MEMORANDUM

TO: STEPHEN KLEIN AND CATHERINE BENHAM, LEGISLATIVE JOINT FISCAL OFFICE
FROM: DANIEL SMITH, IT CONSULTANT FOR THE JOINT FISCAL OFFICE
SUBJECT: VERMONT HEALTH INFORMATION EXCHANGE EFFECTIVENESS AND PATIENT CONSENT
DATE: APRIL 22, 2019

During the 2018 Legislative Session the Legislature passed Act 187, "An act relating to health information technology and health information exchange"[1]. Originating as H.901, this Act is focused on improving the operations and performance of the Vermont Health Information Exchange (VHIE), which is operated by Vermont Information Technology Leaders (VITL) and supervised by the Vermont Department of Health Access (DVHA). One of the items that was addressed in Act 187, and responded to by DVHA, was the issue of patient consent. The purpose of this memo is to describe this issue, discuss the various testimony and opinions that dealt with this issue during the current legislative session, and provide a recommendation.

1. Executive Summary

The VHIE supports the exchange of patient information among providers in different health care networks. Under current policy the sharing of this information is only allowed if a patient specifically consents to do so, and this is referred to as an "opt-in" approach. An "opt-out" policy is one where patient data can be shared unless the patient specifically refuses. The change from an opt-in to an opt-out policy can be made by the Green Mountain Care Board (GMCB) through the approval of a revised Vermont Health Information Technology Plan. The Legislature requested that the GMCB defer a decision pending legislative review, and has held a number of committee hearings on the subject. Based on the history and past effectiveness of the VHIE, various reports submitted over the past year, and legislative testimony to date, **I recommend that the legislature support the GMCB making the change from an opt-in to an opt-out policy**. While there are valid concerns and questions regarding the change, I believe that this is an important step in improving VHIE effectiveness and utilization.

I also recommend that DVHA be directed to create a report that addresses the data ownership question and provides recommendations for any statute changes needed to clarify ownership. This should include ownership of basic patient data, special-category data (mental health and behavioral information, for example), immunization data, and aggregated data.

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[1] https://legislature.vermont.gov/Documents/2018/Docs/ACTS/ACT187/ACT187%20As%20Enacted.pdf

2. Background

In 2017 a growing concern over the performance of the VHIE as operated by VITL resulted in statutory language in Act 73, "An act relating to miscellaneous tax changes"[2]. Section 15 of this Act required DVHA to have prepared a "Health Information Technology Report" that among other things reviewed the Health IT Fund, the Health Information Technology Plan, VITL, and the Health Information Exchange. This report[3] (hereafter referred to as the "Act 73 Report") was completed in November of 2017 by HealthTech Solutions, Inc., and was presented to the Legislature in January of 2018.

The Act 73 Report included a discussion of the effectiveness of the VHIE, and concluded that the current patient consent policy represented an obstacle to greater utilization of the exchange. The report questioned whether Vermont should shift from an "opt-in" policy (where a patient must explicitly state that their data can be shared) to an "opt-out" policy (where data can be shared unless a patient states otherwise).

Legislative reaction to the Act 73 Report resulted in the enactment of Act 187, which mandated a number of actions and reports from DVHA and VITL to address the shortcomings described in the Act 73 Report. This included a requirement that DVHA prepare a report on the consent issue:

- On or before January 15, 2019, the development and submission of recommendations "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."

This report was submitted by DVHA on January 15, 2019. Titled "Opt-in or Opt-out: Patient Consent to Exchange Health Care", the Consent Policy Report[4] addressed the issue discussed in the Act 73 Report and recommended that Vermont change from an "opt-in" to an "opt-out" approach to patient consent.

3. Act 73 Report Findings and DVHA Recommendations

The Act 73 Report, and DVHA's Consent Policy Report, contain a number of facts and findings that relate to the consent issue. These include (1 = Act 73 Report, 2 = DVHA Consent Policy Report):

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[2] https://legislature.vermont.gov/Documents/2018/Docs/ACTS/ACT073/ACT073%20As%20Enacted.pdf

[3] https://legislature.vermont.gov/assets/Legislative-Reports/VT-Evaluation-of-HIT-Activities-FinalReport-Secretary-Signature.pdf

[4] https://legislature.vermont.gov/assets/Legislative-Reports/DVHA-Report-VHIE-Patient-Consent-Policy.pdf

- As of November 2017, only 19.5% (122,431 of 626,042) of Vermonters had been asked to consent to having their healthcare data accessible via the VHIE (1);

- Of the 122,431 Vermonters that have been asked, 117,432 (96%) chose to make their data accessible, while 4,999 (4%) declined (1);

- Health Information Exchanges (HIEs) that operate under an opt-out mechanism have many more patient records accessible to providers than HIEs that operate under an opt-in mechanism. HIEs that are opt-out typically have 2 - 4 percent of their population opting-out or 96 - 98 percent opted-in (1);

- Providers in the UVM Health Network (University of Vermont Medical Center, Central Vermont Medical Center, Porter Medical Center, Home Health & Hospice, Alice Hyde Medical Center, Champlain Valley Physicians Hospital, Elizabethtown Community Hospital, and all doctors and providers employed by the UVM Health Network) share a common healthcare record system. All patients that participate in the UVM Health Network are subject to the UVM Health Network Privacy Practices[5], which represents an "opt-out" consent policy within that network. The Act 73 Report concluded that "Providers [in that network] do not have an incentive to ask their patients for consent to share their data in the VHIE because most of their patients likely get their care within the network. There is little reason to take on the administrative burden of getting consent or for using the VHIE with its low number of patients who have provided consent." (1);

- 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 individual health records to be accessible in their HIEs (2);

- Regardless of opt-in or opt-out, all providers must comply with federal law under the Privacy and Security Rules of the Health Insurance Portability and Accountability Act (HIPAA). This limits the sharing of information involving treatment, payment or health care operations purposes to providers and others with a valid relationship with the individual (2);

- DVHA found only three states besides Vermont that use an opt-in model for consent similar to Vermont's (2).

Based on the above items, DVHA concluded in its report that:

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[5] https://www.uvmhealth.org/medcenter/pages/patients-and-visitors/patients/patient-rights/notice-of-privacy-practices.aspx

- The Green Mountain Care Board (GMCB) should 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;
- Implementation requirements for such a change must ensure ample notice and opportunity to all affected Vermonters to meaningfully engage, and be informed about their health care information privacy decisions;
- No legislative action is necessary to implement this recommendation.

4. Green Mountain Care Board and Legislative Testimony

From January through April of 2019 the Green Mountain Care Board and several Legislative committees heard testimony on the patient consent question. These meetings included:

- January 9, 2019, Green Mountain Care Board: DVHA presentation on Act 187 progress, reports, and recommendations;
- February 6, 2019, House Energy and Technology, House Health Care Joint Meeting: Discussion about Vermont Information Technology Leaders (VITL) Reports;
- March 29, 2019, Senate Health and Welfare: Discussions about the Vermont Health Information Exchange;
- April 10, 2019, Senate Health and Welfare: Discussions about the Vermont Health Information Exchange;
- April 25, 2019 (scheduled): House Health Care: Discussions about the Vermont Health Information Exchange.

During these meetings DVHA and VITL presented their recommendations, including the proposed change to an opt-out policy. While some of the other attendees at these meetings supported this change, others disagreed. Arguments against making the change included:

- Lack of trust in patient informed consent: "I would urge the Green Mountain Care Board to not agree to a change in policy without first reviewing a compelling plan to ensure that consumers understand their options." (Kirsten Murphy, executive director of the Vermont Developmental Disabilities Council, 1/9/2019 testimony to the Green Mountain Care Board[6]);

  - My opinion is that while this is true, it applies to both an opt-in and an opt-out policy. Regardless of the policy implemented by the GMCB, it must be effectively presented to consumers (patients) in order to protect patient rights.

- Lack of trust in the opt-in/opt-out process. "Current low opt-in rates are partially due to providers struggling to obtain and process patient consent. If providers and VHIE cannot effectively manage patient opt-ins, there is no reliable evidence to suggest that they could handle patient opt-outs." (Office of the Health Care Advocate, 3/29/2019 testimony to Senate Health and Welfare[7]);

  - My opinion is that given the number historically choosing to opt-out (4%) and those opting in (96%), providers should find the opt-out policy far less burdensome, with a corresponding increase in their ability to effectively manage patient choice. A provider handling 4 forms for every 100 patients would be less likely to make a mistake than one handling 96.

- Lack of trust in data security: "The idea that we're going to dump all of your records in a bucket, and let anybody who has access to the health information exchange rummage through that bucket, is absolutely absurd and untenable, and yet, that's the model we're currently on." (Stephen Whitaker, 3/29/2019 testimony to Senate Health and Welfare[8]);

  - My opinion is that regardless of the validity of this concern, it again applies to both an opt-out and opt-in approach. It should also be noted that 1) all records are already "in the bucket", i.e. contained in the Vermont Health Information Exchange, and 2) in accordance with Federal law (i.e. HIPAA), no one can "rummage through that bucket" without a specific medical purpose. This is also true of those patient records currently in the UVM Health Network health information system.

- Concerns about data ownership: This relates to the question of who owns patient data, and in what form. For example, does a patient own their health record? Do

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[6] https://vtdigger.org/2019/01/09/health-record-sharing-consent-change-causes-concern/

[7] https://legislature.vermont.gov/Documents/2020/WorkGroups/Senate%20Health%20and%20Welfare/Vermont%20Health%20Information%20Exchange%20(VHIE)/W~Michael%20Fisher~Op-out%20Fact%20Sheet~3-29-2019.pdf

[8] https://vtdigger.org/2019/04/15/advocates-battle-health-record-consent-change/

they own the data when it is aggregated into a larger system (such as OneCare, or the VHIE)?

  - While the issue of data ownership is related to the consent issue, it is also a broader question. Existing statutes imply that at least some of patient data is actually owned by the State (see 18 V.S.A. § 1129[9]), however this is not completely clear. My opinion is that DVHA should be required to specifically address the ownership question, and to provide proposals for statute changes as needed.

  - The UVM Health Network Privacy Practices imply that patients in that system do not own their data: "You can ask us not to use or share certain health information for treatment, payment or our operations. We are not required to agree to your request, and we may say "no" if it would affect your care or our operations."

5. Decision Making Authority

DVHA's Consent Policy Report concluded that the Green Mountain Care Board, in their role as the approving authority for the Vermont Health Information Technology Plan (VHITP), is the entity that can change Vermont's consent policy. This determination is consistent with GMCB's role as described in 18 V.S.A. § 9351[10]. While the Consent Policy Report also mentioned the Agency of Administration, Act 187 removed the Agency of Administration as an approval authority for the VHITP.

However, while the GMCB may have approval authority, the Legislature is also a concerned party as demonstrated by their passage of Act 187. As a result, on March 8 2019 the Legislature provided a letter to the GMCB[11] requesting a delay on any decision while the Legislature continues to hear testimony. The essential outcome is that while GMCB has decision making authority, in practice it would be best if that decision was made with the full participation and support of the Legislature.

6. Recommendations

Based on the Act 73 Report, DVHA's Consent Policy Report, and the testimony provided at Green Mountain Care Board and Legislative Committee meetings, my

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[9] https://legislature.vermont.gov/statutes/section/18/021/01129

[10] https://legislature.vermont.gov/statutes/section/18/219/09351

[11] https://legislature.vermont.gov/Documents/2020/WorkGroups/Senate%20Health%20and%20Welfare/Green%20Mountain%20Care%20Board/W~Ginny%20Lyons~Letter%20to%20the%20Green%20Mountain%20Care%20Board~3-12-2019.pdf

recommendation is that Vermont should change to an “opt-out” consent policy. This is based on the following:

- An effective Health Information Exchange must by definition support the exchange of health information. As such, the default consent policy should be to allow that exchange while still supporting patient choice through the “opt-out” mechanism;
- The majority of those patients that have been presented with the choice to share their data chosen to do so (96%);
- A significant number of Vermont patients are already in an “opt-out” system, specifically those that participate in the UVM Health Network. Changing to an “opt-out” policy for the VHIE simply conforms to an existing common practice;
- Changing to an “opt-out” policy would be more consistent with other states’ practices.

I believe that Legislature should support this change and communicate this support to the GMCB. However, as with most IT activities, the effective deployment of a new system or policy through a strong change management process is as important as the technology change itself. If the GMCB chooses to make this change to policy, it is essential that the change is effectively communicated to the public. Any such communications must also directly address the concerns that have been presented in legislative testimony (security of data, mechanisms for patients to opt out, data ownership, etc.). While past experience indicates that the vast majority of Vermonters will support the opt-out policy change (since 96% of those asked choose to share their data), it is very important to respect the wishes of those patients that do not wish to share their data, or have concerns about the potential use or misuse of their data.

I also recommend that DVHA be directed to create a report that addresses the data ownership question and provides recommendations for any statute changes needed to clarify ownership. This should include ownership of basic patient data, special-category data (mental health and behavioral information, for example), immunization data, and aggregated data.