Minnesota Department of Health
Office of Health Information Technology
Request for Information on impact and costs associated with consent requirements under the Minnesota Health Records Act
September 16, 2016

This Request for Information (RFI) is a project of the Minnesota Department of Health (MDH) Office of Health Information Technology. Chartered by legislative request, this RFI is designed to obtain input from a variety of stakeholders on impact and costs associated with implementing consent requirements under the Minnesota Health Records Act.

Questions are grouped by section. ***Responders are not expected or required to respond to every question and may comment on only those areas which are of interest or importance to them.***

Released: September 16, 2016

Responses due: October 17, 2016

For questions, please email MN.eHealth@state.mn.us.

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I. Introduction and Overview

Summary Objective

MDH, by legislative mandate, seeks public input on both patient impact and costs associated with the consent requirements under the Minnesota Health Records Act (MHRA). MDH and the Minnesota e-Health Initiative frequently receive anecdotal comments from both health care providers and patients about the misalignment between the MHRA and Health Insurance Portability and Accountability Act [HIPAA], often focused on the difficulty of exchanging patient information for treatment. This Request for Information (RFI) is an opportunity to receive formal comments about the MHRA from the community and to study its direct and indirect financial impacts, as well as non-financial impacts such as impacts on quality of care.

This RFI, and responses to it, do not in any way obligate the State to take any action, nor will it provide any advantage to respondents in any potential future Requests for Proposals (RFPs) for competitive procurement on future projects.

The findings will be summarized in a report to the Legislature due in February 2017 and may be used for planning, policy development and decision-making purposes. Results may also inform additional studies on health information exchange and future work on e-health topics related to health information privacy, security and consent.

Legislative Request for RFI

In the spring of 2016, the Minnesota legislature directed MDH, in consultation with the Minnesota e-Health Advisory Committee, to seek public input on the patient impact and the costs associated with the consent requirements under the Minnesota Health Records Act (Minn. Stat., section 144.293, subdivision 2).

> Minnesota Session Laws 2016, Regular Session, Chapter 189, article 20, section 5
> Amending Minnesota Statutes 2015, section 62J.495, Subd. 4:
>
> (6) seeking public input on both patient impact and costs associated with requirements related to patient consent for release of health records for the purposes of treatment, payment, and health care operations, as required in section 144.293, subdivision 2. The commissioner shall provide a report to the legislature on the findings of this public input process no later than February 1, 2017.

This legislative request stems from conflicts between the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Minnesota Health Records Act (MHRA). HIPAA's Privacy Rule requires patient authorization (permission) for certain disclosures of PHI but it does not require authorization when the disclosure is for the patient's treatment, or for payment and health care operations purposes. In contrast, the MHRA requires patient consent (permission) when releasing health records for treatment, payment, or health care operations and for most other releases, with limited exceptions.

For more information about HIPAA, visit: http://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/. For more information about the MHRA, visit: http://www.health.state.mn.us/clearinghouse/medrecords.html.

Who Should Respond?

While this RFI is open to any individual or organization that chooses to respond, the target audience for the RFI includes:

- Providers of health care services from all specialties and sizes
- Individuals, patients and caregivers
- Non-clinical community organizations, neighborhood based agencies or social service organizations that are or will be partnering with clinical health care providers to coordinate care for patients or populations
- Payers of health care
- Vendors of electronic health records and health information exchange solutions

Organizations that have a privacy officer or similar role should consider engaging that person(s) when providing a response. **Any information received from responses to this RFI become public information and will be disclosed upon request.**

II. Procedures and Instructions for Responding

To be assured consideration, comments must be received no later than 7:00 PM Central Time on **October 17, 2016.** Please e-mail an electronic copy of your response to **MN.eHealth@state.mn.us**. Use the subject line: "RFI: MHRA Costs and Impacts."

This RFI includes specific questions for which comment is sought. Any or all of these questions can be addressed, and additional comments are welcome. Comments may be submitted using this document template or another document, preferably in formats such as Adobe PDF, Microsoft Word, or universally-convertible word processing format (e.g., text, rich text file).

Respondents are responsible for all costs associated with the preparation and submission of responses to this RFI. All responses to this RFI are public, according to Minnesota Statutes § 13.03 unless otherwise defined by Minnesota Statutes § 13.37 as "Trade Secrets." If a Respondent submits information that it believes to be trade secret, and the Respondent does not want such data used or disclosed for any purpose other than the evaluation of its response, the Respondent must clearly mark every page of trade secret materials in its response at the time the response is submitted with the words "Trade Secret" and must justify the trade secret designation for each item in its response. If the State should decide to issue an RFP and award a contract based on any information received from responses to this RFI, all public information, including Respondents' identities, will be disclosed upon request.

III. RFI QUESTIONS

Section A: Directed at providers, payers and organizations that collect protected health information and maintain consent (including organizations/ vendors that support them)

Note: the term "patient" is used here as a universal term to refer to any person for whom you provide health-related services. Some settings may refer to these persons as clients, residents, or another term, and responses from those settings should consider these questions in their own context.

Federal law (HIPAA) allows health records to be shared – only the minimum necessary to accomplish the intended purpose of the use – without written permission (consent/authorization) for treatment, payment, and health care operations (which include administrative activities, customer service, personnel evaluation, and business planning and development). Federal law also allows health records to be used or shared without written permission from a patient for a variety other reasons, including sharing information to assist law enforcement in locating a criminal fugitive.

Minnesota law (MHRA), requires written permission (consent/authorization) by the patient to share health records for treatment, payment, and healthcare operations, with a few exceptions.

For example, under HIPAA, a primary healthcare provider could share a patient's health record with a specialist outside the patient's care network for treatment purposes without written permission from the patient. Under Minnesota law, the patient would need to give written permission for the same type of sharing.

A-1. Describe your usual processes for obtaining and managing patient consent for exchange of health information (please include a workflow diagram in your response to this RFI if possible).

Click here to enter text.

A-2. Please provide an estimate of your organization's **annual** cost for managing the consent requirements of MHRA, and briefly describe how you calculate these costs. *As a reminder, this estimate should include only costs associated with the Minnesota-specific consent requirements of the MHRA, not costs associated with HIPAA notification, documentation or consent requirements outside of the MHRA.*

Click here to enter text.

You may find the following worksheet (next page) helpful in estimating these costs.

Cost estimator worksheet

This worksheet is an optional tool or guide to help you estimate costs associated with managing the Minnesota-specific consent requirements of the MHRA. You may want to use all or parts of this to help estimate annual costs.

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Cost element	Cost estimate
For patient check-in:	
(Average per-encounter time spent collecting patient signature, processing and explaining consent with the patient) * (number of encounters per year) * (hourly rate) =	Click here to enter text.
(Average per-encounter time spent storing the completed consent form in the health record) * (number of encounters per year) * (hourly rate) =	Click here to enter text.
Annual costs for training staff to manage consent at patient check-in =	Click here to enter text.
For managing requests to release patient information:	
(Average time spent tracking or locating forms for release requests) * (number of requests per year) * (hourly rate) =	Click here to enter text.
(Average time spent corresponding with organizations with whom you release or receive releases) * (number of requests per year) * (hourly rate) =	Click here to enter text.
Annual costs for training staff to manage requests to release patient information =	Click here to enter text.
Other costs:	
Average annual cost for legal or other expert consultation relating to MHRA =	Click here to enter text.
Average annual costs for equipment, hardware, and form management, duplication services, etc. relating to MHRA =	Click here to enter text.
Average annual costs for EHR system adaptations specific to managing MHRA consents and requests to release patient information pursuant to MHRA =	Click here to enter text.
Other annual costs relating to MHRA (please describe: Click here to enter text.) =	Click here to enter text.
Sum the line items for the total annual estimated cost =	Click here to enter text.

A-3. What is your organization's approximate annual operating budget?
$Click here to enter text.

A-4. What is your organization's approximate annual number of patient encounters?
Click here to enter text.

A-5. For each of the following items, check the box that best describes the extent to which the consent provisions of the MHRA impact your organization's ability to…

	Negatively impact 1	2	3	4	Positively impact 5	Do not know
a. Provide quality care	☐	☐	☐	☐	☐	☐
b. Provide timely patient care	☐	☐	☐	☐	☐	☐
c. Protect patient information	☐	☐	☐	☐	☐	☐
d. Coordinate a patient's care	☐	☐	☐	☐	☐	☐
e. Avoid ordering extra visits, tests, and/or images.	☐	☐	☐	☐	☐	☐
f. Manage patients with complex conditions	☐	☐	☐	☐	☐	☐
g. Ensure patients are satisfied with their care experience	☐	☐	☐	☐	☐	☐

h. Other (please describe): Click here to enter text.

A-6. What changes would you suggest be made to the MHRA that would improve patient care, and why?

Click here to enter text.

A-7. What percent of your organization's patients do not give consent to share their information?

Click here to enter text. %

A-8. Describe any specific examples of how the process of collecting written permission (consent/authorization) to share information and managing release of that information impacts patient care. This can include any positive or negative experiences with signing/managing forms, informing patients about the law, delivering care, protecting patient's information, and any other topics.

Click here to enter text.

Section B: Directed at patients, caregivers and organizations representing them

Federal law (HIPAA) allows health records to be shared – only the minimum necessary to accomplish the intended purpose of the use – without written permission (consent/authorization) for treatment, payment, and health care operations (which include administrative activities, customer service, personnel evaluation, and business planning and development). Federal law also allows health records to be used or shared without written permission from a patient for a variety other reasons, including sharing information to assist law enforcement in locating a criminal fugitive.

Minnesota law (MHRA), requires written permission (consent/authorization) to share your health records for treatment, payment, and healthcare operations, with a few exceptions.

For example, under HIPAA, your primary healthcare provider could share your health records with a specialist outside your healthcare network for treatment purposes without your written permission. Under Minnesota law, you would need to give written permission for the same type of sharing.

B-1. Think about the effort you exert for yourself or someone you care for to share your health information between your doctors, other health care providers you see, and other organizations involved in your care because written permission is required for all sharing (e.g., signing forms, completing paperwork, making phone calls, getting translation assistance, etc.).

	No burden at all				A great deal of burden	Do not know
	1	2	3	4	5	
a. To what extent is this effort a burden for you?	☒	☐	☐	☐	☐	☐

b. If you are able, please estimate the amount of time (in hours) each year you spend with these efforts because written permission is required for sharing information.

.5 hours. Whatever time it takes, I want to have the control over ALL sharing of my private information through the process of giving or withholding written permission.

B-2. Once you sign a form giving consent (permission) for your health provider to view and add to your health record, how long would you prefer that this provider be allowed to access your record? Select one response

- ☐ My provider should have access forever
- ☐ My provider should have access until I take away his or her permissions
- ☐ My provider should have access for 1 year
- ☐ My provider should have access for the duration of that visit and any related follow-up.
- ☒ Other (please describe): I want to continue to have the same consent requirements that I now have under Minnesota law over what is shared and viewed for payment, treatment, and health care operations and more. And I want to decide based on the situation, the doctor and the hospital how long I might want a provider to have access data.

B-3. For each of the following items, check the box that best describes the extent to which you feel Minnesota's law requiring written permission to share your health information impacts your ability to …

	Negatively impact 1	2	3	4	Positively impact 5	Do not know
a. Receive quality care	☐	☐	☐	☐	☒	☐
b. Receive timely care	☐	☐	☐	☐	☒	☐
c. Make sure your health information is protected	☐	☐	☐	☐	☒	☐
d. Receive coordinated care	☐	☐	☐	☐	☒	☐
e. Avoid extra doctor visits, tests, x-rays, etc.	☐	☐	☐	☐	☒	☐
f. Take care of your health	☐	☐	☐	☐	☒	☐

		Negatively impact 1	2	3	4	Positively impact 5	Do not know
g.	Be satisfied with your care experience	☐	☐	☐	☐	☒	☐

h. Other (please describe): As the MN Department of Health notes below in Section IV, Minnesota's consent laws are the only way that patients like me can have any control over who accesses and shares information. MN has the best privacy law. HIPAA doesn't protect my privacy. It shares my data. My medical records have my personal information given for the sole purpose of receiving care. Thus, I receive the best care when I can trust that my data is held in confidence and when I am in control of all data-sharing decisions about my personal information.

B-4. Indicate how important each of the following information sharing considerations are to you?

		Not at all important 1	2	3	4	Very important 5	Do not know
a.	Allowing my doctor/health provider to share my necessary health information with other providers I need to visit, such as referrals to specialists.	☒	☐	☐	☐	☐	☐
b.	Being able to choose which parts of my health record can be shared with other health providers (e.g., physical health, mental health)	☐	☐	☐	☐	☒	☐
c.	Being able to see who has viewed my electronic health record	☐	☐	☐	☐	☒	☐

B-5. Describe any specific examples of how the process of providing written permission to share your health information impacts your care. This can include any positive or negative experiences with signing forms, receiving care, and managing your health and well-being.

My example: Time and time again, I have tried to cross out multiple lines and paragraphs on consent forms at clinics and hospitals trying to secure my privacy rights under MN's strong

privacy law. Sometimes I'm successful. Sometimes I'm told that changing the form is not allowed. I want to keep those rights. Although Minnesota law requires patient consent for certain sharing that HIPAA would otherwise permit, many consent forms used by MN hospitals and clinics bundle many consents together with only one signature line. This forces me to give broad consent to receive care, including many items that I am not required by law to consent to. These consent forms fail to follow MN's privacy law. The MN Department of Health should spend their time enforcing MN's law that gives me a choice to consent or refuse to consent rather than trying to use this RFI to remove the protections of MN's strong privacy law.

Regarding receiving care, these RFI questions seem to presume that treating patients is made more difficult by requiring my consent for the sharing of my data. It also implies that my data will only be shared with my providers when that's clearly not true under the lengthy "health care operations" definition, which is much longer than listed in this RFI (nearly 400 words, including "quality assessment," "cost-management," and "population-based activities"). Equally frustrating is the apparent goal of this RFI to use cost as a justification for using my information without asking my permission. This intrusion would limit my trust in the doctor at a time when I most need to trust that I can say what needs to be said to get the care I need.

Regarding managing my health and wellbeing, neither is improved by having outsiders access my private information without my consent. I want to manage who has access to my records and who does not. Thus, as a patient, I support the consent controls under MN's current privacy law. If anything, I'd ask for more consent requirements rather than less. I also want to be able to see who has accessed my information and that means everyone including, but not limited to, coders, billers, physicians, clinic staff, health plans, attorneys, hospital staff, the state health information exchange, research organizations, government agencies including MDH, and any other entities.

Section C: Respondent Information (optional)

1. Respondent name:
   Click here to enter text.
2. If you represent an organization, what is the organization's name:
   Click here to enter text.
3. Briefly describe your role (e.g., patient, provider, administrator, payer, etc.):
   Click here to enter text.

Thank you for taking the time to respond to this RFI. Your input is important and appreciated.

IV. Additional Information: Background

Federal and State Law Interplay:

Minnesota is nearly unique among states in requiring patient consent to disclose any type of health information to other providers, including for treatment purposes. Most states have instead modeled consent requirements after HIPAA. Therefore, national or multi-state EHR technology and health information exchange (HIE) structures and systems are typically designed to meet only HIPAA requirements. Because Minnesota law requires patient consent to release health information in circumstances that HIPAA does not, health care organizations must customize standard technological systems (for example, EHRs), administrative procedures, and patient care workflows to accommodate Minnesota consent requirements before they can release information even for treatment purposes. (Minnesota Health Records Access Study Report to the Minnesota Legislature, 2013). In addition, patients and patient representatives often devote time to navigating the consent requirements when seeking treatment and care coordination.

Supplementary Information

For information on the Office of Health Information Technology and the Minnesota e-Health Initiative visit http://www.health.state.mn.us/e-health/.

V. Glossary of Terms – Working Definitions

The list below includes a set of working definitions for terms used throughout this RFI. Most terms have more than one possible definition. Comments are also accepted on improvements to the following terms or alternative sources for the working definitions.

Term	Definition
Authorization	(1) Core elements. A valid authorization under this section must contain at least the following elements: (i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion. (ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure. (iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure. (iv) A description of each purpose of the requested use or disclosure. The statement "at the request of the individual" is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose. (v) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement "end of the research study," "none," or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository. (vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided. (HIPAA)
Consent	A provider, or a person who receives health records from a provider, may not release a patient's health records to a person without:(1) a signed and dated consent from the patient or the patient's legally authorized representative authorizing the release; (2) specific authorization in law; or (3) a representation from a provider that holds a signed and dated consent from the patient authorizing the release. Except as provided in this section, a consent is valid for one year or for a period specified in the consent or for a different period provided by law. (MHRA)
Covered Entity	Covered entity means: (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter. (HIPAA)
Disclosure	Disclosure means the release, transfer, provision of access to, or divulging in any manner of information outside the entity holding the information. (HIPAA)

Term	Definition
Electronic Health Records (EHR)	EHR is a real-time patient health record with access to evidence-based decision support tools that can be used to aid clinicians in decision-making. The EHR can automate and streamline a clinician's workflow, ensuring that all clinical information is communicated. It can also prevent delays in response that result in gaps in care. The EHR can also support the collection of data for uses other than clinical care, such as billing, quality management, outcome reporting, and public health disease surveillance and reporting. An EHR is considered more comprehensive than the concept of an Electronic Medical Record (EMR). **Reference:** http://www.hhs.gov/healthit/glossary.html MN e-Health Glossary www.health.state.mn.us/e-health/e.html
Health Information Exchange (HIE)	Health information exchange or HIE means the electronic transmission of health related information between organizations according to nationally recognized standards [Minn. Stat. §62J.498 sub. 1(f)]. **Reference:** https://www.revisor.mn.gov/statutes/?id=62J.498 MN e-Health Glossary www.health.state.mn.us/e-health/h.html "Health information exchange" also means a legal arrangement between health care providers and group purchasers to enable and oversee the business and legal issues involved in the electronic exchange of health records between the entities for the delivery of patient care. (MHRA)
Health Information Technology (HIT)	HIT is the application of information processing involving both computer hardware and software that deals with the storage, retrieval, sharing, and use of health care information, data, and knowledge for communication and decision making. **Reference:** http://www.hhs.gov/healthit/glossary.html MN e-Health Glossary www.health.state.mn.us/e-health/h.html
Individual	Individual means the person who is the subject of protected health information (HIPAA)
Patient	"Patient" means a natural person who has received health care services from a provider for treatment or examination of a medical, psychiatric, or mental condition, the surviving spouse and parents of a deceased patient, or a person the patient appoints in writing as a representative, including a health care agent acting according to chapter 145C, unless the authority of the agent has been limited by the principal in the principal's health care directive. Except for minors who have received health care services under sections 144.341 to 144.347, in the case of a minor, patient includes a parent or guardian, or a person acting as a parent or guardian in the absence of a parent or guardian. (MHRA)

Term	Definition
Permission	This term is used as a general reference to encompass either "consent" or "authorization" as both "consent" and "authorization" have specific legal definitions in either HIPAA or the MHRA.
Provider	"Provider" means: (1) any person who furnishes health care services and is regulated to furnish the services under chapter 147, 147A, 147B, 147C, 147D, 148, 148B, 148D, 148F, 150A, 151, 153, or 153A; (2) a home care provider licensed under section 144A.471; (3) a health care facility licensed under this chapter or chapter 144A; and (4) a physician assistant registered under chapter 147A. (MHRA)
TPO	**Treatment:** The provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another. **Payment:** The activities undertaken by a health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or a covered health care provider or health plan to obtain or provide reimbursement for the provision of health care. **Health care operations:** Health care operations are certain administrative, financial, legal, and quality improvement activities of a HIPAA covered entity that are necessary to run its business and to support the core functions of treatment and payment. (See Code of Federal Regulations Title 45, Section 164.501)