Report to
The Vermont Legislature

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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Report Date:	**August 1st, 2019**

VERMONT

AGENCY OF HUMAN SERVICES
DEPARTMENT OF VERMONT HEALTH ACCESS

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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 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 first required status update on activities to support the transition to an opt-out consent policy and covers the few months from the end of the legislative session to now.

DVHA, in consultation with stakeholders, is developing an implementation plan for the new opt-out consent policy based on meaningful consent. DVHA's intent is to facilitate a consensus-based, multi-party process for engaging diverse audiences in plan development for implementing and managing consent.

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.

Stakeholder engagement through interviews and focus groups will inform the implementation strategy, including variety and content of messages that will be developed, to ensure Vermonters understand the opt-out consent decisions they can make in the context of information in the VHIE. To date, DVHA has engaged the ACLU, Office of the Health Care Advocate, Developmental Disabilities Council, Cultural Brokers Program, Bridges to Health, Planned Parenthood of Northern New England, Pride Center and People with AIDS through interviews completed by July 25th, 2019. The next phase, focus groups and interviews with Vermonters including members of special populations, commenced on July 26th, 2019. DVHA is also asking the advocacy organizations to help deliver messages about consent once the information campaign is ready. Stakeholder engagement is a separate section of this report.

Mechanisms to implement and manage consent for the VHIE are primarily the responsibility of VITL. VITL has extensive policies, procedures, and support resources in place to manage the current opt-in consent policy and will leverage this consent infrastructure to support the opt-out policy. 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. Mechanisms and operational processes for managing consent under the opt-out policy are in development, the workstream is on schedule, and discussed in a separate section of this report.

Evaluation of the extent to which opt-out consent has been successfully implemented is required by Act 53. This evaluation is a major workstream and planning is underway. DVHA will integrate this work into the Health Information Technology Plan and the results of the evaluation will be included in current VHIE evaluation reports to the General Assembly and the GMCB and into the Health Information Technology Plan annual update. The evaluation workstream is in the plan development phase and discussed in a separate section of this report.

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.

DVHA and VITL 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 45 CFR Part 160 and Subparts A and E of Part 164, the HIPAA Privacy Rule. HIPAA is the Health Insurance Portability and Accountability Act of 1996. 42 CFR Part 2 is the Confidentiality of Substance Use Disorder Patient Records. The HIPAA Privacy Rule protects personal health information (PHI) held or transmitted by a covered entity or its business associate in any form, whether electronic, paper or verbal. PHI includes information that relates to the individual's past, present, or future physical or mental health or condition; the provision of health care to the individual; and the past, present, or future payments for the provision of health care to the individual. In general, Vermonters receiving health care anywhere should have been presented with information on HIPAA and they have probably given permission for the provider to share information with payers and other providers who may be involved or consulted on some aspect of the health care delivery.

42 CFR Part 2 regulates the disclosure and use of patient records by a federally-assisted program that holds itself out as providing substance use disorder treatment, diagnosis, and/or referrals to treatment (as defined in the Rule). 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).

There are solutions to electronically manage consent to share information protected under 42 CFR Part 2, but no solution has been implemented in Vermont, which is also true of most states at this time. Thus, 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, where 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 or payer is still subject to the restrictions of HIPAA. Approving access **does not mean that any** provider or other individual or entity can access the information, just those who have consent to see the information through HIPAA consent practices because they have some involvement in the patient's care. Taking no action will allow access by treating providers. 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. The Department is working extensively with advocates and other stakeholders to conduct the necessary interviews and focus groups and endeavoring to accommodate the pace necessary to meet objectives. The Department has determined that stakeholder engagement and public input will be necessary to be ongoing even after activation of the opt-out consent policy in March of 2020, as the processes to manage consent are improved and as new mechanisms to support consent management are developed and introduced. 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 populations or groups of Vermonters who may have special concerns about consenting to make their health information accessible to their providers. 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

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 or have been scheduled with advocates. The objective of these interviews was 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.

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	TBD	
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	TBD	

Focus Groups and Interviews with Vermonters, Including Members of Special Populations
The project team has planned a series of focus groups and individual and small-group interviews with people who are members of the special populations mentioned above. In addition, the team has planned focus groups with Vermonters who are patients of their local Blueprint Community Health Team and/or of their local hospital. In both cases, the first round of focus groups is designed to achieve the following objectives:

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 channels will be most effective;
4) Engage participants in design of easy and accessible opt-out mechanisms.

Focus Groups	Population Engaged	Date
Developmental Disabilities Council board	People with developmental disabilities	7/26/19
People with AIDS Retreat	People living with AIDS	7/27/19
St. Johnsbury-area Community Health Team patients	General population / health care patients	7/31/19
Cultural Brokers	Refugees and New Americans	TBD
Randolph-area Community Health Team patients	General population / health care patients	8/8/19
Burlington-area UVMMC patients	General population / health care patients	TBD

Message Development and Dissemination Strategy

The legislation indicates 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.

Based on findings from the initial interviews and focus groups, the project team will develop concepts and messages that clearly explain the information outlined above, using accessible language. The team will also develop alternative communication approaches including visualizations and audio or video messages, all designed 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 the legislation. The team will develop a list of channels to prioritize, based on focus group participant input and communications/media strategist input. The team will develop a list of organizations that have already agreed to help disseminate messages to the populations they work with, and a list of organizations to approach based on focus group participant input.

The planned approach is to rely heavily on stakeholder organizations to do the communicating about the new consent policy, based on their trusted relationships with the people they serve and/or advocate for and in line with available resources. In order for stakeholders to do this work, DVHA will need to arm the organizations with knowledge, training, and materials. (The focus in this section is on communications and not the mechanism of opting-out or the workflows for presenting options and processing opt-outs. Many of the organizations who will be disseminating communications about the opt-out policy to their members/clients/patients may also be in the role of processing opt-outs for those people. Additional training and support will be provided to those organizations, led by VITL.)

Messenger Training and Prepackaged Materials

- Webinars and/or in person training sessions with messengers
- Messaging toolkit – may include internal communication tools like talking points, email copy, PowerPoint slides and may include external messaging like website content, social media posts, newsletter copy, and more. These messages may be customized by the stakeholders for their audiences.
- Messaging materials – may include information sheets or rack cards, posters, and similar

In addition to stakeholder-generated messaging, DVHA will explore options for sharing information about the new consent policy in high-impact, low-cost channels including earned media (such as news stories). This will serve to inform a wide range of Vermonters through channels they already routinely engage with. Channel strategy will be modified based on stakeholder input. The strategy and tactics deployed may also depend on the resources available for content development and placement. An initial list of tactics under consideration is below.

Channels Under Consideration

- Owned media – state websites and social channels
- Communications from state-based service providers including DVHA-Medicaid
- Statewide news outlets (story pitch)
- Local/town newspapers (submitting an article)
- Front Porch Forum
- Town Meeting materials

Landing pages

- Some of the messages/stories and materials above will include directions to a website with additional information. DVHA and VITL will need to develop a page or pages of the most complete explanations and information and host on one of their websites.
- The landing page(s) will include contact information that will provide people ways to find answers to associated questions, including contact information for the Office of the Health Care Advocate.

Message Testing and Mechanism Development

Early message testing will begin in the first round of focus groups, but additional testing may be necessary to vet more complete communications materials and ensure that they are communicating what they are intended to communicate clearly before deploying. This may require convening the same or new representatives of special populations and Vermonters generally. A second series of focus groups or design workshops would also provide an opportunity to engage people in testing the opt-out mechanisms that will be available at initial roll-out and co-designing future opt-out mechanisms that are easier and more accessible.

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, 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 in 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. VITL will also be an ongoing connector to practices and health care organizations because they will be supporting their switch to processing opt-outs and through this work can support the adoption of new patient education materials, in line with the legislation's stipulation 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 in included.

A provider survey meant to inform the State Medicaid HIT Plan (SMHP) will also include questions about providers' understanding of the VHIE and consent options, the results of which will inform provider communications and education strategies development.

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.

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 1st 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 1st.

Ongoing Engagement and a Culture that Supports Meaningful Consent

Building a culture that promotes and supports meaningful consent for health information exchange under an opt-out policy is a project that will take more than the months between now and March 1, 2020. The Health Information Exchange plan presented to the Legislature 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 will:

- review, update, establish and implement standards and protocols to support the new consent legislation;
- review and update its portfolio of consent and privacy and security related policies and procedures to reflect the new consent legislation;
- consult with stakeholders and legal counsel (if necessary) to ensure policies, processes, and procedures support the new legislation.

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. Related to technical changes VITL supports the development of processes and procedures to expand methods through which an individual can easily opt-out of the VHIE. Any methods developed will include use of the VHIE and other supporting systems to collect patient consent decisions and to process, maintain, and audit decisions to opt-out of the VHIE. To accomplish this VITL will:

- assess existing processes and establish new use cases, business processes/workflows, and requirements to ensure the solutions support the new opt-out policy and new methods to collect consent directly from individuals and stakeholders not currently engaged in consent collection;
- VITL along with Health Catalyst (the VHIE platform currently used to support the consent and associated patient records in the VHIE) will establish a mechanism to update the existing VHIE system to support the patient opt-out decision and hide records for the patient, outside of an emergency;
- Develop, test, and implement solutions based on the new use cases, business processes/workflows, and requirements established within the project to support the new policy;
- Ensure an individual's pre-existing consent decision is maintained and new opt-out consent decision can be audited. Note that in addition to opting in under the current policy some individuals have formally opted out, even though that is the current default. All opt-out decisions recorded prior to March 1, 2020 must be assured to remain opted out as the transition occurs;
- Establish post implementation procedures and processes to provide ongoing support to residents and health care organizations in Vermont;
- In collaboration with the State of Vermont and other stakeholders create/update patient educational materials related to informed consent and decision making;
- Develop workflow recommendations and assistance for providers to implement the new consent policy based on use cases and identified solutions;
- As planned shared services are developed at the VHIE, ensure that sensitive data included in information submitted by providers subject to 42 CFR Part 2 can be identified, isolated, and protected;
- Work with the Designated Agencies as they implement new or updated EHR systems to ensure connectivity to the VHIE and integration with consent mechanisms;

- Execute this project to specifically focus on expanding opportunities for patient consent collection and educating Vermonters about the VHIE, access to information in the VHIE, and consent options to enable or disable that access.

EVALUATION WORKSTREAM

Evaluation of the extent to which public outreach regarding the VHIE, consent, the new policy, and opt-out processes has been successful is required by Act 53. This evaluation is a major workstream and planning is underway. Evaluation questions are being refined to reflect the four topics of the evaluation as directed by Act 53. DVHA is establishing mechanisms for stakeholder involvement using the feedback from initial interviews. DVHA is also defining some of the methods which will be vetted with stakeholders. The timeline for evaluation is being defined to ensure that the full evaluation plan can be incorporated into the HIT Plan update, and DVHA will fold the results of this evaluation into current VHIE evaluation reports to the General Assembly and the GMCB and into the Health Information Technology Plan annual update.

Act 53 requires the evaluation of the success of the stakeholder engagement and the intended purpose of that engagement to support informed consent decisions. As stated in the Executive Summary, planning for this evaluation is identified in the project plan as a workstream but is not yet initiated. Planning for evaluation requires input from the stakeholder engagement workstream to establish objectives for the evaluation. Status of the evaluation plan and associated evaluation activity will be provided in the report on Act 53 due November 1, 2019.

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 is currently being 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 is being developed by DVHA in collaboration with the HIE Steering Committee and it will include both the technology 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 will reflect the consent implementation project as reported here. The Plan will be consistent with the required November 1, 2019 Act 53 update report and will anticipate the successful completion of the consent implementation and the final report due on January 15, 2020.

In addition to the health IT planning work just described DVHA is also required to update the State Medicaid HIT Plan (SMHP) which supports the Promoting Operability Program (previously called the EHR Incentive Program). The SMHP also supports associated funding requests to CMS for funding to support the implementation, maintenance, and operation of certain health IT, including health information exchange. Of interest to the consent implementation project, the SMHP requires an environmental scan of health IT to include characterizing the status and use of health IT for the provider community. A provider survey is currently underway, and questions related to consent have been included in the survey. Other added questions will inform the technology roadmap's stakeholder engagement efforts. DVHA and the HIE Steering Committee have the leadership and oversight of all the planning activity described here and can thus ensure close alignment between these parallel paths of activity.

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 have been identified to ensure a successful implementation: stakeholder engagement, supporting mechanisms, and evaluation of the success of the stakeholder engagement.

Stakeholder engagement is underway with advocacy organizations interviewed and focus groups initiated. 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 and will leverage the infrastructure already in place to support the current opt-in policy. A critical need to protect the opt-out status of individuals who have already made the opt-out decision is acknowledged and will be addressed. VITL will also revise its portfolio of policies and procedures related to privacy and security of patient information.

A plan to evaluate the success of stakeholder engagement will be developed and the status of that plan will be reported in the November 1, 2019 update to Act 53.

The Health Information Technology Plan is being updated as required by Act 187 and will include 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 to Act 53 implementation of the consent policy will be provided on or before November 1, 2019. Progress on all workstreams will be included in that update and will include updates on messages developed as a result of stakeholder engagement, the status of mechanisms to support consent decisions and manage consent status, and an evaluation plan.

DVHA will present the Act 53 implementation status contained in this report to the GMCB on August 7, 2019.

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
Goal: Update the Statewide Health IT Plan			
Objective: Overall coordination of Vermont's statewide **Health Information Technology Plan**. 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 **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 lay **unless the patient has affirmatively elected not to have** the patient's electronic health **information shared in this manner**. **Activity**: DVHA and the Health	June 1, 2019 - November 1, 2019	DVHA Steering Committee Lantana	**On schedule** DVHA and Lantana meet weekly to review status and planned activity; the Steering Committee is updated frequently and approves completed milestones. 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 will include elements related to the change to the consent policy.

Information Exchange Steering Committee (Steering Committee) coordinate the work of Lantana Consulting Group, Inc in developing the roadmap. (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)			
Objective: Submission of the Health Information Technology Plan to the GMCB	June 1, 2019 - November 1, 2019	DVHA	**On schedule**

Objective and Activity	Start and End Dates	Responsible Party	Status
Goal: Stakeholder process to develop an implementation strategy for the consent policy			
Objective: 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. **Activity:** • Begin with stakeholders who advocate for special populations; • Convene focus groups of people who identify as part of special populations; • Convene focus groups to represent Vermonters;	June 1, 2019 - March 1, 2020	DVHA; Health Information Exchange Steering Committee	**On schedule** DVHA has met with eight advocacy organizations. 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. Advocate group representatives are willing to have further

- Seek additional expert interviews as needed; - Plan when and how to engage providers and practices			conversations as needed.
Objective: The implementation strategy shall include substantial opportunities for public input. Current stakeholder engagement with advocacy groups is focused on public input. **Activity:** - Focus groups with people who identify with advocacy groups and with other Vermonters will inform preferred options for further public input; - Media options such as call in radio programs and webinars are under consideration	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)	DVHA; Health Information Exchange Steering Committee	**On schedule** DVHA has met with eight advocacy organizations; Plans are under way to engage other Vermonters in focus groups; Planning for broader public input is under way.

Objective and Activity	Start and End Dates	Responsible Party	Status
Goal: Provide Clear Explanations of Key Elements of the Consent Policy			
Objective: 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	June 1, 2019 – March 2020 and beyond	DVHA; HIE Steering Committee; VITL	**On schedule** This activity will be informed by the stakeholder engagement currently underway. Developing the message is a part of planning

Insurance Portability and Accountability Act of 1996 (HIPAA) **Activity:** • Define informed consent as a minimum requirement; • Define meaningful consent as an ideal objective; • Develop a communications message that explains Act 53 consent management aligned with current HIPAA disclosure requirements; • Develop collateral material in a variety of formats to support the message at the public, practice, provider, and patient level.			conversations, including a review of existing collateral that can be updated and continue to take advantage of existing distribution channels.
Objective: Aim to address diverse needs, abilities, and learning styles with respect to information delivery. **Activity***:* • Identify a limited set of populations for separate messages (providers and practices; patients; other); • Identify a set of needs, abilities, and learning styles to inform message and delivery options; • Follow Vermont's state web accessibility standards for all web content (based on Section 508 of the Rehabilitation Act and W3C	June 1, 2019 – March 2020 and beyond	DVHA; HIE Steering Committee; VITL	**On Schedule** This activity will be informed by the stakeholder engagement currently underway. Developing the message is a part of planning conversations

Web Accessibility Initiative standards)			
Objective: Clearly explain: • the purpose of the VHIE; • the way in which health information is currently collected; • how and with whom health information may be shared using the VHIE; • the purposes for which health information may be shared using the VHIE; • how to opt-out of having health information shared using the VHIE; and • how patients can change their participation status in the future. **Activity:** Develop message material including brief handouts, more detailed descriptions, and presentation materials to address the content requirements identified in this objective.	June 1, 2019 – September 2019	DVHA; HIE Steering Committee; VITL	**On Schedule** In parallel with stakeholder engagement activities, 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.
Objective: 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. **Activity:** Develop messaging and delivery strategies as described above; ensure that information about the Office of the Health	June 1, 2019 – November 2019	DVHA; HIE Steering Committee; VITL	**On Schedule** In parallel with stakeholder engagement activities, DVHA and VITL are identifying the content and format requirements for this material.

Advocate is included, including contact information.			
Objective and Activity	**Start and End Dates**	**Responsible Party**	**Status**
Goal: Identify Mechanisms for Opting Out of Sharing Health Information Through the VHIE			
Objective: 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. **Activity:** 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.	June 1, 2019 – February 2020	VITL; DVHA; HIE Steering Committee.	**On Schedule** 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.
Objective and Activity	**Start and End Dates**	**Responsible Party**	**Status**
Goal: Develop or Supplement Consent Management Processes at the VHIE; Provide Clear Explanations of Key Elements of the Consent Policy			
Objective: Include plans for developing or supplementing consent management processes at the VHIE to reflect the needs of patients and providers.	June 1, 2019 – February 2020	VITL; DVHA; HIE Steering Committee.	**On Schedule** The VITL implementation plan for consent management mechanisms includes operational

Activity: 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 management processes.			considerations including registering individual opt-out choices and establishing audit trails for consent management.
Objective: 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. **Activity:** See previous objectives and activities related to the development of messages and delivery. Identify sectors to benefit from separate communication strategies. Develop variations of message content for each identified sector.	June 1, 2019 – September 2019	DVHA; HIE Steering Committee; VITL	**On Schedule** In parallel with stakeholder engagement activities, DVHA and VITL are identifying the content and format requirements for this material.
Objective and Activity	**Start and End Dates**	**Responsible Party**	**Status**
Goal: Evaluate the Extent to Which Public Outreach Has Been Successful			
Objective: Identify a methodology for evaluating the extent to which the public outreach regarding the VHIE, consent policy, and opt-out processes has been successful. **Activity:** Develop a plan for evaluating the required public outreach associated with Act 53	August 1, 2019 – November 2019	DVHA; HIE Steering Committee	**On Schedule** DVHA has initiated project planning for evaluation; evaluation questions are being developed; mechanisms for stakeholder involvement are being developed; timeline will accommodate

consent implementation; Identify resources to conduct the evaluation; identify and agree on a methodology for the evaluation; conduct the evaluation; report on the evaluation.			folding evaluation into other planning and reporting activities.

Objective and Activity	Start and End Dates	Responsible Party	Status
Goal: Provide Status Updates to Legislative Committees and the GMCB			
Objective: 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. **Activity:** 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.	June 1, 2019 – August 1, 2019 (first update) November 1, 2019 (second update)	DVHA; HIE Steering Committee	**On Schedule** August 1, 2019 report submitted on time.
Objective: 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	November 1, 2019 – January 1, 2020	DVHA; HIE Steering Committee	**Not started**

Mountain Care Board on or before January 15, 2020. Develop a final report on outcomes of the stakeholder engagement process and the consent policy implementation strategy; Include description and discussion of the mechanisms that will support the strategy; Include description and discussion of the evaluation methodology for the stakeholder engagement strategy.			