

Opt-in or Opt-out: Patient Consent to Exchange Health Care Information through the Vermont Health Information Exchange

Recommendation to House Committees on Health Care and on Energy and Technology, and the Senate Committee on Health and Welfare Pursuant to Act 187 (2018), Sec. 7

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Key Terms

The following terms are defined to ensure common understanding among all readers of this report:

“Health information exchange (HIE)” means an organization that collects health information electronically, manages it, and makes it available across the health care system. There is at least one HIE in almost every state in the nation, and HIEs can offer a variety of services. Vermont’s Health Information Exchange is called the VHIE.

“Opt-in” refers to a method of expressing consent that presumes consent is withheld unless stated otherwise. In the context of the VHIE, this means a patient’s records are accessible to VHIE participating providers only if a patient expressly indicates that “I want my records accessible.”

“Opt-out” refers to a method of expressing consent that presumes consent is granted unless stated otherwise. In the context of the VHIE, this would mean a patient’s records are accessible to VHIE participating providers unless a patient expressly indicates that “I don’t want my records accessible.”

Background

The Vermont Health Information Exchange (VHIE) is a Vermont system operated by Vermont Information Technology Leaders, Inc. (VITL) that collects health information electronically, manages it, and makes it available to health care providers across the State as permitted by state and federal law. Currently, a person’s individually identifiable health information is only accessible on the VHIE by participating health care providers if that person has given written permission providing for such access. Giving permission in this way is commonly referred to as “opting in,” or giving “opt-in” consent.

Ongoing oversight and evaluation of the VHIE, including independent review pursuant to Act 73 of 2017, has led to a re-evaluation of the current opt-in consent policy. Act 187 of 2018 (*An act relating to health information technology and health information exchange*) included a provision directing:

The Department of Vermont Health Access, in consultation with Vermont Information Technology Leaders, Inc., the Office of the Health Care Advocate, and other interested stakeholders, [to] provide recommendations to [the Legislature] regarding whether individual consent to the exchange of health care information through the Vermont Health Information Exchange should be on an opt-in or opt-out basis.

Act 187 of 2018, Section 7.

This report provides the recommendations required under Act 187, and an overview of the process used by the Department of Vermont Health Access (DVHA) to arrive at those recommendations. For the reasons described below, DVHA recommends that consent to the

exchange of an individual's health care information on the VHIE should be given effect through an opt-out policy and process.

Act 73: Consultants Review HIE Program Challenges and Vermont's Low Consent Rate

First, DVHA considered the results of the review required under Section 15 of Act 73 of 2017, which required the Secretaries of Administration and Human Services to conduct a comprehensive review of the funding, planning and operation of the VHIE. The State engaged HealthTech Solutions (HTS), a firm with expertise in health information exchange technologies, relevant legal issues, operations, and research, to conduct the review. HTS released its report in November of 2017. Among significant program challenges, HTS noted the "inherent challenges of the opt-in [consent model],"¹ and that due to the labor-intensive and manual process of gathering separate written consent under the opt-in policy, providers were reluctant to ask for consent from their patients. According to HTS in its report, "only 19.5 percent of Vermonters have even been asked to consent to have their data accessible in the VHIE,"² explaining that "[o]ne of the primary reasons for the low number of patients who are asked to provide consent is the cumbersome process that is used."³ The report posits that the requirement may have the effect of unduly constraining information sharing in the VHIE, undermining its essential purpose and reducing its value to our health care system. Furthermore, HealthTech contrasted the Vermont experience to other states in testimony to State of Vermont officials, emphasizing that all "nine successful HIEs HealthTech assessed" as a basis for comparison to the VHIE are "opt-out exchanges, meaning that patient health data is automatically incorporated into the exchange unless a patient explicitly opts out."⁴

Approaches to HIE Consent Used in Other States

Because Vermont law requires the State's Health Information Technology Plan to "ensure the use of national standards for the development of an interoperable system, [including those] relating to . . . privacy,"⁵ DVHA sought to determine whether national standards exist for HIE privacy-related consent policies.

While practices vary in the 40 other states identified by DVHA to have statewide HIEs, 33 of them have either opt-out consent policies or no consent requirement at all for individuals' health records to be accessible in their HIEs. The handful of states with no state-level consent requirement at all default to federal law to govern how individually identifiable health information is shared through their HIEs. These states choose not to supplement the already-robust controls embodied in federal law under the Privacy and Security Rules of the Health Insurance Portability and Accountability Act (HIPAA), which already generally limit the sharing of such information to treatment, payment or health care operations purposes among

¹ Evaluation of Health Information Technology Activities – Final Report, November 15 2017, HealthTech Solutions, at page 43.

² *Id.*

³ *Id.*

⁴ <https://ehrintelligence.com/news/review-reveals-problems-with-vermont-health-information-exchange>

⁵ 18 V.S.A. § 9351(b)(3)

providers and others with a relationship with the individual whose health information is at issue.

Among the states using an opt-out consent model, there are a variety of means used to implement an individual's election to opt out, placing a greater or lesser burden on those seeking to opt out. Some states make it easy to opt out, for example, by offering online options for opting out. Other states increase the burden on those desiring to opt out, for example, by requiring written opt-out forms to be notarized or signed by a provider.

By contrast, DVHA found only three states besides Vermont that use an opt-in model for consent similar to Vermont's.

While there may be no established "national standard" for whether or in what form consent may be required for individually identifiable health information to be accessible in statewide HIEs, the number of states using opt-out consent or no consent at all (33) vastly outnumber those using an opt-in model like Vermont's (4).⁶ As noted above, all nine successful HIEs assessed by HTS were among that majority, with four of those requiring notarized forms for opting out, which makes opting out more difficult. DVHA draws a strong inference from this data that Vermont's current policy is outside the mainstream.

Vermont Stakeholder Engagement and Views

In accordance with the Act 187 of 2018, DVHA consulted with VITL, the Office of the Health Care Advocate, and other interested stakeholders to develop its recommendations regarding individual consent to the exchange of health care information through the VHIE. Stakeholder engagement proceeded in two phases. First, DVHA's General Counsel led a series of interviews and discussions with interested parties. Second, DVHA listened and reflected upon public comment provided following a presentation on this report at a meeting of the Green Mountain Care Board. DVHA's good-faith summary of the discussions follows; however, these organizations are encouraged to speak for themselves.

I. August through December 2018.

From August through December 2018, DVHA met with individuals representing the following organizations (some on multiple occasions) and received input regarding opt-in and opt-out consent models for the VHIE, and the implications and concerns arising under each model:

- Vermont Information Technology Leaders, Inc.
- Office of the Health Care Advocate
- Green Mountain Care Board
- ACLU of Vermont
- BiState Primary Care Association (representing FQHCs)
- Vermont Medical Society (VMS)
- Vermont Association of Hospitals and Health Systems (VAHHS)
- Medicaid and Exchange Advisory Board (MEAB)

⁶ Among the 41 states including Vermont identified by DVHA to have statewide HIEs. The remaining four states had a mix of opt-out and case-specific opt-in, or some other unique combination of consent requirements.

- Primary Care Advisory Board (briefly during HIE Plan “roadshow”)
- DVHA HIE/HIT Steering Committee members, with representation from:
 - Blueprint for Health
 - OneCare Vermont Accountable Care Organization (ACO)
 - Blue Cross Blue Shield of Vermont
 - Community Providers (Vermont Care Partners)
 - Vermont Agency of Digital Services
 - Public Health (Department of Health)
 - Vermont Health Information Exchange (by VITL)

All but two of these stakeholders voiced support for a switch to opt-out consent for the VHIE. The ACLU of Vermont and the Office of the Health Care Advocate expressed a preference for continuing the existing opt-in policy.

Among stakeholders supporting an opt-out consent model, DVHA felt it heard consensus that such a model would:

- increase the number of Vermonters whose records are accessible in the HIE, making it consistent with other states and a much more valuable and useful resource for providers;
- reduce the administrative burdens and costs borne by providers to capture and process consent; and
- support patient privacy and autonomy at least as well as the current model.

Additionally, DVHA and supportive stakeholders drew a general inference that the fact 95% of the 217,397 Vermonters asked have chosen to make their health information accessible to all participating providers in the VHIE demonstrates a low rate of resistance to sharing this data.⁷

Beyond potential benefits, stakeholders share a concern that under the current consent model, with its cumbersome and manual process, the VHIE will not achieve the critical mass of records availability that will make it a dependably useful resource for providers. They generally reject the idea that changing to opt-out would degrade privacy or security of health information, several of them noting that the health records themselves are already in the VHIE, and that consent only determines whether participating providers are permitted to access them. Further, many observed that the practical effect of making hundreds of thousands of records inaccessible through the VHIE, an organization established through legislation to enable exchange of health records across providers, may reduce opportunities to improve patient care.

DVHA is respectful of the fact that consensus among consulted stakeholders is not unanimity. The Office of the Health Care Advocate (HCA) expressed opposition to any proposed modification of the existing opt-in consent policy. The ACLU of Vermont voiced similar opposition to changing the current opt-in policy. They expressed generalized concern that an opt-out consent model would be somehow less protective of patient privacy and autonomy than the existing opt-in policy. Also, the parties expressed a desire for more patient

⁷ Of the 217,397 Vermonters asked as of late December 2018, 95.2% indicated by express written consent that they want their records accessible in the VHIE by participating providers who may have occasion to treat them.

engagement and choice in health care. DVHA supports these goals; however, DVHA does not believe that a change to an opt-out policy undermines these goals.

DVHA also heard, most clearly from the ACLU, a desire for robust implementation measures if the consent policy for VHIE does change to opt-out. Among those recommendations were multiple cycles of public notice and publicity, intensive provider training, and a thoughtful implementation plan allowing ample time for those desiring to opt out to do so. DVHA considers this good advice in the event the Green Mountain Care Board changes the policy.

II. January 2019 Update.

On January 9, 2019, DVHA presented its progress on its Act 187 outreach, report and recommendation effort at a public meeting of the Green Mountain Care Board. Board members who provided comment were generally supportive of considering a switch to opt-out, conditioned on careful implementation planning and ensuring that appropriate consumer protections are in place regarding use of health information, including de-identified health information. During the public comment portion of the presentation, more stakeholder feedback was received reflecting a range of perspectives and views.

Among the commenters were those representing the disability community, including the Vermont Developmental Disabilities Council (VTDDC) and the Vermont Coalition for Disability Rights. These speakers voiced opposition to opt-out consent, which they view as less suitable for developmentally disabled individuals who may have reduced health literacy. They asserted that opt-out would compromise self-determination by impairing informed decision-making and that consumers would be at greater risk to be confused or uninformed about their options under opt-out. They called for further engagement and analysis before GMBC discusses potential changes to the VHIE consent policy. A speaker authorized to speak on behalf of the ACLU of Vermont reiterated that group's opposition to changing the policy.

A commenter authorized to speak on behalf of the HCA restated their opposition to opt out, which in their view compromises consumer privacy and self-determination. The commenter also challenged DVHA's assertion that over 95% of Vermonters want their health information accessible within the exchange, expressing doubt that the 217,397 Vermonters who were asked the question were a statistically significant or a representative sample of Vermonters. The commenter suggested a survey or study be conducted of the whole population instead to reveal the true disposition of Vermonters on the issue.

Another commenter stated that informed consent is critical and expressed the sentiment that opt-out is against the freedom and rights of individuals and is very disturbing.

A second representative of the VTDDC commended the recent progress made toward increasing the total number of Vermonters asked for consent under opt-in, and questioned whether a change to opt-out was really needed.

The last commenters both voiced strong support for a change in policy to opt-out. First, a representative from Vermont Medical Society (VMS) (representing medical professionals) said

its members support a change to opt-out, and that it would be for the good of the health of Vermonters. In the view of VMS membership, the HIE needs to have the records of most Vermonters accessible for it to be a useful tool for providers; they recognize that opt-out would support this goal. The commenter pointed out that consent only means consent for records to be viewable by providers, noting that the records themselves are already in the VHIE.

The final commenter, the Interim President and CEO of VITL, responded to a prior commenter's suggestion that recent gains in securing consents might signal that consent policy change is unnecessary, stating that VITL has good reason to believe that such gains will soon reach a plateau, and that a change to opt-out would be necessary to build on those gains. He said that the change of policy would move the number of records accessible within the exchange from those representing a minority of Vermonters, to those representing a majority. He voiced on behalf of VITL a commitment to work with all appropriate parties to implement any consent policy change with great care and in a manner respectful of the concerns of those opposing change.

A Note on Legal Concerns

During DHVA's discussions with stakeholders, questions frequently arose relating to the legal framework for VHIE consent requirements. These questions mainly centered around common misconceptions about the source of authority for and statutory constraints relating to the existing opt-in policy, and what actions would be necessary to change it. DVHA has concluded that no legislative action would be necessary to modify the current consent policy

The current opt-in consent model is embodied in a policy approved by the Agency of Administration and the Green Mountain Care Board titled, *Policy on Patient Consent for Provider Access to Protected Health Information on VHIE or through the Blueprint*, which is incorporated into the Vermont Health Information Technology Plan. In order to change the opt-in policy to opt-out or some other policy, the Agency of Administration and the Green Mountain Care Board need only adopt and approve a new policy reflecting the desired change.

There is no state statute that requires patient consent for exchange of ordinary medical records between and among treating providers as enabled by the VHIE, so no statutory change would be required to adopt a different consent model. As previously noted, HIPAA allows for the exchange of records among treating providers, such as those in a network.

It has been argued in the past that the "Patients' privilege" statute at 12 V.S.A. § 1612 should be expansively read to require some form of consent to the disclosure of medical records generally. The Supreme Court of Vermont, however, recently clarified that 12 V.S.A. § 1612 "codifies an evidentiary privilege . . . limiting its application to judicial proceedings."⁸ As such, this statute does not apply to sharing of medical records among treating providers in the VHIE.

⁸ *Kuligowski v. Brattleboro Retreat*, 203 Vt. 328, 360 (2016)

Similarly, past discussions⁹ relating to the potential applicability of parts of the mental health hospitalization statutes in Title 18 of the Vermont Statutes¹⁰ reappeared in our current stakeholder conversations. DHVA agrees with past determinations that such provisions have no applicability outside of their specific context. Since mental health providers including mental health and psychiatric care hospitals do not participate in the VHIE, this statute has no relevance to our question.

In sum, no legislative action would be necessary to modify the current consent policy. The Agency of Administration and the Green Mountain Care Board have the authority to change their own policy under existing law.

Conclusion and Recommendations

DVHA has undertaken its Act 187 work recognizing (i) the value a successful and broadly inclusive health information exchange would bring to Vermont's health care system,¹¹ and (ii) the paramount importance of Vermonters' rights to privacy and self-determination with respect to their health information. After thorough review and consideration, DHVA believes that a carefully crafted and implemented opt-out consent policy would best support the former, while also ensuring the protection of the latter. Accordingly, for the following reasons and subject to the following conditions, DVHA recommends that consent to the exchange of an individual's health care information in the VHIE should be given effect through an opt-out policy and process, and that the Agency of Administration and the Green Mountain Care Board should commence their policy revision without delay.

I. Opt-out would enable the VHIE to effectively support the health care system.

The State of Vermont has made an enormous investment of time, effort and taxpayer dollars in developing the VHIE. It has become clear to DVHA that at a basic level, the VHIE will not be successful if providers do not find it useful. Whether the VHIE is useful to providers depends first and foremost on whether they have access to the records of a high proportion of Vermonters. While there is no universal agreement about what proportion is enough, all agree that after years under the opt-in consent policy (with the administrative burdens it entails), the number remains short of the mark (about 39% as of this writing).

After consultation with VITL and other stakeholders best positioned to understand the underlying reasons, DVHA concludes that:

- If continued, the current opt-in consent model will continue to impede progress toward a goal of having Vermonters' records accessible to providers engaged with the VHIE; and

⁹ In 2014 (leading up to the last time the consent policy at issue was amended)

¹⁰ 18 V.S.A. § 7103

¹¹ DVHA agrees with HTS in its Evaluation of Health Information Technology Activities – Final Report, dated November 15 2017: “**HIE systems are essential.** Aggregated clinical data is central to understanding the impact of populationwide reforms, such as the All-Payer Model. And the exchange and aggregation of clinical data through a central hub makes clinical data available to providers at the bedside, which supports informed, quality decision-making for patients. Providers must also exchange clinical data to meet federal requirements to receive full Medicare reimbursement. Therefore, despite difficulties in execution, it is no surprise that 92 percent of stakeholders HTS interviewed in Vermont indicated that the state needs to continue Vermont's HIE efforts. HIE is foundational to good healthcare and successful system reform that impacts both health and the costs of care.”

- The reduced burdens of administering an opt-out consent model, coupled with the presumption of provider permission to access records inherent in such a policy, would result in a substantial majority of Vermonters' records being accessible in the VHIE.

DVHA accepts the professional expert opinion of HTS consultants, supported by their evaluation of successful HIEs in other states, that Vermont's opt-in policy and process undermine our ability to achieve a critical mass of provider-accessible records and that a change in policy to implement opt-out consent would facilitate that objective.

II. Opt-out better reflects prevailing practices in other states.

33 out of the 40 other states identified by DVHA as having statewide HIEs use opt-out or do not require consent at all for exchange of health records in their HIEs. In this respect, opt-out would be better aligned with the requirement under Vermont law¹² that the State's Health Information Technology Plan (into which the VHIE consent policy is incorporated) reflects national standards for privacy.

III. Opt-out does not degrade Vermonter privacy or self-determination.

DHVA believes that a carefully crafted and implemented opt-out consent policy would not degrade consumer privacy or autonomy.

Opt-in consent and opt-out consent can be viewed as simply two different paths to get to the same fundamental goal shared by all stakeholders: to give effect to an individual's fully informed decision about whether to permit access to the individual's health care information through the VHIE to providers involved in treatment of the individual. These paths differ only in how the decision, once reached, is given effect: one requires an overt act, the other requires no further action. Under either approach the, the validity and integrity of the decision depends not on how it is expressed (i.e., through action or inaction), but rather on whether the individual has meaningfully engaged the question, and whether sufficient information has been provided to support an informed choice. DVHA's recommendation to adopt opt-out is conditioned on the development of a policy and process that provides ample notice and opportunity to all affected Vermonters to meaningfully engage, and be informed about their decisions. The satisfaction of this condition would ensure that no affected Vermonter was denied self-determination regarding their health care information privacy choice. DVHA further recommends that any proposed opt-out policy should require mechanisms for opting out that are easy to use and access (like online or simple paper forms) rather than those making opting out more difficult (like requiring notarized or provider-signed forms). DVHA is confident that a policy can be devised that meets these conditions for all populations, including those with reduced health literacy.

DVHA acknowledges that neither model is perfect, i.e., neither will capture the actual intent of all Vermonters in all cases. But if we are concerned about giving effect to the actual intent of the most Vermonters in the most cases, the difference between opt-out and opt-in is stark. Under an opt-out model, DVHA concedes that some number of individuals may fail to engage the question and make a conscious choice notwithstanding every opportunity to do so. In such cases, the consequence would be that the health records of such individuals -- records that are already in the VHIE -- would be accessible to providers involved in the treatment of those individuals.¹³ Based on our sample of over 200,000 Vermonters who have made their preferences known, DVHA believes that the current evidence indicates that this is the outcome that would have been chosen in most cases anyway had the decision been fully engaged.

¹² 18 V.S.A. § 9351(b)(3)

¹³ DHVA notes that even if consent is in place, all such VHIE participating providers are restricted by the terms of their agreements with VITL and by federal law (HIPAA) regarding the circumstances under which they may access and use individually identifiable health information.

By contrast, under opt-in, the actual consequence is that hundreds of thousands of Vermonters are denied outright the opportunity to express their preferences regarding the accessibility of their health information because the burdensome nature of the current policy and process discourages providers from even asking for consent. In DVHA's view, this result is a greater affront to consumer autonomy and self-determination than could be reasonably argued to arise under opt-out.

IV. Recommendation. In sum, after careful consideration of stakeholder feedback, the advice of expert consultants, and its own research, DVHA recommends that the Agency of Administration and the Green Mountain Care Board revise the *Policy on Patient Consent for Provider Access to Protected Health Information on VHIE or through the Blueprint* to provide for an opt-out consent model and implementation requirements ensuring ample notice and opportunity to all affected Vermonters to meaningfully engage, and be informed about their health care information privacy decisions. DVHA has concluded that no legislative action is necessary to implement this recommendation.