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**Report to  
The Vermont Legislature**

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**Progress Report on the Stakeholder Engagement Process and Consent Policy  
Implementation Strategy**

**In Accordance with Sec. 5 of Act 53 (2019): An act relating to informed  
health care financial decision making and the consent policy for the Vermont  
Health Information Exchange.**

**Submitted to:** House Committee on Health Care  
Senate Committee on Health and Welfare  
Health Reform Oversight Committee  
Green Mountain Care Board

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## EXECUTIVE SUMMARY

Act 53 of 2019, An act relating to informed health care financial decision making and the consent policy for the Vermont Health Information Exchange, adopts an opt-out consent policy for the sharing of patient health information through the Vermont Health Information Exchange (VHIE) and specifies that the implementation strategy shall include substantial opportunities for public input. Act 53 further specifies several requirements for associated patient education mechanisms and processes. This second progress update is being submitted in accordance with the requirements of Act 53 to provide updates on the stakeholder engagement process and the consent policy implementation strategy to the House Committee on Health Care, the Senate Committee on Health and Welfare, the Health Reform Oversight Committee, and the Green Mountain Care Board (GMCB).

Act 53 was signed by Governor Scott on June 10, 2019. The Act includes two major areas of implementation that are the responsibility of the Department of Vermont Health Access (DVHA) – an updated statewide Health Information Technology Plan that provides for the new consent policy and development of an implementation strategy for the new consent policy (the change to consent policy is effective March 1, 2020). This report is the second required status update on activities to support the transition to an opt-out consent policy and covers the few months from the submission of the August 1<sup>st</sup> progress report to now.

DVHA, in consultation with stakeholders, has developed an implementation plan for the new opt-out consent policy based on meaningful consent. DVHA has been facilitating a consensus-based, multi-party process to engage diverse audiences in plan development for implementing and managing consent. The implementation team considers the workstreams to be on schedule to ensure the activation of the new consent policy on March 1, 2020.

### **Consent Implementation Project Work Streams**

The consent implementation project breaks down into three major work streams: stakeholder engagement for implementation strategy development, mechanisms to implement and manage consent for the VHIE, and evaluation of the success of stakeholder engagement objectives. In the two months since the first report was drafted, DVHA has made significant progress with the implementation planning and activities for the new consent policy. Workstream highlights include:

**Stakeholder Engagement:** Additional interviews and focus groups have been conducted and a good understanding of the messaging requirements has emerged. Planning for broader public input is under way. Messages and delivery mechanisms are now being developed to ensure that common message elements can be delivered to a variety of groups and Vermonters, using an appropriate mix of communications channels. DVHA is also asking the advocacy organizations to help deliver messages about consent once the information campaign is ready. The Stakeholder Engagement workstream section of this report expands on this work and how it is being structured.

**Mechanisms to Implement and Manage Consent for the VHIE:** In addition to the policy and procedure updates that are being planned, Vermont Information Technology Leaders is significantly expanding the mechanisms through which Vermonters can act on a decision to opt-out if that is their choice, including the use of fax, telephone, web form and US Mail. An important consideration that is being addressed will ensure that people who have opted out under the existing policy will remain opted out when the new policy goes into effect on March 1, 2020. The Mechanisms workstream section of this report provides an update on the progress attained in this area.

**Evaluation:** An evaluation plan has been drafted and reviewed with the HIE Steering Committee. The draft question anchoring this evaluation is: “Can Vermonters meaningfully consent to whether or not their health care providers and organizations are able to view their health information available through the Vermont Health Information Exchange?” Additional questions to evaluate the anchor question have been drafted and data sources, including the Patient Experience Survey, are identified. Members for the evaluation committee are currently being recruited.

## BACKGROUND

Act 53 of 2019, An act relating to informed health care financial decision making and the consent policy for the Vermont Health Information Exchange, adopts an opt-out consent policy for the sharing of patient health information through the Vermont Health Information Exchange (VHIE) and specifies that the implementation strategy shall include substantial opportunities for public input. Act 53 further specifies several requirements for associated patient education mechanisms and processes. This progress update is being submitted in accordance with the requirements of Act 53 to provide updates on the stakeholder engagement process and the consent policy implementation strategy to the House Committee on Health Care, the Senate Committee on Health and Welfare, the Health Reform Oversight Committee, and the Green Mountain Care Board (GMCB).

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## MEANINGFUL CONSENT

Per the Office of the National Coordinator for Health Information Technology (ONC), meaningful consent “occurs when the patient makes an informed decision and the choice is properly recorded and maintained. Specifically, a meaningful consent decision has six aspects. The decision is:

- made with full transparency and education,
- made only after the patient has had sufficient time to review educational material,
- commensurate with circumstances for why health information is exchanged (i.e., the further the information-sharing strays from a reasonable patient expectation, the more time and education is required for the patient before he or she makes a decision),

- not used for discriminatory purposes or as a condition for receiving medical treatment,
- consistent with patient expectations, and
- revocable at any time.

The Department and Vermont Information Technology Leaders will promote meaningful consent as described as the gold standard for consent. The minimum acceptable consent as implemented by providers, practices, and the VHIE must satisfy the requirements of Act 53 and current federal requirements.

### **Federal Requirements Related to Consent to Share Health Information in the VHIE**

Federal regulations cannot be overruled or relaxed by state regulations although state regulations can impose restrictions that go beyond the constraints of federal regulations. The two federal regulatory areas that relate to the sharing of health information are found in the HIPAA Privacy Rule and in 42 CFR Part 2. HIPAA is the Health Insurance Portability and Accountability Act of 1996. 42 CFR Part 2 is the Confidentiality of Substance Use Disorder Patient Records. Vermonters receiving health care anywhere should have been presented with information on HIPAA and they have probably given permission for the provider and health care organizations to share information with payers, other providers, and health care organizations who may be involved or consulted on some aspect of the health care delivery.

The purpose of 42 CFR Part 2 is to ensure that a patient receiving treatment for a substance use disorder in a Part 2 program is not made more vulnerable than an individual with a substance use disorder who does not seek treatment. 42 CFR Part 2 requires patient consent for disclosures of protected health information for the purposes of treatment, payment, or health care operations; consent for disclosure must be in writing; re-disclosures without patient written consent are prohibited (with certain exceptions).

The VHIE does not currently receive information from designated 42 CFR Part 2 programs. Any patient who does not opt-out of health information sharing will know that information from designated 42 CFR Part 2 programs (related to substance use disorder and treatment) is not being transmitted.

### **The VHIE and the New Opt-out Consent Policy**

Information related to health care treatment, in most cases, is transmitted to the VHIE where longitudinal health information is viewable by participating health care organizations. Data is also extracted and transmitted to support stakeholders involved in health care reform efforts such as the Blueprint for Health, the Vermont Department of Health, the Vermont Chronic Care Initiative and OneCare Vermont.

The existing Vermont opt-in consent policy and the new Act 53 opt-out consent policy have to do with an individual's management of who can access the information about the individual that is in the VHIE, and how the information that can be accessed under opt-out consent will never include the sensitive protected information described in the discussion of 42 CFR Part 2. A decision to approve access to a provider, health care organization, or payer is still subject to the restrictions of HIPAA. Taking no action will allow access by treating providers and health care organizations. Opting-out is simply removing electronic access through the VHIE as an option and forcing other methods which would most likely resolve to faxing information.

Consent discussions with patients including the presentation of opportunities to make informed consent decisions will continue to occur where individuals interact with the health care system, independent of Act 53. These points of interaction include the front desk of medical practice facilities, emergency rooms and urgent care centers, hospital admission and procedure locations, and a variety of settings where other providers and care coordinators interact with individuals. These discussions will still be about consent for treatment and the subsequent access to information in the VHIE. The difference now is the decision to allow access to information in the VHIE will change from opt-in to opt-out.

## CONSENT IMPLEMENTATION GOVERNANCE AND PROJECT ORGANIZATION

DVHA is facilitating the implementation of the opt-out consent policy with the participation and advice of the Health Information Exchange Steering Committee. The consent implementation project is an included agenda item at Steering Committee biweekly meetings.

DVHA has formed a project team including representation from VITL to address best practices of project management while focusing on the main workstreams of the project – stakeholder engagement, mechanisms for consent management, and evaluation of the success of stakeholder engagement. This team meets weekly, the project log and schedule are maintained, and project activities are monitored for progress.

## HEALTH INFORMATION TECHNOLOGY PLAN CONSIDERATIONS

Act 53 states requirements for Vermont's statewide Health Information Technology Plan (HIT Plan), to be revised annually and presented to the Green Mountain Care Board on or before November 1. Act 53 requires the HIT Plan to provide that patient information in the VHIE will be accessible to health care facilities, professionals, and payers unless the patient has opted out of having their electronic health information shared in this manner. Accommodating the HIT

Plan requirement involves coordinating additional threads of related health IT planning work currently underway at DVHA and this work is described in a section of this update.

DVHA has a significant amount of work to meet the requirements of Act 53 but the Department is confident the opt-out consent policy will be implemented on March 1, 2020 with full alignment with the requirements of Act 53.

## STAKEHOLDER ENGAGEMENT WORKSTREAM

Stakeholder engagement emerges as a critically important workstream, one which will inform Vermonters about consent and any decisions to opt-out and the mechanisms that will be required to support those decisions. Act 53 identified the need to consider both the general public and populations or groups of Vermonters who may have special concerns about consenting to make their health information accessible to their providers and health care organizations. DVHA's intent is for a multi-party process for engaging diverse audiences in a meaningful consensus strategy which differentiates this work from past efforts. This consideration helped DVHA develop its approach to stakeholder engagement which is described here.

### Interviewing Advocates for the Rights of All Vermonters

During the legislative session, some advocacy organizations working on behalf of the general population (all Vermonters) were actively involved in conversations about the consent policy. These organizations included the ACLU and the Office of the Health Care Advocate. Both were interviewed in the early stages of the stakeholder engagement work, in order to communicate DVHA's objectives for the project and solicit their recommendations for how to achieve an effective rollout of the new policy - a rollout that supports meaningful consent.

Advocate Interviewed	Interview Date
ACLU	6/12/19
Office of the Health Care Advocate	6/17/19

A meeting on August 30<sup>th</sup> engaged both organizations with updates and solicited their input on the project.



## Identifying and Engaging Special Populations, Interviewing Advocates

The project team has identified special populations whose members may have concerns about sharing their health data, based on stigma (e.g. people living with HIV/AIDS), personal safety (e.g. people with experience of partner violence), or other reasons. The team has also identified special populations whose members may require different communication approaches than those used with the general public in order to fully understand their options and rights. The project team reached out to advocates for the special populations. Initial interviews were conducted and DVHA continues to schedule additional interviews with advocates. The objective of these interviews is to:

- 1) Inform advocates about the VHIE and the new opt-out consent policy,
- 2) Begin to understand each population's current understanding of and perspectives on health data sharing including benefits and risks,
- 3) Ask for help engaging members of these populations in conversation via interviews or focus groups,
- 4) Ask for the advocacy organizations to consider being messengers and possibly processing opt-out decisions for members of the populations they serve,
- 5) Develop a shared definition of success regarding the rollout of the opt-out consent policy.

A few themes emerging in these early interviews with advocates for special populations and through the previously mentioned advocacy organizations representing the general population include:

- A shared understanding that a multi-channel communications approach that relies on both a wide range of messengers and mediums will have the best chance of reaching most Vermonters. Most advocacy organizations interviewed committed to participating as messengers. This does not guarantee that every Vermonter will have been individually contacted with information about their rights and an opportunity to opt-out. There were differing opinions as to whether a mailing to every Vermont household would be an effective method of communicating the key messages, with many advocates indicating that it may be prohibitively expensive with poor outcomes.
- Some advocacy organizations representing special populations recognize unique risks of health information exchange to the people they represent and/or unique challenges in communicating with them about the Vermont Health Information Exchange and their rights – while also recognizing that they may experience more

benefit from effective health information exchange than members of the general public.

- Some advocacy organizations have cautioned that messaging about the Vermont Health Information Exchange must be carefully designed to not create fear or uncertainty. Potential sources of fear cited include confusion that this impacts health insurance and some action is necessary to maintain coverage and/or access to care. People encountering the messaging should understand that no action is necessary and that they will continue to receive high quality care whether they take no action or choose to opt-out.

Special Populations Identified	Advocates Interviewed	Interview Date
People with developmental disabilities	Developmental Disabilities Council	6/4/2019
Families of people with developmental disabilities and/or special health care needs	Vermont Family Network	8/14/19
Refugees and New Americans	Cultural Brokers Program	7/15/2019
Migrant farm workers	Bridges to Health, UVM Extension	7/25/2019
People accessing sexual and reproductive health services	Planned Parenthood of Northern New England	7/2/2019
LGBTQ people	Pride Center	7/1/2019
People living with HIV/AIDS	People with AIDS	7/10/2019
Teenagers / young adults	TBD	
Elders	Southwestern Vermont Council on Aging, AgeWell	8/5/2019

### Focus Groups and Interviews with Vermonters, Including Members of Special Populations

The project team has planned a series of focus groups, question and answer sessions, and individual and small-group interviews with people who are members of the special populations mentioned above and with members of the general public. All of these engagements were designed to:

- 1) Understand participants’ expectations of how their health data is shared and used;

- 2) Understand what information (about the VHIE, benefits and risks of health information sharing, and rights and options) matters most to participants and how to express it clearly;
- 3) Understand how best to communicate about the new policy – what messengers and communication channels will be most effective;
- 4) Engage participants in design of easy and accessible opt-out mechanisms.

The project team has learned a lot from focus group participants. Early findings include:

- ✓ In this small sample there was a lack of awareness of the Vermont Health Information Exchange and how personal health data is stored and shared beyond practice, organization, or network electronic health records.
- ✓ Participants generally agreed that the more information their health care providers have access to, the better. Some concern was noted about old or sensitive information being available to their current provider.
- ✓ Participants wanted clarification about who would have access to their health information in the VHIE. They were interested in understanding both who is allowed access and who is capable of accessing, and what protections exist to limit access to the appropriate viewers.
- ✓ A few participants wanted reassurance about the overall security of the system (against hacking, etc.)
- ✓ The message “when my doctors have access to more complete information about my health, I may not need to tell my health story over and over again” resonates with many. Participants expect their providers will continue to ask them questions (including some seemingly repetitive questions) and listen closely to them. They also hope some repetition can be reduced (this is especially true among people with severe chronic conditions and their family members).
- ✓ People with severe chronic conditions and family members of people with severe chronic conditions expend substantial time managing personal health data. They are hopeful about tools that enable data sharing and require less logistical/administrative work of them.

- ✓ Participants want to learn about how their health data is stored, shared, and used from their health care provider. They are also open to learning from staff in their provider’s office and in a wide variety of health care settings and other venues.
- ✓ People want easy but reliable mechanisms to activate an opt-out decision.

Focus Groups	Population Engaged	Date
Developmental Disabilities Council Board	People with developmental disabilities	7/26/19
People with AIDS Retreat	People living with HIV/AIDS	7/27/19
St. Johnsbury-area Community Health Team patients	General population / health care patients	7/31/19
Vermont Family Network	Families of people with developmental disabilities and/or special health care needs	8/14/19
Burlington-area UVMMC patients	General population / health care patients	8/19/19
Cultural Brokers	Refugees and New Americans	9/11/19
Williston Rotary* *Informal question and answer session	General population	10/10/19

Importantly, in addition to completion of interviews and focus groups, planning for broader public input is also under way.

**Message Development and Dissemination Strategy**

Act 53 of 2019 requires that the policy implementation strategy shall “focus on the creation of patient education mechanisms and processes” that clearly explain:

- i. the purpose of the VHIE;
- ii. the way in which health information is currently collected;
- iii. how and with whom health information may be shared using the VHIE;
- iv. the purposes for which health information may be shared using the VHIE;
- v. how to opt-out of having health information shared using the VHIE; and
- vi. how patients can change their participation status in the future.

The project team has used the interviews and focus groups to learn about the best messaging approaches and do preliminary message testing. The team has also used these groups to learn about what communications channels will be most effective for reaching general audiences and special populations – where people want to learn about the Vermont Health Information Exchange and who they want to hear about it from. The team is developing a website to host information about the Vermont Health Information Exchange for Vermonters, and to provide all necessary information about how to opt-out. Simultaneously, the team is developing an outreach strategy that relies on three sets of messengers: health care organizations, advocacy organization and other partners, and the State of Vermont and VITL. With a marketing and communications agency and internal resources, the State is developing a broad set of outreach tactics and tools to be used by these messengers to reach Vermonters with information about what the Vermont Health Information Exchange is, why it matters to them, and their rights and options.

### Core Information Resources

Communications will be supported by the VITL hotline and a website. The website will be designed with the help of an agency partner and hosted by VITL, and will provide accessible, clear information about what the Vermont Health Information Exchange is, why it matters to Vermonters, and their rights and options. Planning for the website is underway now, content may include:

- Brief video about the Vermont Health Information Exchange and options
- Directions for: how to opt-out, how to opt-back-in, how to request a personal health record, and how to request an audit of viewers of a personal health record
- Numbers for the VITL hotline and the Office of the Health Care Advocate – to reach a person who can answer questions, process opt-outs (VITL only), and support decision-making
- Extensive FAQ, answering questions received to date about the Vermont Health Information Exchange

Messengers & Channels		
<b>1. Messenger: Providers (practices and health care organizations)</b>	<b>2. Messenger: Advocacy organizations &amp; other partners</b>	<b>3. Messenger: Direct from the State of Vermont and VITL</b>
Inform patients about health data where it is created and used	Reach special populations through existing strong and trusting relationships	Reach Vermonters not reached in other channels and reinforce the message

1. Provider-Led Communications	
<b>At providers' offices</b>	<b>Via health care organizations' communications channels</b>
<ul style="list-style-type: none"> <li>• Provide all participating health care organizations with sample script and handout to use at check-in*</li> <li>• Provide all participating health care organizations with language that may be inserted into HIPAA paperwork / notice of privacy practices</li> <li>• May also produce posters and/or other materials to use in on-site education.</li> </ul>	<ul style="list-style-type: none"> <li>• Provide interested practices and health care organizations with a toolkit of materials they may choose to use in their existing communications channels. Toolkit will be the same, or similar to, toolkit provided to advocacy organizations. <ul style="list-style-type: none"> <li>▪ Suite of social content</li> <li>▪ Newsletter item and/or blog post</li> <li>▪ Other content TBD</li> </ul> </li> </ul>
<p><b>*Note: Focus group participants have been clear that they want to hear about how their health data is shared and used directly from their provider.</b> However, it is unlikely that sharing this information can fit into the limited time providers have with their patients. The project team is looking for the closest proxy that does not place undue burden on providers or practices. The team is working with provider organizations to develop in-office education opportunities that are meaningful for patients and low-burden for health care organizations.</p>	

## 2. Communications from advocacy organizations and other partners

All interested advocacy organizations and other partners (such as health insurance providers) will receive a toolkit of materials they can use to inform the people they serve. At least one training will also be provided.

- Toolkit including
  - Suite of social content
  - Newsletter item and/or blog post
  - Slides and/or talking points for meetings
  - Handouts
  - Other content TBD
- Team members may be available to present in person at gatherings hosted by advocacy organizations for the people they serve – about the Vermont Health Information Exchange and opt-out options.

## 3. Communications from the State of Vermont and VITL

- The State of Vermont will use internal resources to develop content for the news media about the Vermont Health Information Exchange and Vermonters' options
  - An article for town/local papers
  - Pitch to statewide news organizations
- The State of Vermont will use its own relevant social media accounts to share information about the Vermont Health Information Exchange
- Within a limited budget, the State of Vermont may use some broad-reaching paid media to share information about the Vermont Health Information Exchange. Front Porch Forum is among the channels under consideration.

### Engaging a Marketing and Communications Agency

The project team has developed a marketing firm work request and is in the process of selecting a vendor to support development of many of the communications tactics above. They will build on the findings from the interviews and focus groups to develop messages that are compelling and accessible. Tactics will support a wide range of learning styles and will include visualizations of the health information exchange. Communications will include translation into

many languages spoken by Vermonters. The overall approach and complete set of tactics will aim to support full understanding of health data sharing options and the process of opting-out for people of “diverse needs, abilities, and learning styles with respect to information delivery” as required by Act 53 of 2019.

### **Engagement with Health Care Practices and Provider Organizations**

The implementation plan aims to balance the goals of reducing the burden of explaining the VHIE on providers, practice staff, and health care organizations of explaining the Vermont Health Information Exchange with the recognition that these same professionals and organizations may be the most trusted communicators about health and health care-related issues and that point-of-care is the most natural moment for engaging Vermonters in conversations about how their health care data is collected and shared.

VITL has extensive experience educating providers about the Vermont Health Information Exchange and working with practices and health care organizations to build the opt-in consent process into workflows. That experience will inform the work to support practices and health care organizations in the consent policy change to an opt-out policy. In its expanded role of processing and managing consent decisions, VITL will support the adoption of patient education materials, which will be in line with the requirement of Act 53 that new information about the consent policy be included with existing patient education obligations, such as the disclosure requirements under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). DVHA and VITL will work together to engage provider organizations to ensure this new information is included.

Additionally, the project team has met with Bi-State Primary Care Association and will engage the Vermont Association of Hospitals and Health Systems and OneCare Vermont to build the project team’s understanding of the communications needs of providers and the organizations supporting them and garner the organizational commitment necessary for leading or supporting education of their providers on this topic. VITL and Association perspectives will be supplemented by survey data from the provider and provider health care organization survey used to inform the State Medicaid HIT Plan (SMHP), in which consent specific questions are included. More information on the survey and preliminary results can be found in Evaluation section of this report.

### **Communications Roll-Out**

March 1, 2020 marks the date of the consent policy change. February 1, 2020 is when the first phase of mechanisms for Vermonters to use in opting-out of sharing health data on the VHIE will be available. Communications letting people know about the option to opt-out must begin



at or ahead of this February 1<sup>st</sup> date, although not so far in advance that Vermonters are given information with no ready opportunity to act upon it. In order to achieve this, all stakeholder organizations who will be acting as messengers must have the messaging toolkit and any other materials they need, and must be educated about the VHIE and the new consent policy and trained to support communications with their patients/clients/members in advance of February 1<sup>st</sup>.

### **Ongoing Engagement and a Culture that Supports Meaningful Consent**

While the objectives and goals established in Act 53 of 2019 will be met and the State will be prepared to move to an opt-out policy by the target date, building a culture that promotes and supports meaningful consent for health information exchange is a project that will be ongoing beyond March 1, 2020. The Health Information Exchange plan presented to the General Assembly this fall will include recommendations for continued promotion of meaningful consent. The plan is updated yearly, and future updates will modify these recommendations based on the findings of the evaluation.

## **MECHANISMS AND CONSENT MANAGEMENT WORKSTREAM**

The VHIE must technically and operationally support the new opt-out consent policy while managing the transition, on March 1, 2020, from an opt-in policy to the opt-out policy. Managing the current opt-in policy has given VITL significant experience in implementing and operating technical and operational solutions to manage consent and VITL will leverage that experience and much of the supporting infrastructure to engage the new policy. VITL has assembled a consent implementation team that meets weekly and has the requisite project management and technical assistance to support the new policy.

### **Policy and Procedure Changes in the VHIE to Support Opt-out Consent**

VITL has existing policies and procedures to address the privacy and security of patient data and records and they follow best practices in periodically reviewing these documents and testing the actual security of systems and data. Related to this portfolio of existing policies and procedures VITL is:

- reviewing, updating, establishing and implementing standards and protocols to support the new consent policy;
- reviewing and updating its portfolio of consent and privacy and security related policies and procedures to reflect the new consent policy;
- consulting with stakeholders and legal counsel to ensure policies, processes, and procedures support the new consent policy.

## Technical Changes in the VHIE to Support Opt-out Consent

In addition to policy and procedures changes to support the new policies there are technical changes that must occur to ensure that consent decisions can be captured, used to manage information access, and audited for compliance. Currently, the only method for Vermonters to opt-in or opt-out of the Vermont Health Information Exchange is by visiting a participating health care organization. Related to technical changes:

- VITL is developing processes and procedures to expand methods in which an individual can easily opt-out of the VHIE.
  - VITL is currently evaluating the following options:
    - Fax
    - In-person at VITL
    - Phone
    - USPS
    - VITL ticketing system
    - Web-based forms
  - This will also include use of the VHIE platform and other supporting systems to collect patient consent from participating health care organizations.
  - VITL is establishing a systematic way to maintain, audit, and process the decision of an individual to opt out of the VHIE.
- VITL is assessing existing processes and establishing new use cases, business processes/workflows, and requirements to ensure the solutions support the new opt-out consent policy and new methods to collect consent directly from individuals and stakeholders. This assessment is scheduled to complete in October of 2019.
- VITL along with Health Catalyst (the VHIE platform used to currently support the consent and associated patient records in the VHIE) has scheduled an update to the existing VHIE system to support the patient opt-out decision and hide records for the patient, outside of an emergency. This update will be deployed to a test environment in October of 2019.
- VITL will develop, test, and implement solutions based on the new use cases, business processes/workflows, and requirements established within the project to support the new consent policy. This work is scheduled to complete in early December.
- VITL will ensure an individual's pre-existing consent decision is maintained and new opt-out consent decision can be audited. This work is in progress.

- VITL is establishing post-implementation procedures and processes to provide ongoing support to residents and health care organizations in Vermont. This work is in progress.
- VHIE Consent Policy and Patient Information - VITL in collaboration with the State of Vermont and other stakeholders will create/update educational materials. This work is in progress.
- VITL is developing workflow recommendations and assistance for providers and health care organizations to implement the new consent policy based on use cases and identified solutions. This work is in progress.
- Work specifically focusing on expanding opportunities for patient consent collection and education for Vermont residents is in progress and will be ongoing even after the opt-out consent policy is implemented.

## EVALUATION WORKSTREAM

### Overview

In the first progress report submitted on August 1<sup>st</sup>, DHVA noted that Act 53 of 2019 requires the evaluation of the success of the stakeholder engagement and the intended purpose of that engagement to support informed consent decisions. DVHA also indicated that status of the evaluation plan and associated evaluation activity would be provided in the November 1<sup>st</sup> progress report. What follows is the current status of the evaluation plan.

Act 53 asks that Department of Vermont Health Access (DVHA), in consultation with the HIE Steering Committee, “identify a methodology for evaluating the extent to which the public outreach regarding the VHIE, consent policy, and opt-out processes has been successful.” To date, DVHA, in partnership with the Agency of Digital Services and VITL (the Consent Policy Implementation Team), has begun the process of developing the plan and methodology to evaluate the effectiveness of this public outreach. These steps include:

- 1) Establishing an Evaluation Committee and outlining its role;
- 2) Drafting an evaluation approach with specific aims; and
- 3) Identifying potential data sources to be used for the evaluation.

Regarding the Evaluation Committee, membership includes those who have expertise in evaluation methodology, those who can ensure the evaluation is asking the right questions to address the key concerns, and those who can support identifying and accessing data sources. The role of the Committee is to further define the primary research question and its underlying

components, identify additional and feasible data sources, and finalize the best methodology given the available data.

The draft question anchoring this evaluation is: “Can Vermonters meaningfully consent to whether or not their health care providers and organizations are able to view their health information available through the Vermont Health Information Exchange?” The ability to meaningfully consent is based on the patient having enough information, including understanding the risks and benefits, to make a decision with which they are comfortable. As Act 53 identifies, this evaluation needs to assess whether Vermonters have this information and understanding, which involves ascertaining three key elements:

- 1) Are Vermonters aware of their ability to decide whether their health care providers can view their health information available through the VHIE?
- 2) Do they have enough information to understand the risks and benefits of providers viewing their health information available through the VHIE, and make a decision with which they are comfortable?
- 3) Can Vermonters easily register their decision to not allow their health care providers to view their health information available through the VHIE?

### **Baseline**

One of the first steps in this evaluation is understanding the awareness and use of the current opt-in consent policy, which requires health care organizations participating in the VHIE to manage their patient’s consent decision. To assess this baseline, the Consent Policy Implementation Team will use results from the

- 1) State Medicaid HIE Plan Provider Survey;
- 2) Questions included in the statewide patient experience survey administered DVHA; and
- 3) VITL’s current records of organizations currently collecting and maintaining consent.

**1) State Medicaid HIE Plan Provider Survey:** A provider and health care organization survey, fielded in August of 2019 and meant to inform the State Medicaid HIT Plan (SMHP), included questions about providers’ understanding of the VHIE and consent options. Surveys went to providers across the continuum of care including mental health providers, primary care, and specialists. While these results are informing communications and education strategies for health care organizations, it must be noted that in some instances the survey was completed by an individual representing their health care organization, which could have included several providers. Therefore, their responses may or may not reflect the views and knowledge of all

providers in that organization. The following survey results are based on responses from the 293 participants; however, selection bias may limit their generalizability. With these cautions in place, below are select survey results relevant to the consent implementation plan.

- Generally, providers who responded to the survey expressed interested in using services related to the HIE and involving the sharing of electronic health information including: VITL Access (ability to see a longitudinal health record); VITL Direct Secure Messaging; Emergency Notification Services; and cross community electronic health information.
- Related to consent:
- In response to the question, “What is your familiarity with Vermont’s current law regarding patient consent to share electronic health information?”:
  - 46% comfortable explaining it to staff and patients
  - 36% know a little about it
  - 9% heard of it but do not understand it
  - 6% never heard of it
- In response to the question, “How does your organization CURRENTLY obtain patient consent to share electronic health information?”:
  - 66% paper consents – signed consents are gathered and filed in paper forms
  - 22% hybrid capture – signed papers are scanned into the EHR
  - 13% electronic – consents are obtained electronically with a verbal explanation
- In response to the question, “How does your organization PLAN to obtain patient consent to share electronic health information in the future?”:
  - 44% paper
  - 24% hybrid
  - 20% electronic
- In response to the question, “How often is consent to share electronic health information discussed with patients?”:
  - 30% As necessary per clinical event (e.g., before every surgical procedure)
  - 27% Once, only upon the first visit
  - 12% Annually
  - 6% Every visit

**2) Patient Experience Survey:** The two patient experience questions from the 2019 survey included:

The next two questions ask about your knowledge of the Vermont Health Information Exchange. The Vermont Health Information Exchange may electronically collect information about the health care you receive. You can choose whether your health care providers can see this information.

1. Have any of your health care or other service providers asked you whether you want your health care providers to be able to see your health information in the Vermont Health Information Exchange?

- 1.  Yes
- 2.  No (skip to Q\_\_\_)
- 3.  I don't know

2. Did you get enough information to feel comfortable deciding whether your health care providers will be able to see your health information in the Vermont Health Information Exchange?

- 4.  Yes
- 5.  No
- 6.  I don't know

### **Draft Evaluation Plan**

This evaluation plan is still in the development phase. While some data and methods are anticipated and spelled out below, the evaluation plan will continue to evolve as the educational campaign and consent mechanisms further develop.

Currently planned evaluation methods include monitoring activity leading up to the policy change date on March 1, 2020. For example, the Consent Policy Implementation Team will monitor the number of calls to the consent information hotline at VITL and the number of hits to VITL and the State's online information websites.

The team will also continue to monitor the number of individuals either opting in or out prior to the policy change. This information is currently reported to DVHA monthly and GMCB quarterly. Once the opt-out policy goes into effect on March 1, 2020, the Team will continue to monitor calls to the VITL's information hotline, hits to information websites, and the number of individuals opting out through any available mechanism. This continual monitoring could provide early indications of awareness or concern about the consent policy.

However, low numbers in any of these markers could mean awareness of but low concern about the opt-out consent policy or low awareness of the VHIE and opt-out consent policy. Therefore, the Consent Policy Implementation Team will also include questions in the 2020 patient experience survey that will continue to assess Vermonters' awareness, their level of understanding, and the ease with which they can record their decision to opt out. This survey goes out to a wide sample of Vermonters receiving primary care and will provide an additional view into whether Vermonters are aware of and understand their decision to make their health information viewable through the VHIE.

Additional data and methods will need to be developed in the Evaluation Committee, which will begin meeting in November. For example, how should the evaluation assess health care organizations' understanding of VHIE, the impact of consent, and their role in informing and supporting Vermonters to make consent decisions.? How can the state and VITL more accurately assess gaps in awareness? Other tasks that need to be addressed by the Evaluation Committee include determining evaluation methods to determine if Vermonters perceive mechanisms are in place to "easily opt out" and finalizing the 2020 patient experience questions to reflect an opt-out environment compared to the current opt-in environment. As noted above, finalizing the educational campaign methods and opt-out mechanisms may provide answers to these outstanding questions and issues. Updates to the evaluation plan will be made as the plan evolves.

## HEALTH INFORMATION TECHNOLOGY PLAN ALIGNMENT

Act 187, an act relating to health information technology and health information exchange, required DVHA to submit a Health Information Technology Plan to the Green Mountain Care Board on or before November 1, 2018. The submitted plan, entitled Health Information Exchange Strategic Plan, was subsequently approved by the GMCB. The Health Information Technology Plan is subject to annual updates and a comprehensive update every five years. The approved Plan includes the development of a technical roadmap that will illustrate a path forward for exchange across the HIE network, including consent management. This technical roadmap has been developed and will be a significant part of the first annual update to the Plan which will be submitted on or before November 1, 2019.

Act 53 sustains the requirement to submit an annual update and adds a requirement that the updated 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 this manner.” The annual update to the Health Information Technology Plan has been developed by DVHA in collaboration with the HIE Steering Committee and includes both the roadmap required by the current approved plan and the provisions called for by Act 53 to provide for the opt-out consent policy. The Act 53-related content in the updated Plan reflects the consent implementation project as reported here. The Plan is consistent with the required November 1<sup>st</sup> progress report and anticipates the successful completion of the consent implementation and the final report due on January 15, 2020.

## SUMMARY

In the short amount of time since Act 53 was signed into law on June 10, 2019, initial activities completed included establishment of a project team and planning for the successful implementation of the requirements of the Act. Three main workstreams were identified to ensure a successful implementation: stakeholder engagement, supporting mechanisms, and evaluation of the success of the stakeholder engagement. An initial progress report was submitted on August 1<sup>st</sup> and this second progress report is required to be submitted on or before November 1<sup>st</sup>, with the final report due January 15<sup>th</sup>, 2020.

Stakeholder engagement is underway with advocacy organizations interviewed and focus groups initiated. Planning for broader public input is under way. Advocates are being recruited to help deliver the messages that will be developed. Stakeholder engagement will also continue after the implementation date of March 1, 2020, as discussions about consent will continue to occur where individuals meet the health care system. Materials will be defined and developed to support informed decisions by all Vermonters and those materials will be informed by the stakeholder conversations reported in this update.

Mechanisms and operating procedures to support the opt-out consent policy are being developed by VITL to leverage the infrastructure already in place to support the current opt-in policy. The critical need to protect the opt-out status of individuals who have already made the opt-out decision is acknowledged and is being addressed. VITL is also revising its portfolio of policies and procedures related to privacy and security of patient information. For opting out, mechanisms will be added to accommodate fax, telephone, and USPS notifications by individuals to activate an opt-out decision.

A plan to evaluate the success of stakeholder engagement has been drafted and presented to the HIE Steering Committee. The primary and exploratory secondary evaluation questions have been drafted and an evaluation committee is currently being recruited.



The Health Information Technology Plan has been updated as required by Act 187 and includes the provisions specified in Act 53. There are three concurrent planning activities underway, but all the planning work is being coordinated by DVHA and VITL with the HIE Steering Committee.

42 CFR Part 2 and HIPAA are the federal regulations that must always be followed for the appropriate sharing of health information. Act 53's opt-out consent policy is a flip of the current opt-in consent policy but the conversation about consent will be very similar and individuals will still decide whether or not to grant access to their information in the VHIE to their providers.

The next update for the implementation of the consent policy will be a final report of the implementation plan and will be submitted on or before January 15, 2020. Progress on all workstreams and a description of final preparations for the March 1, 2020 implementation will be included in the final report.

## APPENDIX I: DETAILED ACT 53 IMPLEMENTATION WORK PLAN 2019 - 2020

The following table identifies the goals, objectives and activities associated with updating the statewide Health Information Technology Plan and stakeholder engagement process to create an implementation strategy for the change to the consent policy. The objectives are presented in terms of the requirements specified in Act 53. Overlaps between objectives are identified. Reporting and tracking progress in this way will ensure that Act 53 is being implemented as written and intended, keeping in mind that the overarching goal is to implement an environment and mechanisms that support informed and meaningful consent for all Vermonters.

Objective and Activity	Start and End Dates	Responsible Party	Status
<b>Goal: Update the Statewide Health IT Plan</b>			
<p><b>Objective:</b> Overall coordination of Vermont’s statewide <b>Health Information Technology Plan</b>. The Plan shall be revised annually and updated comprehensively every five years to provide a strategic vision for clinical health information technology. The Plan shall provide for <b>each patient’s electronic health information</b> that is contained in the Vermont Health Information Exchange <b>to be accessible</b> to health care facilities, health care professionals, and public and private payers to the extent permitted under federal law <b>unless the patient has affirmatively elected not to have</b> the patient’s electronic health <b>information shared in this manner</b>.</p> <p><b>Activity:</b> DVHA and the Health Information Exchange Steering</p>	<p>June 1, 2019 - November 1, 2019</p>	<p>DVHA Steering Committee Lantana</p>	<p style="text-align: center;"><b>On schedule</b></p> <p>DVHA and Lantana meet weekly to review status and planned activity; the Steering Committee is updated frequently and approves completed milestones.</p> <p>The plan is called the Health Information Exchange Strategic Plan and the initial version was approved by the GMCB on November 19, 2018. The updated Plan includes elements related to the change to the consent policy.</p>

<p>Committee (Steering Committee) coordinate the work of Lantana Consulting Group, Inc in developing the roadmap.</p> <p>(Steering Committee Composition: VITL, OneCare Vermont, Blue Cross Blue Shield of VT, Blueprint for Health, Vermont Care Network, Department of Health, Agency of Digital Services)</p>			
<p><b>Objective:</b> Submission of the Health Information Technology Plan to the GMCB</p>	<p>June 1, 2019 - November 1, 2019</p>	<p>DVHA</p>	<p><b>On schedule</b></p>
<p><b>Objective and Activity</b></p>	<p><b>Start and End Dates</b></p>	<p><b>Responsible Party</b></p>	<p><b>Status</b></p>
<p><b>Goal: Stakeholder process to develop an implementation strategy for the consent policy</b></p>			
<p><b>Objective:</b> Administer a robust stakeholder process to develop an implementation strategy for the consent policy for the sharing of patient health information through the Vermont Health Information Exchange (VHIE) as revised pursuant to the above requirements.</p> <p><b>Activity:</b></p> <ul style="list-style-type: none"> <li>• Begin with stakeholders who advocate for special populations;</li> <li>• Convene focus groups of people who identify as part of special populations;</li> <li>• Convene focus groups to represent Vermonters;</li> <li>• Seek additional expert</li> </ul>	<p>June 1, 2019 - March 1, 2020</p>	<p>DVHA; Health Information Exchange Steering Committee</p>	<p><b>On schedule</b></p> <p>DVHA has met with ten advocacy organizations.</p> <p>Some of these organizations are helping to identify participants and communications to initiate focus group conversations; some program managers from the Blueprint program are helping to create focus group opportunities with Vermonters.</p> <p>Advocate group representatives are willing to have further conversations as needed.</p>

<p>interviews as needed;</p> <ul style="list-style-type: none"> <li>Plan when and how to engage providers and practices</li> </ul>			
<p><b>Objective:</b> The implementation strategy shall include substantial opportunities for public input. Current stakeholder engagement with advocacy groups is focused on public input.</p> <p><b>Activity:</b></p> <ul style="list-style-type: none"> <li>Focus groups with people who identify with advocacy groups and with other Vermonters will inform preferred options for further public input;</li> <li>Media options such as call in radio programs and webinars are under consideration</li> </ul>	<p>June 1, 2019 - March 1, 2020 (March 1, 2020 is the consent policy start date; public input will be welcome up to and past this date)</p>	<p>DVHA; Health Information Exchange Steering Committee</p>	<p><b>On schedule</b> DVHA has met with ten advocacy organizations;  Plans are under way to engage other Vermonters in focus groups;  Planning for broader public input is under way.</p>
<b>Objective and Activity</b>	<b>Start and End Dates</b>	<b>Responsible Party</b>	<b>Status</b>
<b>Goal: Provide Clear Explanations of Key Elements of the Consent Policy</b>			
<p><b>Objective:</b> Focus on the creation of patient education mechanisms and processes that combine new information on the consent policy with existing patient education obligations, such as disclosure requirements under the Health Insurance Portability and Accountability Act of 1996 (HIPAA)</p> <p><b>Activity:</b></p>	<p>June 1, 2019 – March 2020 and beyond</p>	<p>DVHA; HIE Steering Committee; VITL</p>	<p><b>On schedule</b> This activity is being informed by the stakeholder engagement currently underway.  Developing the message is a part of planning conversations, including a review of existing collateral that can be updated and</p>

<ul style="list-style-type: none"> <li>• Define informed consent as a minimum requirement;</li> <li>• Define meaningful consent as an ideal objective;</li> <li>• Develop a communications message that explains Act 53 consent management aligned with current HIPAA disclosure requirements;</li> <li>• Develop collateral material in a variety of formats to support the message at the public, practice, provider, and patient level.</li> </ul>			continue to take advantage of existing distribution channels.
<p><b>Objective:</b> Aim to address diverse needs, abilities, and learning styles with respect to information delivery.</p> <p><b>Activity:</b></p> <ul style="list-style-type: none"> <li>• Identify a limited set of populations for separate messages (providers and practices; patients; other);</li> <li>• Identify a set of needs, abilities, and learning styles to inform message and delivery options;</li> <li>• Follow Vermont’s state web accessibility standards for all web content (based on Section 508 of the Rehabilitation Act and W3C Web Accessibility Initiative standards)</li> </ul>	June 1, 2019 – March 2020 and beyond	DVHA; HIE Steering Committee; VITL	<p><b>On Schedule</b></p> <p>This activity is being informed by the stakeholder engagement currently underway. Developing the message is a part of planning conversations</p>
<p><b>Objective:</b> Clearly explain:</p> <ul style="list-style-type: none"> <li>• the purpose of the VHIE;</li> </ul>	June 1, 2019 – September 2019	DVHA; HIE Steering Committee;	<p><b>On Schedule</b></p> <p>In parallel with stakeholder engagement activities,</p>

<ul style="list-style-type: none"> <li>• the way in which health information is currently collected;</li> <li>• how and with whom health information may be shared using the VHIE;</li> <li>• the purposes for which health information may be shared using the VHIE;</li> <li>• how to opt-out of having health information shared using the VHIE; and</li> <li>• how patients can change their participation status in the future.</li> </ul> <p><b>Activity:</b> Develop message material including brief handouts, more detailed descriptions, and presentation materials to address the content requirements identified in this objective.</p>		VITL	DVHA and VITL are identifying the content and format requirements for this material. This material should be available to meet a broader public engagement following focus group discussions. VITL has announced the effective date of the new consent policy and has provided a link to Act 53 on its website.
<p><b>Objective:</b> Enable patients to fully understand their rights regarding the sharing of their health information and provide them with ways to find answers to associated questions, including providing contact information for the Office of the Health Advocate.</p> <p><b>Activity:</b> Develop messaging and delivery strategies as described above; ensure that information about the Office of the Health Advocate is included, including contact information.</p>	June 1, 2019 – November 2019	DVHA; HIE Steering Committee; VITL	<p style="text-align: center;"><b>On Schedule</b></p> <p>In parallel with stakeholder engagement activities, DVHA and VITL are identifying the content and format requirements for this material.</p>
<b>Objective and Activity</b>	<b>Start and End Dates</b>	<b>Responsible Party</b>	<b>Status</b>
<b>Goal: Identify Mechanisms for Opting Out of Sharing Health Information Through the</b>			

VHIE			
<p><b>Objective:</b> Identify the mechanisms by which Vermonters will be able to easily opt-out of having their health information shared through the VHIE and a timeline identifying when each mechanism will be available, which shall begin at least one month prior to the March 1, 2020 change to the consent policy.</p> <p><b>Activity:</b> Identify opt-out mechanisms, including paper-based and electronic, for initial implementation to meet the required date; Identify any additional mechanisms for consideration at a later date; include patient, provider, and practice perspectives including practice workflows and EHR considerations.</p>	June 1, 2019 – February 2020	VITL; DVHA; HIE Steering Committee.	<p><b>On Schedule</b></p> <p>VITL has established a project team for this activity and has a project plan in place to complete the activity. VITL is aware of EHR upgrade and replacement activity with the DAs and is considering that in its project plan.</p>
Objective and Activity	Start and End Dates	Responsible Party	Status
<p><b>Goal: Develop or Supplement Consent Management Processes at the VHIE; Provide Clear Explanations of Key Elements of the Consent Policy</b></p>			
<p><b>Objective:</b> Include plans for developing or supplementing consent management processes at the VHIE to reflect the needs of patients and providers.</p> <p><b>Activity:</b> In addition to the mechanisms activity described above, there are several VHIE policies related to privacy and security that will require updating; develop operational procedures at the VHIE to support consent</p>	June 1, 2019 – February 2020	VITL; DVHA; HIE Steering Committee.	<p><b>On Schedule</b></p> <p>The VITL implementation plan for consent management mechanisms includes operational considerations including registering individual opt-out choices and establishing audit trails for consent management.</p>

management processes.			
<p><b>Objective:</b> Include multisector communication strategies to inform each Vermonter about the VHIE, the consent policy, and their ability to opt-out of having their health information shared through the VHIE.</p> <p><b>Activity:</b> See previous objectives and activities related to the development of messages and delivery.</p> <p>Identify sectors to benefit from separate communication strategies.</p> <p>Develop variations of message content for each identified sector.</p>	June 1, 2019 – September 2019	DVHA; HIE Steering Committee; VITL	<p><b>On Schedule</b></p> <p>In parallel with stakeholder engagement activities, DVHA and VITL are identifying the content and format requirements for this material.</p>
<b>Objective and Activity</b>	<b>Start and End Dates</b>	<b>Responsible Party</b>	<b>Status</b>
<b>Goal: Evaluate the Extent to Which Public Outreach Has Been Successful</b>			
<p><b>Objective:</b> Identify a methodology for evaluating the extent to which the public outreach regarding the VHIE, consent policy, and opt-out processes has been successful.</p> <p><b>Activity:</b> Develop a plan for evaluating the required public outreach associated with Act 53 consent implementation; Identify resources to conduct the evaluation; identify and agree on a methodology for the evaluation; conduct the evaluation; report on the evaluation.</p>	August 1, 2019 – November 2019	DVHA; HIE Steering Committee	<p><b>On Schedule</b></p> <p>DVHA has developed a plan for evaluation; evaluation questions are being developed; mechanisms for stakeholder involvement are being developed; timeline will accommodate folding evaluation into other planning and reporting activities.</p>



Objective and Activity	Start and End Dates	Responsible Party	Status
<b>Goal: Provide Status Updates to Legislative Committees and the GMCB</b>			
<p><b>Objective:</b> DVHA shall provide updates on the stakeholder engagement process and the consent policy implementation strategy to the House Committee on Health Care, the Senate Committee on Health and Welfare, the Health Reform Oversight Committee, and the Green Mountain Care Board on or before August 1 and November 1, 2019.</p> <p><b>Activity:</b> Develop an update report for the identified legislative committees and the GMCB for August 1, 2019 and November 1, 2019 submission dates. Present updates based on these reports as invited or as opportunities are available.</p>	<p>June 1, 2019 – August 1, 2019 (first update)</p> <p>November 1, 2019 (second update)</p>	<p>DVHA; HIE Steering Committee</p>	<p style="text-align: center;"><b>On Schedule</b></p> <p>August 1, 2019 report submitted on time.</p> <p>November 1, 2019 report submitted on time.</p>
<p><b>Objective:</b> DVHA shall provide a final report on the outcomes of the stakeholder engagement process and the consent policy implementation strategy to the House Committee on Health Care, the Senate Committee on Health and Welfare, and the Green Mountain Care Board on or before January 15, 2020.</p> <p>Develop a final report on outcomes of the stakeholder engagement process and the consent policy implementation strategy;</p>	<p>November 1, 2019 – January 1, 2020</p>	<p>DVHA; HIE Steering Committee</p>	<p style="text-align: center;"><b>Not started</b></p>

<p>Include description and discussion of the mechanisms that will support the strategy;</p>			
<p>Include description and discussion of the evaluation methodology for the stakeholder engagement strategy.</p>			