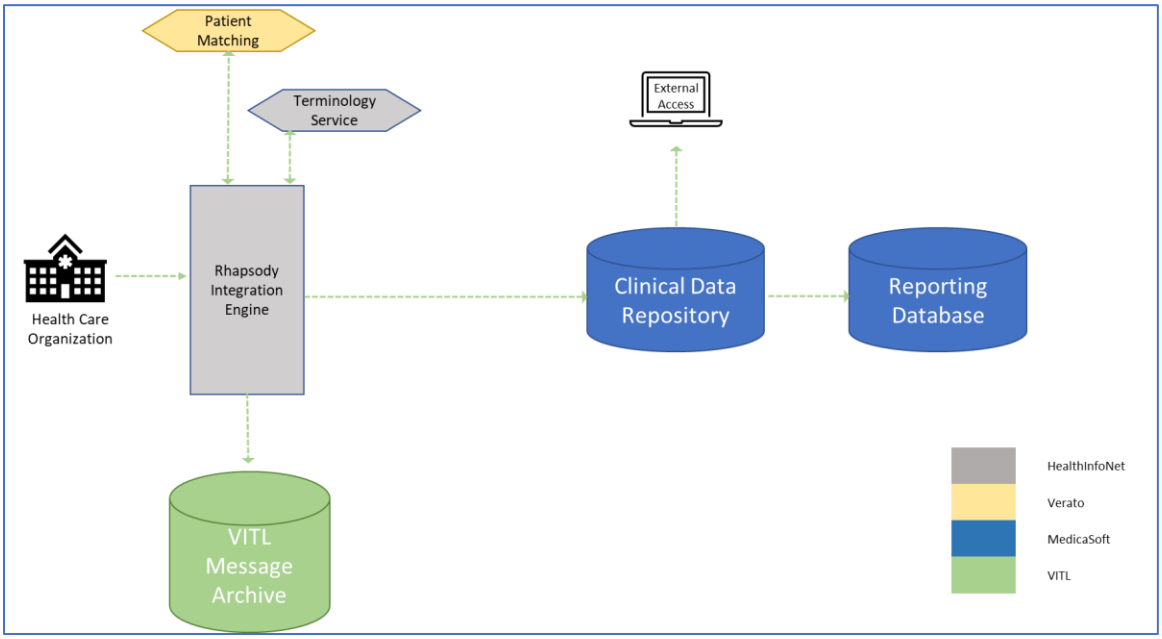
Securing Sensitive Data in the VHIE

Securing sensitive data includes measures to ensure that Part 2 data is fully identified and protected as Part 2 data. VITL is restricted from re-disclosing patient records from the DA/SSA beyond the purposes outlined in the executed VHIE Services Agreement, which includes a combined Business Associate Agreement/Qualified Services Organization Agreement (BAA/QSOA). During the initial phase, sharing of data will also be subject to being consented to by the individual patients. Individual consent needs for future phases will be assessed once the new federal rules are enacted.

VITL has proposed a current state in compliance with the current Part 2 provisions, an interim state, and a future state once the Proposed SAMHSA provisions are finalized.

Current State:

VITL maintains the state's HIE infrastructure, which is founded on a Clinical Data Repository and Reporting Database licensed from MedicaSoft whereby data from healthcare organizations is ingested, matched across the VHIE, and stored for archival and reporting purposes. The platform supports the exchange and access to data with appropriate permissions and patient consent. The diagram below demonstrates the flow of non-sensitive data through the VHIE.



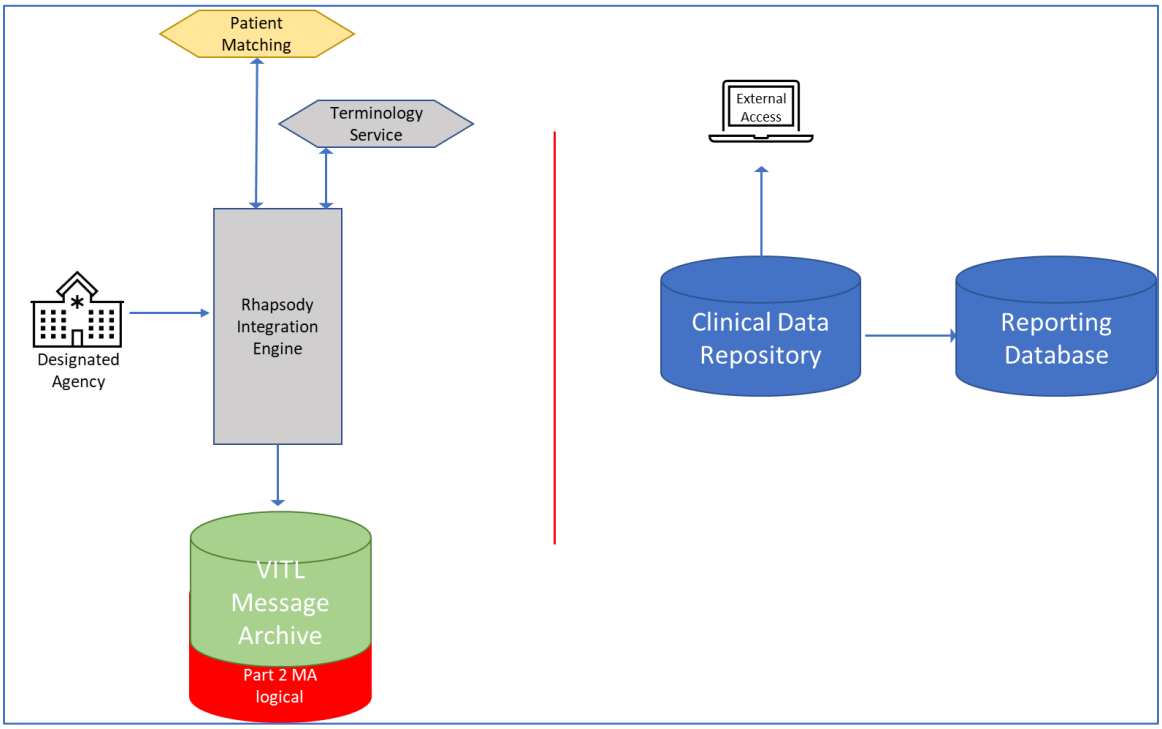
Interim State:

Part 2 Data: Initial Phase

The initial phase of the interim state ensures Part 2 sensitive data is segregated from other traditional data feeds and stored in a segregated message archive location where it will be available for future authorized use. Data received from the Designated Agencies will not be made available to VHIE participants. The data will not be delivered to or made available in the FHIR Clinical Data Repository or the Reporting Database.

At this point in time, VITL will be acting as a Qualified Service Organization (QSO) of the DA/SSA, and individual data will only be shared as specified by the DA/SSA and consented to at the DA/SSA by the patient. A QSO is an organization that provides services to a 42 CFR Part 2 program.

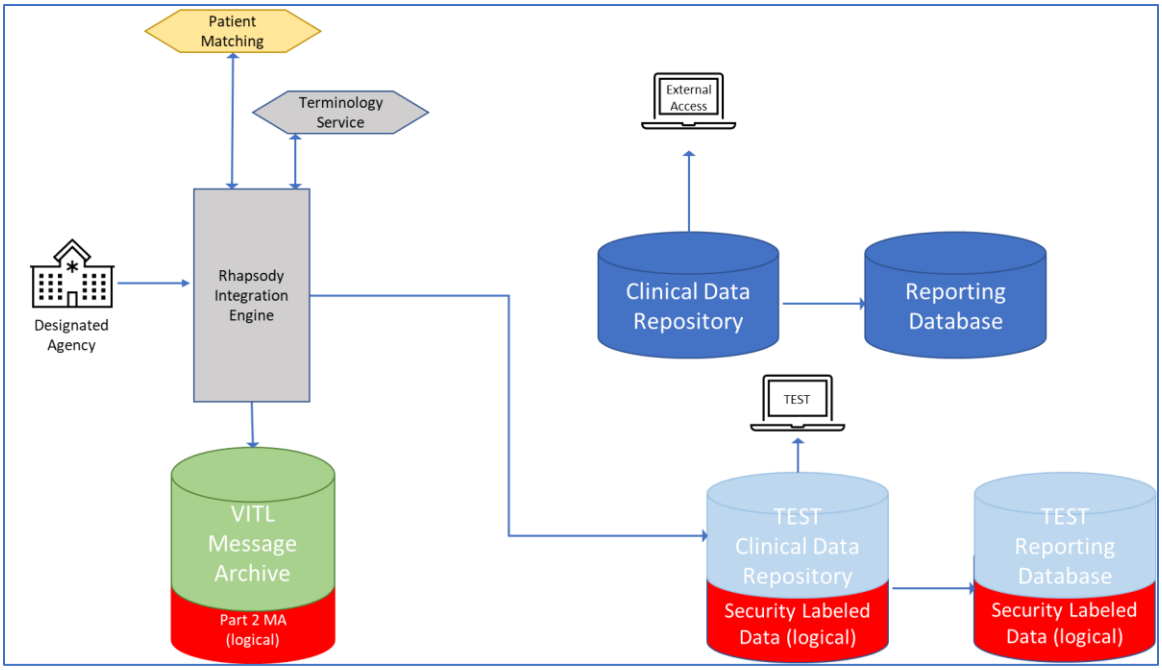
The diagram below represents the initial phase of the interim state of the project to ingest sensitive data and store it in a separate message archive (represented by the red "locker" in the Message archive) until it can be processed through the remainder of the VHIE architecture. As noted in the diagram, processing of sensitive data will terminate at the message archive where it is stored and segregated from non-part 2 data.



Part 2 Testing Security Model

As the design evolves, security labels will be applied to enforce data segmentation and patient privacy obligations in the VHIE. Security labels are used in access control systems governing the collection, access, use, and disclosure of information to which they are assigned and in conjunction with applicable organizational, jurisdictional, or personal policies related to privacy, security, and trust. Security labeling is also used to communicate specific handling requirements associated with the data. In the context of 42CFR Part 2, each disclosure of the data must be accompanied with a notice that unauthorized disclosure of the data is prohibited.

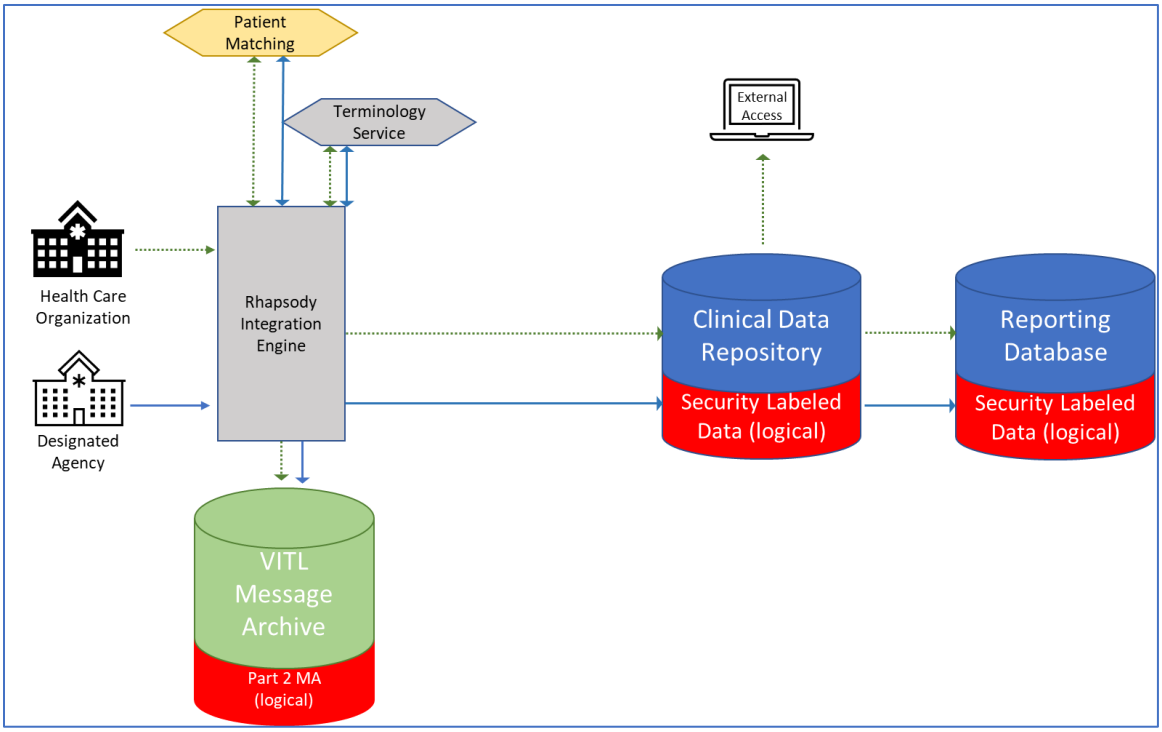
In this phase of the design, Part 2 data with security labels applied will be stored in the VHIE FHIR Clinical Data Repository and Reporting Database Test environments for testing purposes only. Part 2 data will not be promoted to the Production environment (represented by the blue databases). Testing will ensure that the security model properly protects access to the data.



Part 2: Security Labels & State Reporting

The diagram below represents the state of data transmitted by DA/SSA and health care organizations as data processes through the VHIE Production environment. In this phase, data will not be accessible to external authorized users in accordance with the QSOA between VITL and the DA/SSA and the patient's authorized Part 2 and VHIE consent. Data may be accessible by AHS for testing purposes dependent upon report development with the DA/SSA.

- Health care organizations will contribute patients' clinical records (PHI) to the VHIE where it will be processed, stored, and accessible to authorized users in accordance with HIPAA federal privacy rules. This data flow is represented by the green dotted data flow lines and the green and blue databases.
- DA/SSA will contribute Part 2 protected PHI to the VHIE where it will be processed (including security label assignment) and stored so that it may be made accessible for specifically designated purposes to AHS in accordance with 42 CFR Part 2 and HIPAA federal rules. This data flow is represented by the blue data flow lines and the red segregated "lockers" within each of the databases.

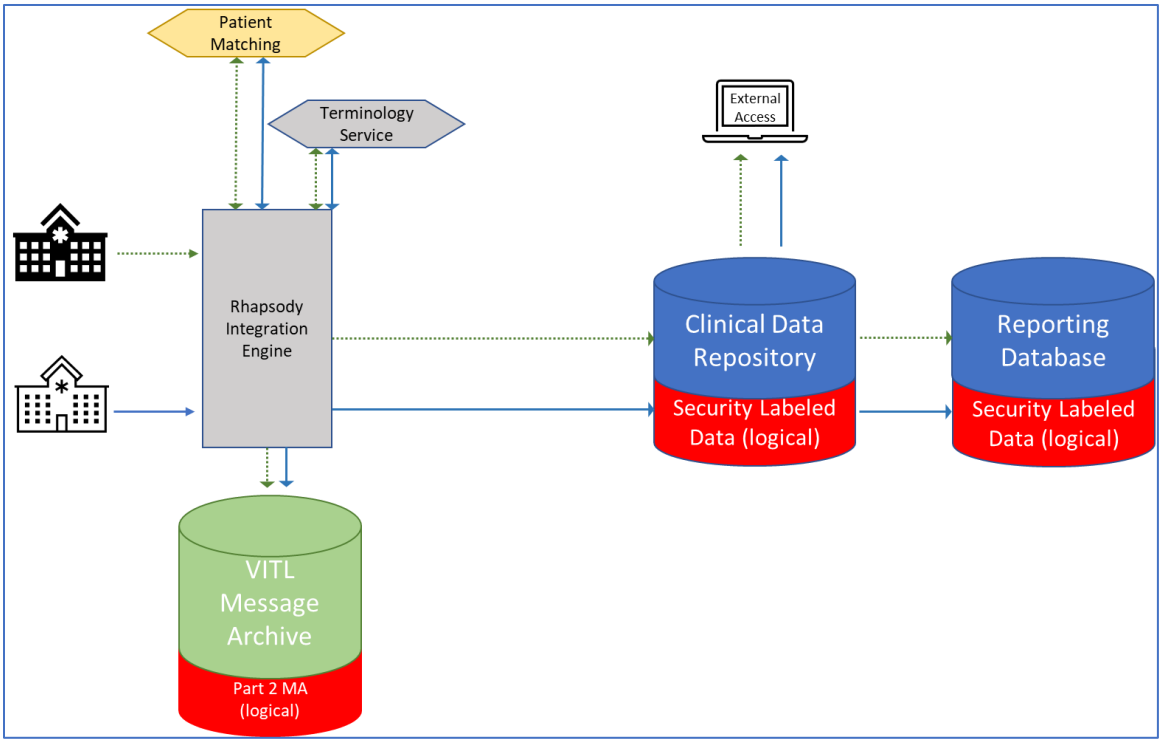


Future State:

Part 2: Updated Rule – External Sharing

The diagram below represents the future state of data transmitted by DA/SSA and health care organizations as data processes through the VHIE. Access by external authorized users beyond AHS will be dependent upon final SAMHSA rules.

- Health care organizations will contribute PHI to the VHIE where it will be processed, stored, and accessible to authorized users in accordance with HIPAA federal privacy rules. This data flow is represented by the green dotted data flow lines and the green and blue databases.
- DA/SSA will contribute Part 2 protected PHI to the VHIE where it will be processed (including security label assignment) and stored so that it may be made accessible to authorized users in accordance with 42 CFR Part 2 and HIPAA federal rules. This data flow is represented by the blue data flow lines and the red segregated "lockers" within each of the databases.
    - Appropriate external access to the data, such as through the provider portal, will be determined subject to the new rules.
- VITL will work with the DAs/SSAs to develop the data quality solution.



Audit Reporting

<Audit Reporting requirements yet to be defined>

Part 2 Consent, VHIE Consent (Opt-Out) and Revocation

The 42 CFR Part 2 regulation imposes privacy and confidentiality restrictions with respect to patient records from Part 2 programs. Based on the current rule, in order for VITL to collect data from the DA/SSA and for VITL to make that data available to AHS, VITL will act as a QSO, or service provider, for the DA/SSA. This will require the DA/SSA to collect patient consent for any specific uses of the patient's data and electronically transmit that consent to VITL. Part 2 patient consent is managed by the DA. The DA/SSA will be required to submit consent when new records are submitted to the VHIE, and when a patient changes their consent status. Revocation or changes to consent by a patient may occur at any time and must be communicated to VITL as soon as possible so they can be applied to the VHIE records.

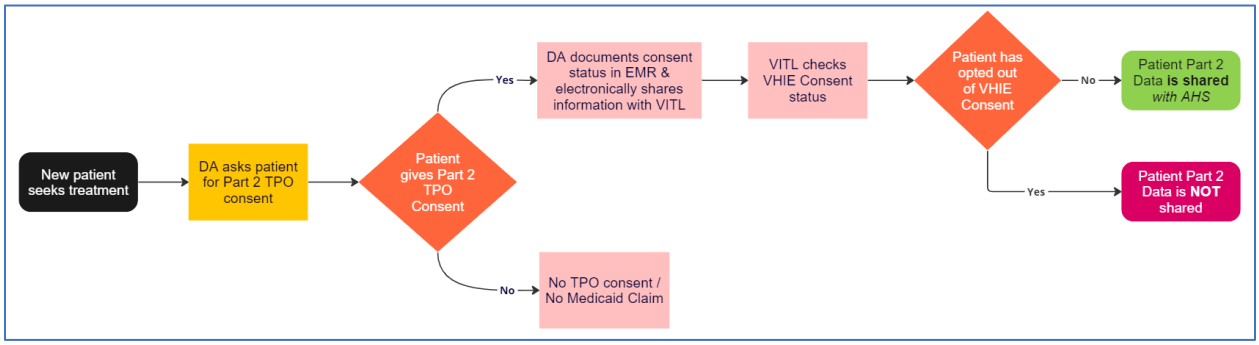
Regarding clinical health data (not Part 2 records) individuals must provide written consent to permit access to their health information residing in the VHIE (VHIE consent). Since March 2020, the VHIE has been an opt-out health information exchange, meaning that individuals agree to VITL sharing records residing in the VHIE until the individual revokes their consent. Individuals can opt-out by online form, printed and mailed paper form, or by phone. VHIE consent is managed by VITL.

A patient's VHIE consent decision to opt-out of sharing their electronic health information will be treated as superseding their Part 2 consent decision. In other words, both the individual's Part 2 consent must be opt-in and VHIE consent must not be opt-out for Part 2 records to be disclosed to AHS. The high-level workflow updates required for capturing, updating, and sending Part 2 Consent from the DA/SSA EHR system to the VHIE and the subsequent steps at VITL to address the VHIE Opt-out with or without revocation has been discussed and examined by this subcommittee. AHS also agrees with the general direction pursued by the DA/SSA to have the forms updated as necessary.

Part 2 and VHIE Consent Process for New Patient

When a new individual presents for their visit, the DA will collect the individual's consent decision. The DA will document the individual's consent decision in the EHR. The consent decision status (Yes or No) as well as date and time of consent will be transmitted in an electronic message to VITL through the established interface. If the individual does agree to share their data with AHS, VITL will also check the individual's VHIE consent status to ensure they have not opted out before sharing encounter information with AHS. If the individual has opted out, encounter information will not be shared with AHS.

The diagram below represents the Part 2 and VHIE consent process for new patients.



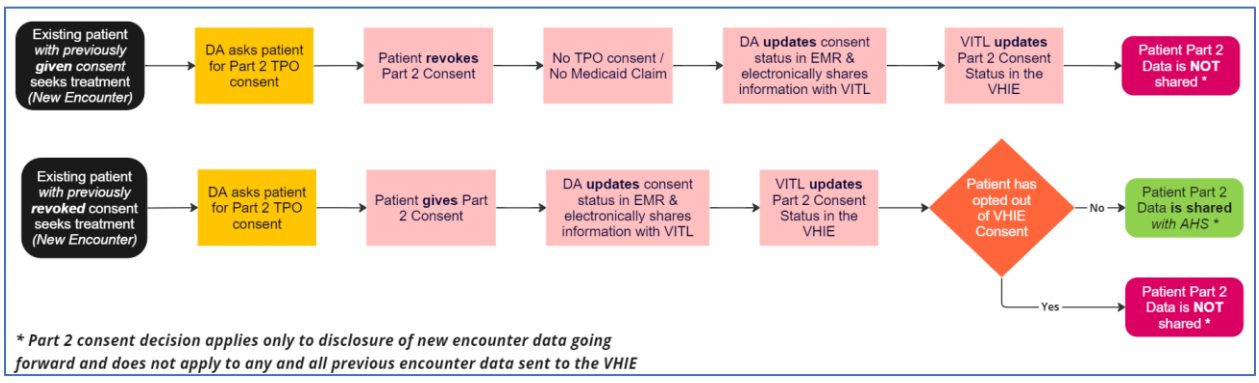
Part 2 and VHIE Consent Process for Existing Patient

An individual may revoke or change their Part 2 consent at any time. This may occur when they return for treatment or outside of an encounter or visit. When revocation or the change to consent occurs, the Designated Agency will collect the patient's consent decision and update the consent status in the EHR. The consent decision as well as date and time of consent will be transmitted in an electronic message to VITL through an established interface.

If the existing patient changes their consent to share their data with AHS and that consent change is electronically transmitted from the Designated Agency, VITL will also check the individual's VHIE consent status to ensure they have not opted out before sharing encounter information with AHS. If the individual has opted out of the VHIE, encounter information will not be shared with AHS.

If an individual revokes or changes Part 2 consent outside of an encounter (e.g., phone call to the agency days after an encounter) the first and subsequent records after the consent change will reflect this change to "no consent" status.

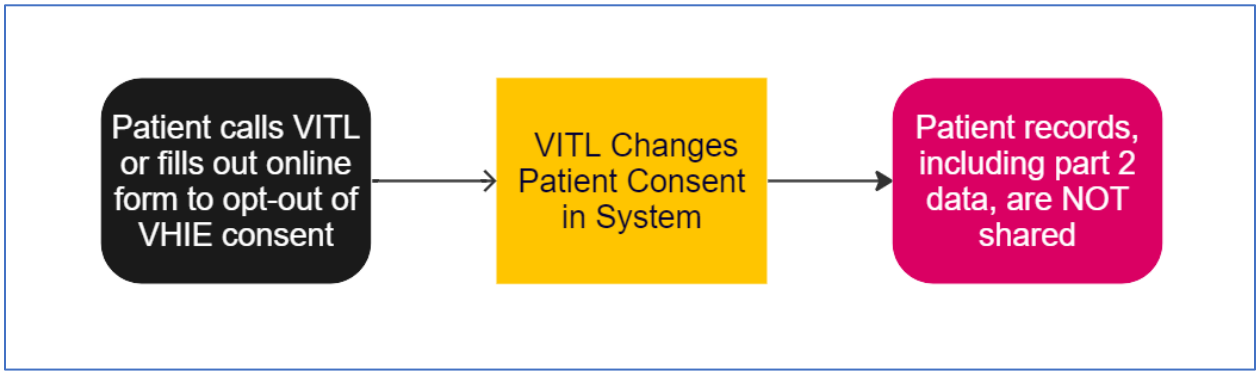
The diagram below represents the Part 2 and VHIE consent process for existing individuals.



VHIE Consent Revocation (opt-out) Process

Individuals may choose to revoke or change their consent to share their health information residing in the VHIE at any time. Individuals may complete a consent form to revoke or change their consent to share health information or call the VITL hotline. VITL will document the consent decision in the VHIE system.

The diagram below represents the VHIE revocation process.



Data set

AHS had provided the DAs/SSAs with the specific data elements AHS is seeking to access.

See Appendix 1.

Data Access and Data Use

With the current Part 2 Provisions in place –

1. Data access in the VHIE will be limited to VITL only.
2. AHS will be provided data extracts to satisfy the below mentioned data uses but will not have direct access to the data in the VHIE.

Once the proposed Part 2 provisions at SAMHSA become finalized, the subcommittee will reconvene to discuss and agree on future uses.

Example Data Uses – AHS Reporting

42 CFR Part 2 Provision	Use Case	Example (not an exhaustive list)
2.33 (b); #2, #10, #11, #12	CMS Compliance Reporting	# of unique individuals receiving treatment for SUD; engagement rate; follow up with in 7 days and 30 days, Value-Based Payment measures
2.33 (b); #2, #10, #11	State Operations Reporting	# / % screening for depression and follow up plan; screening for SDOH; follow up after hospitalization for SUD/Mental Health; follow up after ED visit for SUD; rate of growth of ED visits for SUD/Mental Health
2.33 (b); #1, #2, #4ii, #4iii, #5, #6, #7, #9, #10, #11, #12, #14, #15, #16, #17, #18, #19	• Departmental Clinical Operations • Replacement/sunsetting of Monthly Service Report (MSR) processes *	• Performance Measures listed in Provider Agreement contracts • Clinical Operations conducted by Departmental Care Management Teams (Children/Adults)
2.33 (b); #1, #2, #4ii, #4iii, #5, #6, #7, #9, #10, #11, #12, #14, #16, #17	SAMHSA Grant Funding Requirement (SATIS – Substance Abuse Treatment Information System)*	SAMHSA - Admission, and Discharge data DSU/AHS Reporting - Services data
2.33 (b); #2, #10, #11, #12	CMS Compliance Reporting (Future Requirement)*	Quality measures which include (subset): Reassessment or care Plan Update after Patient Discharge; Admission to facility from the Community; Plan All-Cause Readmission

Data Output

Before data roll up occurs for any data extracts, AHS, will collaborate with DA/SSA to agree on extract and extract use, AHS will not extract data without DA/SSA consent on use. AHS, DA/SSA and VITL will make sure there is coordination and validation checks with the DA/SSA prior to publishing the content or sharing with other entities and AHS and DA/SSA will meet to discuss narrative and/or analytic conclusions drawn from the data prior to publishing and sharing.

Record Retention and Destruction

Considering guidance from the following 42 CFR statutes, VITL will maintain patient records for 6 years consistent with VITL's record retention policy.

Approvals

Approver	Organization	eSignature/Date
Kristin McClure	Agency of Human Services – Central Office **(AHS-CO)**	DocuSigned by: Kristin McClure 2D24B62BE34A4C5... 8/30/2023
Steve DeVoe	Department of Mental Health (**DMH**)/AHS	DocuSigned by: Stephen DeVoe 64A5233662DB48B... 8/29/2023
Anne VanDonsel	Division of Substance Use Programs (**DSU**)/VDH/AHS	DocuSigned by: Anne VanDonsel F453AF91A5964C4... 8/29/2023
Beth Anderson	Vermont Information Technology Leaders (**VITL**)	DocuSigned by: Beth Anderson 79BE3F9AE223445... 8/29/2023
Ken Gingras	Vermont Care Partners (**VCP**)	DocuSigned by: Ken Gingras 8FF70C36820E48B... 8/29/2023
Michele Boutin	Clara Martin Center (**CMC**)	DocuSigned by: Michele Boutin AA0565D8BE1642A... 8/28/2023
John Wurzbacher	Counseling Service of Addison County (**CSAC**)	DocuSigned by: John Wurzbacher D66F07FB1C5D452... 8/24/2023
Dave Kronoff	Howard Center (**HC**)	DocuSigned by: Dave Kronoff B834F0A74E61493... 8/28/2023
Cheryl Cavanagh	Health Care & Rehabilitation Services (**HCRS**)	DocuSigned by: Cheryl Cavanagh F786C0144DE94AC... 8/25/2023
Asa Kuhn	Lamoille County Mental Health Services (**LCMHS**)	DocuSigned by: A4FFBF8DC2AD449... 8/28/2023
Kim McClellan	Northwestern Counseling & Support Services (**NCSS**)	DocuSigned by: Kim McClellan DEEEE4F015934D3... 8/23/2023
Tim Gould	Northeast Kingdom Human Services (**NKHS**)	DocuSigned by: Tim Gould 778EFCBF46644AD... 8/28/2023
Jit Singh	Rutland Mental Health Services (**RMHS**)	DocuSigned by: Jit Singh 0A7B1753810241E... 8/25/2023
Eva Leonetti	United Counseling Service of Bennington County (**UCS**)	DocuSigned by: Eva Leonetti CD308646E491482... 8/28/2023
Scott Adams	Washington County Mental Health Services (**WCMHS**)	DocuSigned by: Scott Adams 582B0F11DC3D40C... 8/23/2023
Jennifer Epstein	Northeastern Family Institute (**NFI**)	DocuSigned by: F61482064C7D481... 8/28/2023

Appendix 1

Data Elements

Please refer to the supporting documentation - “Updated Tier 2 HC Data Elements_20230807_AHSedits_v2_Final.xlsx”