

Impacts and Costs of the Minnesota Health Records Act

MINNESOTA DEPARTMENT OF HEALTH

REPORT TO THE MINNESOTA LEGISLATURE 2017

Impacts and Costs of the Minnesota Health Records Act

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PROTECTING, MAINTAINING AND IMPROVING THE HEALTH OF ALL MINNESOTANS

February 15, 2017

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To the Honorable Chairs:

The enclosed report summarizes the input the Minnesota Department of Health (MDH) received in response to a request for information about the impacts to patients and providers, as well as costs, associated with the requirements of the Minnesota Health Records Act (MHRA) related to patient consent for the release of health records. MDH was directed to seek public input on this topic pursuant to Minnesota Statutes, Section 62J.495, Subd. 4, paragraph (b)(6).

Our analysis of the responses and relevant observations highlights a number of considerations and opportunities for lawmakers as they weigh options related to the MHRA:

1. The MHRA does not adequately support the majority of patients whose preference, as reported by providers, is to share their health information to ensure they receive the appropriate care.

2. If the consent requirements of the MHRA remain in place, some clarifications to operationalize the current MHRA intentions are needed.
3. Education, resources and legal assistance related to the MHRA are needed by providers, especially providers in smaller practices. Education and resources are also needed by patients.
4. Implementing MHRA often requires a manual (work around) process for obtaining patient consent outside of the electronic health record system digital workflow. This implies more resources are needed for implementation of customized systems that are MHRA-compliant.
5. It will be difficult for Minnesota to achieve its goals related to coordination of care for complex patients, improved quality of care, and cost savings due to varied interpretations of the consent requirements in the MHRA.

Questions about this report may be directed to Diane Rydrych, Director of the Division of Health Policy at the Minnesota Department of Health, by phone at (651) 201-3564 or by email at Diane.Rydrych@state.mn.us.

Sincerely,



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Executive Summary

In 2016, the Minnesota Legislature directed MDH, in consultation with the Minnesota e-Health Advisory Committee, to seek public input on the costs and patient impact associated with the consent requirements included in the Minnesota Health Records Act (MHRA). With input from the Minnesota e-Health Advisory Committee and related workgroups, MDH released a request for information (RFI) in September 2016. Eighty-six responses were received by the deadline, including 24 responding from the patient perspective, 35 responding from the provider perspective, and 22 responding from both perspectives.

Patient responses reflected a range of opinions, with little agreement on the positive or negative impacts of the MHRA:

- Some patients who have complex health care needs want a smoother, more efficient, and less restrictive information sharing process. Others who responded want control of who sees their personal information.
- The RFI addressed the concept of “cost” by asking about patient burden and time associated with signing consent forms. We saw minimal and varied responses, with little conclusive determination that there is a cost for patients.
- The limited number of patient responses to this RFI means that these responses are not a statistically valid sample of the overall Minnesota patient population.

Responses from health care providers and payers were much more consistent in their views about the MHRA:

- Providers indicated consensus that MHRA has a negative impact on patients relating to: interrupted care coordination; duplicative labs, test and imaging; delays in care; signing many forms; and in general going against patient expectations that providers share relevant health information with the patient’s other providers.
- Providers report that there are costs and confusion associated with managing the MHRA requirements. Costs are varied, and not all could calculate the costs other than to point out that the requirements take time and attention away from patient care.
- Providers report that processes to obtain consent vary widely.
- Providers report that the vast majority of patients (>95%) provide consent to share their information.
- Providers report that they would like MHRA to align with the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).
- Providers from hospitals, clinics, dental care, mental health care, payers, and associations that represent large numbers of providers responded to the RFI. Collectively these responses represent a substantial share of Minnesota’s healthcare providers.

The range of RFI responses from a patient/individual and a health care provider perspective suggest a number of considerations and implications. The following considerations were reviewed and endorsed by the Minnesota e-Health Initiative's Advisory Committee and are offered as part of this analysis.

- The MHRA does not adequately support the majority of patients whose preference, as reported by providers, is to share their health information with their providers.
- Some clarifications to operationalize the current MHRA intentions are needed.
- Providers need education, resources and legal assistance to understand MHRA requirements, especially providers in smaller practices. Patients also need education and resources.
- Implementing MHRA often requires a manual work around process for obtaining patient consent outside of the electronic health record system digital workflow.
- It will be difficult for Minnesota to achieve its goals related to coordination of care for complex patients, improved quality of care, and cost savings due to varied interpretations of the consent requirements in the MHRA.

Introduction

In 2016, in response to a recommendation of the Governor's 2015 Health Care Financing Task Force, the Minnesota Legislature directed MDH, in consultation with the Minnesota e-Health Advisory Committee, to seek public input on the costs and patient impact associated with the consent requirements under the Minnesota Health Records Act (MHRA):

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.

The legislative request stems from inconsistencies between the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Minnesota Health Records Act (MHRA) and the resulting tension, confusion and sometimes misunderstanding amongst patients and providers when it comes to the appropriate sharing of health information. HIPAA's Privacy Rule requires patient authorization (consent) for certain disclosures of protected health information (PHI) but it does not require consent when the disclosure is for the patient's treatment, for payment for that treatment, or for health care operations purposes. In contrast, the MHRA requires patient consent when a health care provider discloses an individual's health records for treatment, payment, or health care operations and for most other releases, with limited exceptions.

In response to the Legislature's charge to explore this issue, the Minnesota Department of Health issued a Request for Information (RFI) to receive formal comments about the MHRA from the community and to study its impacts on quality of care, as well as direct and indirect financial impacts. This report is a summary of the information provided by patients and health care providers through the RFI process.

RFI Process

In carrying out its responsibilities related to e-Health in Minnesota, MDH works closely with a large, legislatively mandated e-Health Advisory Committee that includes representatives from a wide range of health care provider settings, physicians, nurses, health systems, small hospitals, local public health departments, behavioral health, long term care and consumers. MDH consulted with this Advisory Committee on ways of structuring and disseminating the RFI questionnaire. During an annual planning session in August 2016, Advisory Committee members suggested an approach to capture both provider and patient feedback in separate sections of a structured request for information. The Advisory Committee also suggested

creating a cost calculating “formula” or worksheet that providers could use to respond the RFI cost portion, and proposed some cost elements to include. The updated RFI question set was endorsed by the Minnesota e-Health Advisory Committee at its quarterly meeting on September 13, 2016.

MDH released the request for information on September 16, 2016, with a 39-day response period ending October 24, 2016. MDH used multiple distribution methods to promote the RFI. The RFI was shared via email with members of key advisory committees, health associations and patient advocacy groups. It was promoted at several workgroups and also published in multiple email newsletters maintained by MDH and the Minnesota Department of Human Services (DHS) as well as others maintained by stakeholder partners of the Minnesota e-Health Initiative.

Key distribution outlets included:

- Minnesota e-Health Weekly Update, MDH (about 5,000 subscribers)
- e-Health Roadmap Community of Interest, MDH (about 1,200 subscribers)
- Health Reform listserv, MDH (about 6,800 subscribers)
- SIM listserv, DHS (760 subscribers)
- Minnesota Health Care Programs Provider News, DHS (about 13,300 subscribers)

Eighty-six responses were received by the October 24, 2016 deadline. An additional response was received several days after the deadline but was not included in the analysis. Five other responses were excluded from analysis, including: an email with no information and no attached document; a duplicate response; and three responses that addressed only payer explanation of benefits and patient confidentiality (the comments did not address the topic of this RFI). The total number of responses included in the analysis was 81.

The RFI approach was very qualitative, and respondents were not required to answer all RFI questions. As such, responses include information in a variety of formats. A systematic approach was developed to review and analyze the responses. Two teams of reviewers comprised of staff from MDH and the Minnesota Department of Administration developed a process to review each question, identify themes at the question level, and synthesize those themes by cost and impact of the MHRA. More about the process may be found in Appendix B, “Methodology.”

Response Analysis

Individual/Patient Responses

Forty-six responses included the patient perspective (22 of these also responded from the provider perspective). Of 46 responses:

- Thirty-one responded to some or all of the RFI questions and 15 provided a letter regarding MHRA impact and costs, but that may or may not have addressed the RFI questions.
- Twelve provided a form letter that addressed the general topic of the MHRA but did not directly address the RFI question set.

The responses to this RFI should be considered as examples of patient/individual opinions and experiences, and not necessarily generalizable to the greater Minnesota population.

Theme #1: Patients do not agree on the positive or negative impact of MHRA

The concept of “impact” was addressed by asking a scaled response to seven topics relating to receiving health care. The question and items include:

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 ...

- 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*
- g. Be satisfied with your care experience*

Table 1 shows the count and percent responses for each item. For items relating to health care, the responses show a polarization of opinion on negative versus positive impact of MHRA. For the item relating to protection of health information (item c), there is consensus that MHRA has a positive impact.

Table 1: Patient Perspectives on Impact of MHRA (count and percent)

	Negatively impact				Positively impact	Do not know	No response
	1	2	3	4	5		
a. Receive quality care	6 13%	6 13%	8 17%	1 2%	6 13%	2 4%	17 37%
b. Receive timely care	8 17%	7 15%	7 15%	0 0%	5 11%	2 4%	17 37%
c. Make sure your health information is protected	1 2%	0 0%	6 13%	6 13%	15 33%	1 2%	17 37%
d. Receive coordinated care	7 15%	7 15%	6 13%	2 4%	7 15%	0 0%	17 37%
e. Avoid extra doctor visits, tests, x-rays, etc.	6 13%	5 11%	8 17%	2 4%	6 13%	2 4%	17 37%
f. Take care of your health	6 13%	2 4%	11 24%	2 4%	8 17%	0 0%	17 37%
g. Be satisfied with your care experience	5 11%	6 13%	10 22%	1 2%	7 15%	0 0%	17 37%

Patients who indicated that they (or those they care for) have complex health care needs wanted a smoother, more efficient, and less restrictive information sharing process. There were many comments from individuals about receiving unnecessary, redundant or duplicative tests or having to re-tell their story every time they saw a new provider. Examples include:

- “Providers are oblivious to the spectrum of participants in the health care team of my grandchildren. When presented Release of Information forms, only one or two obvious care partners are considered. So in the midst of concern about grandchild(ren), I have to take time from attending their sessions to complete the forms and request additional releases for others including educators and specialty providers like OT/PT.”
- “I was referred to a pain specialist. The pain clinic wanted to have all of my records – specialists, diagnostic studies, procedures, reports, etc. that I have for this problem. This medical issue have [sic] been going on for over 2 years now and I have seen many specialists, have had numerous diagnostic tests and needed to remember all of these clinics, MD, therapists, specialists, diagnostic and procedural center and have a referral for ROI sent to each location. Not all of the Release of Information (ROI) forms were received by the locations I sent them to. I needed to wait, check in to see if each of these locations received the ROI, and whether they forwarded my records to the pain center. If the ROI was not received, then I needed to send another form and wait again until all of the records were sent from all of the locations.”
- “It is very time consuming and also probably is not well explained because everyone is in a hurry. Most of the time I get a paper shoved at me and they say ‘Sign here.’”

- “Current system communication issues negatively impact the ability to make sure that medication information is correct and current.”
- “I was diagnosed with ALS in February of 2014. To be sure, receiving this diagnosis was devastating all by itself, but the road to receiving this news was fraught with needless complexity and poor communication between health systems, doctors, nurses, and other health care professionals. It was necessary for me to travel between different health systems because no one system had expertise in every specialty I needed to see. Moreover, it was, and remains necessary to frequently obtain a second opinion from an outside source. All of this poor coordination resulted in me having to repeat my story every time I saw a different provider, and I'm convinced that I received unnecessary, duplicative lab and other diagnostic tests. At each different office visit I was presented with a new consent form to sign. I did so at every request. I assumed that this would facilitate a free flow of important information about me from my primary care doctor to various specialists and diagnostic testing sites. It did not. It was the rare exception that relevant records and testing data preceded my visits. This lack of information necessitated me to retell my story, what tests had been done so far, and the results of those test. This is a faulty process at best. From my perspective, the policies and procedures designed to protect my privacy have gone over- board. It seems like we've confused privacy with secrecy. Although this paperwork and lack of coordination might seem like a harmless by-product of laws designed to protect me, this "protection" comes with a heavy cost. The cost is wasted time of patients, doctors, and clinic staff; duplicative tests; unnecessary out-of-pocket costs; and finally, delays in getting appointments and receiving care.”
- “It is our experience that the current system of sharing and using medical information is extremely flawed. Our patients and caregivers often do not distinguish the difference between HIPAA and the MHRA; they simply know that their information does not get to their clinicians and care team. They experience redundant testing, countless hours on the phone with clinic staff and records departments, and become accustomed to re-telling their story every time they see a new provider. This is undoubtedly frustrating, especially at a time when a person is unwell and should be focused on recovery, not record keeping.”
- “Sometimes I cannot get my records as quickly as I would like them because I have to stop and sign something. I don't always understand why I have to sign something again. If someone is going to take care of me, then my information should be available to them.”

Some patients expressed that managing their privacy preferences is an important part of their care and well-being. Examples include:

- “Obtaining my written permission for specific medical care record releases is a positive aspect of my various encounters with the health care system. Discussing and obtaining my written consent for data releases requires a personal interaction with my physician or other professional.”

- “MN’s privacy laws either positively affect or do not affect my ability to receive good health care. I am most open to receiving care when I feel confident about the privacy of my personal information.”
- “I support the MHRA and its current patient consent requirements for sharing of medical information. The law as it stands today gives me the right to determine what doctors, hospitals, clinics and business associates my data is shared with for payment, treatment, health care operations and more.”

Theme #2: Patients have varied experiences relating to the “cost” of providing consent for sharing their personal health information.

The RFI addressed the concept of “cost” by asking patient burden and time associated with signing consent forms, as presented by this scenario”

“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.).

The concept of “burden” was addressed by asking patients, upon considering that scenario, to respond to a scaled question:

To what extent is this effort a burden for you?”

Table 2 shows the response as count and percent responses to this question. Responses are distributed across the scale, with nine respondents indicating no burden at all and five indicating a great deal of burden. These responses show that there is not a common consensus among patients who responded to the RFI on the level of burden posed by the consent requirements of MHRA.

Table 2: Self-reported Burden of Providing Written Permission

	No burden at all 1	2	3	4	A great deal of burden 5	Do not know	No response
Count	9	2	5	8	5	2	15
Percent	20%	4%	11%	17%	11%	4%	33%

The concept of “time” was addressed by asking patients, upon considering that scenario, to respond to this question:

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.

Just sixteen responders provided an answer to this question, ranging from “negligible” to 132 hours per year, along with several comments that the time/cost does not matter. This minimal and varied response show that there is not a common consensus on the time expenditure posed by the requirements of the RFI.

Theme #3: Patients have varied opinions on how their personal health information should be controlled and used.

Some patient respondents expressed a desire for a smoother, seamless process for sharing their health information amongst providers and others who need to have access to it. Example comments include:

- “As a patient I would feel that it is my provider’s obligation to get my records to a specialist if I had to go to one. I think this rule overcomplicates things for the patient.”
- “ALS claimed my father’s life in 2013. I watched as this debilitating disease affected his concentration, sapped his energy, and as the disease progressed limited his ability to speak. This crippling disease required him to interact with a multitude of healthcare professionals and offices throughout the remainder of his life. At each different visit he was presented with a new consent form to sign, and was again required to repeat his story to each new provider he met. The burden to ensure medical information is provided at the right time and place should not fall to ailing patients and their caregivers. With the technology available today to share clinically appropriate data amongst healthcare providers, it is time for Minnesota to update our laws to match the current federal laws.”
- “In a perfect world, each person would have one medication list that would be shared among all providers and pharmacies, regardless of affiliations between or among those entities. Even better, a record that patients could update themselves. I’m sure that written permission requirements are a huge barrier to that and also coordinated access to other medical information, along with software challenges and terminology variations.”
- “The information I complete at each visit is redundant and duplicated each visit. It takes time and resources for me and the staff to complete these forms each visit. I would be comfortable with signing a consent stating that I consent to each visit unless I request differently. I feel this would save me and my provider time.”

Others expressed a desire to have more control over how their information is shared, expressed their support of the current consent provisions in the Minnesota Health Records Act

and/or felt that HIPAA does not provide adequate protection of their information. In particular, the provisions of HIPAA are to share information for the purposes of treatment, payment and operations. However, several patients indicated that they are not comfortable with the broad provisions in HIPAA for “operations;” instead they want to control who has access to their information for that purpose as well. Several patient respondents also indicated that they want to know who has accessed their information. Example comments include:

- [Form letter] “I support the current MHRA and its current patient consent requirements for sharing of medical information. The law as it stands now gives me the right to determine what doctors, hospitals, clinics and business associates my data is shared with for payment, treatment, health care operations and more. I will not stand for having you decide with whom my private records are shared. That decision is mine and mine alone. It is important that Minnesota does not remove or change the Minnesota Health Records Act because this law protects each and every Minnesotan.”
- “The state of MN has the best privacy for me and my family when compared to HIPAA. Why? Our medical records filled with very personal information are shared with the doctor/clinic so that we might be able to get the appropriate care. Part of this care we receive is simply begins with the trust that the information given is held in complete confidence of the clinicians we choose. In contrast HIPAA SHARES OUR INFORMATION! We need to be in control of our family’s medical records!”
- “Although MN requires consent for a number of areas beyond HIPAA requirements, many consent forms are bundled with only one signature illegally forcing me to give broad consent for [sic] everything, including the items that I am not required to consent to. It is my data and I want to control who sees it... As a patient, I want to have control over my information through MN’s consent requirements. I also want to be able to see who has accessed my information and that means everyone including physicians, staff, research organization, government agencies including MDH. Managing my health and wellbeing requires that I manage my data.”
- “[T]he definition of health care operations by HIPAA is too vague, too encompassing, and too long for a health care consumer to trust.”
- “[T]here should be no attempt to cut costs by eliminating patient consent requirements. The Minnesota Health Records Act is unique in its protection of the legal foundation for confidentiality: consent requirements for sharing of private patient data. MHRA protects what HIPAA does not.”
- “Minnesota’s consent laws are the only medium by which patients can have control over who accesses and shares their information. ... HIPAA doesn’t protect patient privacy – Minnesota law protects patient privacy through the consent requirements. Medical records contain personal information and are entrusted to doctors and hospitals for the sole purpose of receiving care. Thus, a patient receives the best care when he or she is in control over all data-sharing decisions and can trust that personal information and data are held in confidence.”

- The Hippocratic Oath underscores that the principle of confidentiality is a critical facet of patient care. It is essential for developing and maintaining patient trust and for eliciting truthful answers to the doctor’s questions. Thus, there should be no attempt to cut costs by eliminating patient consent requirements. The Minnesota Health Records Act is unique in its protection of the legal foundation for confidentiality: consent requirements for sharing of private patient data. MHRA protects what HIPAA does not.”
- “1) I specifically search out providers who provide clear statements about privacy rights, abide by MN law regarding consent, and follow the rule regarding data "of minimum necessary to provide treatment". I avoid providers and healthcare entities who attempt to request me to "blanket releases" regarding my consent, as this is not in my best interest as a healthcare consumer. 2) The definition of healthcare operations by HIPPA is too vague, too encompassing, and too long for a healthcare consumer to trust.”

The RFI also asked questions pertaining to patient preferences for allowing provider access to information. One question addressed the duration of consent.

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?

Table 3 provides count and percent responses to the question options. Most of the responders (19) desire their provider to have access forever or until the patient takes away those permissions.

Table 3: Patient Preferences for Duration of Provider Access (count and percent)

count	percent	
5	11%	My provider should have access forever
14	30%	My provider should have access until I take away his or her permissions
2	4%	My provider should have access for 1 year
3	7%	My provider should have access for the duration of that visit and any related follow-up.
5	11%	Other
15	33%	No response

The RFI also asked patients how important three aspects of sharing personal health information are, including:

- *Allowing my doctor/health provider to share my necessary health information with other providers I need to visit, such as referrals to specialists.*
- *Being able to choose which parts of my health record can be shared with other health providers (e.g., physical health, mental health)*
- *Being able to see who has viewed my electronic health record*

Table 4 shows that patient respondents generally agree that it is important to allow their health providers to share their necessary health information with other providers, that they be able to choose what parts of the health record can be seen, and that they be able to see who has viewed their record.

Table 4: Importance of Information Sharing Considerations (count and percent)

	Not at all important 1	2	3	4	Very important 5	Do not know	No response
a. Allowing my doctor/health provider to share my necessary health information with other providers I need to visit, such as referrals to specialists.	5 11%	0 0%	0 0%	3 7%	19 41%	0 0%	19 41%
b. Being able to choose which parts of my health record can be shared with other health providers (e.g., physical health, mental health)	3 7%	0 0%	3 7%	8 17%	12 26%	2 4%	18 39%
c. Being able to see who has viewed my electronic health record	2 4%	2 4%	3 7%	7 15%	13 28%	1 2%	18 39%

Provider Responses

Fifty-seven responses included the provider perspective (22 of these also responded from the patient perspective). Of these:

- Forty-five responded to some or all of the RFI questions and 11 provided a letter regarding MHRA costs and impact, but that may or may not have addressed the specific RFI questions.
- Fifty-one clearly indicated that they are directly involved in providing patient care, and six indicated that they represent provider interests (e.g., an association).

Theme #4: Providers report negative impact on patient care due to MHRA

The concept of “impact” was addressed by asking a scaled response to seven topics relating to the perceived impact of MHRA on the organization’s ability to provide care. The stem question and follow-up items include:

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...

- 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*

Table 7 shows the count and percent responses for each item. About half of provider respondents completed this question. Of these, there is generally strong agreement that MHRA negatively impacts care coordination, providing timely care, avoiding extra visits/test, and their ability to provide quality care. There is generally strong agreement that MHRA positively impacts their ability to protect patient information.

Table 7: Provider Opinion of MHRA Impact on Patient Care (count and percent)

	Negatively impact				Positively impact	Do not know	No response
	1	2	3	4	5		
a. Provide quality care	12 21%	9 16%	16 28%	0 0%	2 4%	1 2%	17 30%
b. Provide timely patient care	19 33%	11 19%	11 19%	0 0%	0 0%	0 0%	16 28%
c. Protect patient information	1 2%	4 7%	15 26%	5 9%	13 23%	3 5%	16 28%
d. Coordinate a patient’s care	22 39%	2 9%	12 21%	0 0%	2 4%	0 0%	16 28%
e. Avoid ordering extra visits, tests, and/or images.	14 25%	7 12%	12 21%	0 0%	1 2%	7 12%	16 28%
f. Manage patients with complex conditions	19 33%	10 18%	10 18%	0 0%	2 4%	0 0%	16 28%
g. Ensure patients are satisfied with their care experience	9 16%	16 28%	9 16%	0 0%	2 4%	3 5%	18 32%

Providers also report that consent requirements impact care coordination. Providers responded that they only share relevant information to coordinate care, but the MHRA consent requirements often interfere with their efforts, especially as related to vulnerable populations. Providers described a need for care continuity and a holistic approach to patient care, requiring complete, current, and up-to-date records, all of which is difficult when complying with both HIPAA and the MHRA.

The following examples illustrate responses relating to this theme:

- “The Minnesota HRA consent requirement often complicates care coordination disclosures for vulnerable populations. For example, [Provider] is a Medicaid program that serves high risk individuals who often have comorbid conditions, behavioral health and chemical health diagnosis, and receive (or are eligible for) multiple social services. Without consent, it is hard to facilitate care coordination efforts to support this population. It is particularly difficult for providers when the disclosures would otherwise be allowed under HIPAA as treatment and payment disclosures for which patient authorization is not necessary. Great efforts are being taken by [Provider] to create processes that increase the ability to obtain consent from this population, and those efforts require significant resources that could be put into other aspects of this vital program. If the Minnesota consent requirement did not exist, HIPAA privacy regulations would still adequately protect the health information of

this vulnerable group, while also fostering information sharing that could improve health outcomes for these individuals.”

- “Just about every case we see could benefit from better communication/coordination efforts, but it is particularly important in the area of behavioral health. Psychiatrists and primary care doctors should be constantly exchanging information every time there is a medication change or change in a patient’s functioning. Medications can have subtle yet harmful interactions with each other. If a primary care doctor does not know their patient is experiencing psychosis, they could have difficulty communicating treatment plans and achieving positive outcomes.”
- “The burdens and delays the MHRA places on patients may be seen at every point of health care delivery. For example, a patient with a complex medical condition, who obtains primary care and specialty care from multiple health systems, must obtain consent for each provider to share with each other provider across systems - which for complex patients may amount to dozens of consents across multiple locations, visits, and providers. In an emergency setting, the MHRA often interferes in care delivery indirectly, because an emergency provider does not know what key providers to contact for information, due to the limited scope of the patient’s medical records. In long-term-care, home health and other settings that utilize social services, the MHRA often hinders the timely delivery of coordinated care because medical providers and social service agencies must manage multiple consents before they are able to provide patients with housing supports, cash assistance, or other benefits to support and maintain the health care patients receive. The MHRA adds delay and burden to an already-complex health care system, to the detriment of patients.”
- “Our patients and caregivers often do not distinguish the difference between HIPAA and the MHRA; they simply know that their information does not get to their clinicians care team.”
- “[T]he best care decisions are made with the most complete information, and under federal law, this 360° review is possible, because HIPAA permits providers that share clinically appropriate information with other providers. Unfortunately for patients in Minnesota, this 360° effort requires multiple consents: a consent to release information must be received by both the creator of the record (like a cardiologist), and with the eventual recipient of the record (like a primary care physician). This must be repeated for every member of the care team who may have, or need to see information pertaining to that patient’s condition. As a result, the full picture often emerges at the expense of additional labs and images; which notably, have inherent costs and risks.

Theme #5: Providers report patient burden due to duplicative effort/tests generally.

Providers responded that MHRA consent requirements often cause duplication of testing, procedures, and costs for patients. The requirements result in delayed care, patient anxiety and discomfort, and ultimately, impact patient safety. In addition, providers responded that the

MHRA consent requirements negatively impact their communications with patients, family members and caregivers.

The following examples illustrate responses relating to this theme:

- “It has been the experience of [Provider] that the MHRA creates unnecessary barriers to sharing critical health information related to our members. This hampers our ability to provide those members opting out with access to high-quality, affordable care that is optimized for their specific circumstances. Each inefficiency adds expense, erodes quality, and diminishes improved outcomes, which in turn results in higher costs across the system and impacts premiums across the market.”
- “The MHRA creates many limitations that negatively impact medication management. We often face instances where we know members are on multiple medications that could result in negative drug interactions that include safety and efficacy concerns. Additionally, we are aware of instances in which a member is seeing multiple providers for the same health issue, possibly receiving duplicative and/or contrary care. Due to Minnesota’s overly strict privacy laws, we cannot share information in either of these instances with the providers to aide in improving quality of care and outcomes, while ensuring efficient resource use and minimizing overall costs.”
- “It is important to acknowledge that [Provider conducted] a limited study, however, the analysis identified two very strong themes: 1) having access to information reduces unnecessary diagnostic procedures, and 2) providers overwhelming cited the burden of getting a consent at every patient visit as a barrier to using a health information exchange.”
- “Eliminate unnecessary medical procedures. Understanding if a test or other medical service has been performed already and knowing the results of those tests reduces the need for providers to repeat procedures. Duplicative testing is both costly to the health care system but it can also result in patients having to wait to receive care until their consent is given again. This reduces the quality of care for patients and is extremely inefficient and costly.”
- “[T]he most common and concerning example of the negative impact on patient care in our specialty care setting is the challenge of obtaining referring provider records that are necessary for treatment purposes. Providers and staff express frustration with the time and effort that is spent on obtaining and relaying consents for that purpose. Patients also express dissatisfaction with repeated requests to sign consents as well as frustration if their providers do not receive the records they need for their visit.”

Theme #6: Providers report that consent requirements frustrate and overwhelm patients

Providers responded that the MHRA requires too many forms and obtaining consent is often overwhelming and burdensome for patients. Providers described that patients do not understand why there are such strict consent requirements and generally just sign the forms.

The following examples illustrate responses relating to this theme:

- “The burden of sharing medical information should not fall on the patient and their family, yet, because of the complexity of layering state and federal regulations, it often does. Many of our patients have experienced being in a room with a clinician who cannot access medical information from another facility, even when the patient wants the clinician to see it. Frequently, this is because the consent was not received at the right time and in the right location. Other times, it is because some providers err on the side of not releasing information, since the layering of these laws creates doubt or confusion about what can be shared, and with whom.”
- “Consent has become almost meaningless to patients who just want to sign the paperwork and get on with their issues. Making this as complex as it is only makes the process more burdensome and less effective.”
- “The requirement for written consent under the MHRA can negatively affect payment for services billed, which affects not only the provider, but the patient as well. For example, say a patient was seen in the hospital for gallbladder surgery and the patient did not sign a written consent for release of medical records to support payment by the patient’s health insurance company. In this case, the patient’s medical records cannot be sent to the patient’s insurance provider. Therefore, the bill for services may eventually be sent directly to the patient. The patient would then have to undertake the long and often frustrating process of reaching out to the various providers and insurance company to reconcile payment for services.”
- “The burdens and delays the MHRA places on patients may be seen at every point of health care delivery. For example, a patient with a complex medical condition, who obtains primary care and specialty care from multiple health systems, must obtain consent for each provider to share with each other provider across the systems – which for complex patients may amount to dozens of consents across multiple locations, visits, and providers.”
- “The volume of forms required for various levels of release of information can be confusing and overwhelming to patients, particularly in an acute care setting. Explaining what permissions each form gives in regards to ROI is not necessarily taxing to the staff though I don’t think the patients are always absorbing the information being provided.”
- “The more forms patients must read and sign, the more likely it is that they are not reading through all of the language on the forms and therefore not fully understanding what they are signing. This means patients are less likely to be giving informed consent. Too often, the summary of the form when handed to the patient is inaccurate, which has led to patients either believing they are authorizing information to be shared broadly across a system when

that is not the case, or patients believing their authorization is more limited than what it really is. Reducing the number of forms or the forms' complexity would help provide more useful information to patients in a form more easily understood."

Theme #7: Providers report that consent requirements run contrary to patient expectations

Providers responded that patients expect providers to share relevant personal health information and they also expect a seamless payment process. Many providers indicated that there is high patient dissatisfaction with the consent process they must follow.

The following examples illustrate responses relating to this theme:

- "[A]llowing the sharing of information for purposes of payment is consistent with patients [sic] expectations. When patients provide information about the guarantor/payor of their medical expense, they expect that a provider will bill that payor. Having to sign a consent permitting a provider to share information in order to bill for services adds an unnecessary and redundant administrative step to seeking care. In the event a consent is not collected – for example, if a patient enters the emergency department unconscious, is admitted to the hospital and the front-end process for collection of consent cannot be followed – the patient's payor cannot be billed and, as a result, the patient may receive a bill for the full amount of the emergency department and hospital admission charges."
- "The current MHRA requirements restrict the ability to focus on the patient and meet their expectations for coordinated care. Examples might include patients that are transitioning from an inpatient episode or specialty care back to their primary care provider which might not be in an organizationally related clinic. The lack of the ability to readily share information results in duplications and increases in the cost of care as potential misalignment of care. These examples of inability to coordinate care negatively impact the patient, care providers/facilities and payers."
- "[T]he release of health information for treatment, payment, and operations is consistent with patient expectations. Most individuals expect, even appreciate, that their health information will be released as necessary to provide the individuals with services, billing for services, and quality improvement. Despite these advantages to release of health information for treatment, payment, and health care operations, the consent requirement in the MHRA creates an unnecessary barrier and burden on the release of health information even for these most essential purposes."

Theme #8: Providers report that consent requirements are complex and confusing for providers

Providers responded that collecting the consent required by the MHRA, at various times and places and for various reasons, is often complex, time-consuming, burdensome, confusing, and a barrier for providing care. Providers also reported collecting consent on various forms, which requires ongoing training because staff have a hard time understanding requirements under both HIPAA and the MHRA. Additionally, providers that operate across state lines indicated that the additional Minnesota consent requirements are difficult and confusing to implement and share information.

The following examples illustrate responses relating to this theme:

- “Reduce administrative burden, allowing more health care dollars to be focused on providing care instead of handling bureaucratic requirements. Navigating laws governing which data may be disclosed, who must consent (and on what form, for what duration), or what data subsets must be deleted is administratively burdensome for patients and providers alike. It is frustrating, time consuming, and can result in providers spending their time dealing with paperwork instead of patients.”
- “Obtaining and tracking patient authorization for treatment, payment, and operations is time and resource intensive. Because Minnesota’s CHCs [Community Health Centers] are not affiliated with large, integrated health systems, they must refer their patients to external organizations for specialty and other ancillary services at high volumes. Authorizations must be obtained before any information can be disclosed to begin this referral process. This extra step creates additional work and sometimes a delay in patients receiving recommended services.”
- “In addition, the misalignment of consent requirements between the MHRA and the Health Insurance Portability and Accountability Act (HIPAA) creates additional regulatory complexity for CHCs who have sites across state borders.”
- “Requiring a written consent to obtain records for patients that are referred to our organization for specialty services delays care and ties up resources. The process is cumbersome – sending an authorization form to the patient; waiting for the mailback [sic] before sending to the organization. In certain clinics work needs to be done prior to patient visit and this delays that process and frustrates patients and providers.”

Theme #9: Providers report that there is a cost associated with managing the consent requirements of MHRA

Providers estimate that the annual cost of administering the consent requirements of the MHRA ranges from negligible to significant. About half of the provider respondents (29 of 57) included a cost estimate relating to managing the requirements of MHRA. Some providers have absorbed costs into their workflows and were unable to attribute a particular cost to the MHRA requirements specifically.

Of the 29 provider respondents who reported cost estimates, the costs ranged from \$0 to \$2,543,328, with a median of \$66,910. In some cases these costs were calculated using a worksheet provided in the RFI, and in some cases the respondents provided an estimate based on their own calculation.

These costs estimates should be viewed in the context of the organization’s overall budget, as there was a wide range in the size of the responding organizations. Twenty respondents provided both a cost estimate and a budget estimate, with MHRA costs calculated as a range from 0% to 17.35% of operating budget, and median of 0.16%. Table 5 summarizes the costs and budget information submitted by provider respondents.

Table 5: MHRA Costs and Operating Budget

	MHRA Cost	Operating budget	Cost as a percent of operating budget
Number responding	29	25	20
Range	\$0 to \$2,543,328	\$241,756 to \$3,600,000,000	0.00% to 17.35%
Median	\$66,910	\$50,000,000	0.16%

Another measure of MHRA costs is the cost per patient encounter. Twenty-six provider respondents were able to provide both cost and encounter information. Table 6 shows the cost per encounter ranges from \$0.00 to \$24.31, with a median of \$0.83. Table 2 summarizes the responses by providers that listed their organization’s approximate annual number of patient encounters and the correlating cost related to the MHRA per encounter.

Table 6: MHRA Costs per Encounter

	Encounters	Cost per Encounter
Number responding	30	26
Range	538 to 10,700,000	\$0.00 to \$24.31
Median	70,900	\$0.83

The following examples illustrate responses relating to how costs were calculated:

- “Costs for complying with the requirements of the MHRA are difficult to estimate, but we have estimated costs to be somewhere in the range of \$800,000 to \$1,500,000 annually. These costs include the costs of (a) requesting, obtaining, storing, and managing the consents, (b) training staff to appropriately handle consents, and (c) developing policies and procedures and providing support to administer the processes and reviewing these policies and procedures on a regular basis. These costs do NOT include the costs associated with delayed treatment, treatment provided without the benefit of the patient’s medical records history, or duplicative treatment/tests associated with the process of obtaining or failing to obtain the appropriate consents under MHRA.”

- “The average number of requests per week is around 10, annual 520. Average salary is \$19.45/ hour. We do not bread [sic] down our software costs by module so I could not fill in that data.”
- “Managing the Minnesota consent requirements involves multiple departments across the hospital system. The departments most involved in the process include Registration and Health Information Management. Other departments support the work done by these departments, such as Information Privacy and Security, Organizational Learning and Development, Electronic Health Record, and Legal. Consent is collected annually for all outpatient encounters, and upon every Emergency Department visit and Inpatient Admission. On average, Registration staff spend 2.5 minutes per encounter collecting the patient consent at check-in, and 1.5 minutes scanning and documenting the consent. Registration staff require initial training (upon hire) related to the consent collection process, as well as refresher training and training when processes are updated.”
- “Health Information Management staff, along with the health system’s contracted record vendor, are responsible for managing request to release patient information. The health system receives over 116,000 requests per year for release of patient information. For each of these releases, staff must be aware of the Minnesota HRA requirements, how this law impacts release for various purposes (i.e., personal access requests, care provider requests, third party payor requests, law enforcement requests, etc.). In addition to staff time required to analyze the request in accordance with the Minnesota HRA significant time is invested in training Health Information Management staff on the various aspects of the HRA.”
- “The health system encounters additional costs for equipment, hardware and duplication services in order to maintain processes related to the MHRA. Additionally, costs are incurred through electronic health record system adaptations to accommodate the Minnesota consent requirement and electronic storage space to store all scanned consent forms within the electronic health record.”
- “Information Privacy and Security, along with Legal, also invest time to support these departments and others in analyzing Minnesota HRA requirements.”
- “Cost estimate includes the following elements: Cost to track and locate release forms; Cost to manage signatures required for HIE; Vendor cost to correspond with organizations with whom we release; Vendor cost to manage to different state requirements; Vendor cost to train on requirements”
- “Approximately \$40,000. This approximation, assisted by the table included in the RFI, includes a portion of the expense associated with collecting consents that would be required by HIPAA. The majority of the cost is associated with (1) communicating with outside providers, payors, and patients in an effort to document the additional consents required by the MHRA; (2) training staff on requirements unique to the MHRA; and (3) resolving patient and organizational issues resulting from the additional burdens of the MHRA.”

Theme #10: Providers report that processes to obtain consent vary widely

Many providers did not describe a process to obtain and manage patient consent for the exchange of health information in their responses to the RFI. Those providers that did document a process provided descriptions that varied widely depending on the size, location, and type of organization. This variation may be due to lack of clarity in MHRA, as well as variation in operational practices.

The most common response (67% of respondents) described that consent forms must be in writing, on a paper form, and signed. The providers usually obtained consent prospectively, at registration, or at the patient's first visit. Some providers indicated that they then have to scan the written consent into an Electronic Health Record (EHR) system. Some providers use a process that requires the printing, mailing or faxing of paper forms (26% of respondents), while others indicated they have an e-consent process where a consent form is signed and sent via email, or contains an electronic signature (12% of respondents).

The following examples illustrate responses relating to this theme:

- “New patients have several documents they must complete for consent, patient privacy, financial arrangement, etc. Additional consent forms related to care are obtained at the time the care is going to be completed.”
- “Our organization has the patient sign a life time consent for release of information for treatment, payment and operations. A separate patient signed consent is needed for other types of releases, but not for treatment, payment and operations.”
- “At a high level, our processes generally involve sending an Authorization to Release Information form to the member who must complete the form and return it via mail. [Provider] must then maintain a copy of this form on its systems. Pursuant to Minnesota law, this form is only valid for one year so the process must be repeated annually. In addition, various segments of a health plan's business may have other, separate processes that must be accounted for and met.”
- “1. All patients are sent an electronic form via secure email for their signature for the release of records. Patients are asked to immediately sign and return, via secure email, so we can obtain the records in a timely manner – preferably prior to the patient's appointment. 2. If patient does not have email, the consent forms are mailed to the individual. We again request that the signed forms are sent ahead of their scheduled appointment so we can obtain records prior to the patient's arrival so we can be fully prepared for making clinical decisions based on a complete medical history. Our Medical Assistants place confirmation calls prior to the patient's appointment if we have not received their signed release prior to their appointment to remind them to send/mail the consent. 3. If the patient has not signed a release prior to their appointment, we will have them sign a release immediately upon arrival. From there, our administrative team goes into action trying to retrieve the medical records while the patient is still with our doctor.”

- “Even where a separate written consent is not actually required to exchange information for a particular treatment, payment, or health care operations purpose because the patient has already signed a written consent authorizing the exchange, staff may still request another written consent or else simply decline to make the disclosure. Those undesirable responses may occur because staff is unable to verify that there is a written consent on file due to time lags in scanning and filing the consent, or difficulty in finding the form in the record, or time and resource constraints. They also occur due to the discrepancies between the MHRA and HIPAA with regard to consents. Those discrepancies cause significant confusion about when a written consent is required and, when in doubt, staff will exercise caution.”
- “Registration staff across the medical center and clinics collect the health system’s ‘Information Authorization and Disclosure’ form, which contains the information necessary to meet the requirements of the Minnesota Health Records Act (this document is entirely separate from the Notice of Privacy Practices required under HIPAA). Registration staff gives each patient a copy of the form to review and sign. The staff then collect the completed form, scan it into the patient’s electronic health record, and document that the form was collected. Patients may opt out of certain information sharing, which is described and documented on the form. The organization has a verbal consent process for patients who are unable to sign the form on their own. Various departments reference the form and/or functionality within the electronic health record to determine if patients have opted out of specific types of information sharing (e.g., external research disclosures).”

Theme #11: Providers report that most patients provide consent to share their information

Provider respondents were asked what percent of their organization’s patients do not give consent to share their information. Thirty-six responders provided an answer, ranging from 0% to 75%, with a median of 2%. It should be noted that many responded along the lines of “very few;” for purposes of this analysis these responses were assigned a numeric value of 2%, when in fact they could be a smaller percent.

These numbers should be viewed as a general guide and not necessarily as discrete values. One consideration with this question is that “consent” has a variety of interpretations (e.g., consent to treat vs. patient consenting to share information with an outside provider). Providers responded to this question based on their interpretation and consequently, some responses could be related to consent to treat, whereas others are related to consent to share with an outside provider.

The following examples illustrate responses relating to this theme:

- “It is not always practical and is quite burdensome to obtain consent or a written authorization from a patient to release records to another provider. One example that negatively affects nursing homes is when they are discharge planning for a resident, both involuntary and voluntary discharges. Nursing facilities are required to conduct discharge

planning which often requires the facility (as opposed to the resident) to find a safe location. Depending on the resident’s cognition, the resident may not sign an authorization to release information to another facility. In the case of an involuntary discharge when the nursing home must discharge for non-payment or any other reason under Federal law like the resident is a danger to the health or safety of others in the facility, the resident may not want to leave the facility and will refuse to give consent to release information. This places the nursing facility in an impossible situation because they need to contact other facilities (nursing homes, home care, assisted living) to make sure the resident is going to be properly cared for but they are limited by the statute in what they can provide the next facility without an authorization. This situation of providing another facility health records is allowed under HIPAA under the ongoing treatment, and payment provisions if it is a discharge due to nonpayment.”

- “This varies by the complexity of care they are receiving from us. Outpatient therapy has the highest percentage at 50%. Those who receive complex care do not have an issue signing releases for care providers, but may object to family or friends, for example at our IRTS, where they only refuse 5-10% of the time. Case management and representative payee clients get annoyed that they have to sign releases for everyone when they just want help with their housing, bill paying, jobs, appointments, etc. They just want it to happen without releases being signed. Outpatient therapy clients are most annoyed at intake with the question of whether they have another care provider they want to send their records to because they do not see a need for signing a release for primary care when they are discussing marital issues, etc. They are the highest percent of people who refuse to sign – 50-60%.”
- “Approximately 7% of [Provider’s members] “opt out” or do not give their consent for data sharing. This low percentage signifies that an overwhelming majority of our members typically do not object to sharing their data. While their participation furthers progress in improving health care quality and outcomes and reducing overall costs, it does not lessen the additional complexity of the operational processes required because Minnesota law does not align with HIPAA.”
- “Based on our analysis:
 - 0% of patients decline consent to share information for payment. Occasionally a patient may initially decline to consent sharing information for payment, but a patient will generally agree to the consent upon understanding that declining to consent for payment has the effect of making the patient personally responsible for charges for services.
 - 0.5% of patients decline consent to share information with other providers
 - 1.67% of patients decline to consent to share information for purposes of a record locator service
 - 4.47% of patients decline to consent to share information for research

Note that a patient could fall into more than one of these categories.”

- “Less than 1% of our patients opt out of sharing records for continued clinical care. Clinic patients with scheduled or unscheduled appointments need a signed general consent. For scheduled hospitalizations, a consent / authorization signature is obtained before care is given to the patient. For hospital patients, a consent/authorization is not always obtained because of an emergency or unconscious state of the patient. In those cases, a signature is sought later from either the patient or a family member of the patient.”

Theme #12: Providers report that they would like MHRA to align with HIPAA

The most common answer from providers to the question, “What changes would you suggest be made to the MHRA that would improve patient care” was to align the MHRA with HIPAA. Almost three-fourths of provider respondents (41) specified that patient consent should not be required for the purposes of treatment, payment, and health care operations. Another six providers did not specify alignment with HIPAA, but indicated a need for clarity and/or simplification. Five provider respondents indicated that they support the current consent provisions of the MHRA.

Providers further responded that both providers and patients have a greater understanding of HIPAA than the MHRA, it is very difficult to comply with both sets of laws and regulations, and/or compliance with both HIPAA and the MHRA is too costly. Providers also noted that there are many more resources and training materials related to HIPAA than MHRA, the consent process is complicated because many non-Minnesota providers do not understand MHRA, and effective compatibility requires integration of systems/records, universal forms, and standardization of legal requirement and processes.

A small number of providers also mentioned the difference in the treatment of psychotherapy notes/mental health records in MHRA and HIPAA and proposed bringing those requirements in alignment, as well. For example, HIPAA allows mental health professionals to share psychotherapy notes, at the provider’s discretion, with patient consent. In recognition of the sensitivity of this information, HIPAA requires that this consent be captured on a form only documenting the consent to release psychotherapy notes. Minnesota law is more stringent than HIPAA with respect to the rights of individuals. In Minnesota, patients have the right to view or release all parts of their medical record and psychotherapy notes are part of that medical record that can be viewed or released. The added protection of the notes included in the medical record is to assure greater access for patients to all of their protected health information.

The following examples illustrate responses to this theme.

- “Overall MHRA It [sic] can be confusing for both staff and clients and is costly in both time and dollars. It would be ideal for state law to match HIPAA. This change would give staff and clients more resources about patient health information. Currently, it is confusing because HIPAA resources, such as the HHS.gov/hipaa, do not reflect all requirements for Minnesota patients. Updating the law would keep strict privacy protections in place while also allowing us to share health information for payment, treatment, or health care operations, make it

easier to provide integrated service delivery and ultimately provide better services for our clients.”

- “We recommend that MHRA permit the sharing of information for treatment, payment and health care operations purposes, without consent, as permitted under HIPAA. This could be accomplished by adding these categories as to 149.293, subd. 5 as exceptions to the broad consent requirement.”
- “The only effective change to the MHRA that will improve patient care is to fully align the MHRA with HIPAA by removing the restrictive consent for disclosure requirement. Modern health care is dependent on rapid exchange of patient information, often at times when the patient is unavailable. Current models for population health involve cooperation not just between health care providers but also health plans to ensure effective and streamlined use of resources. Exchange of patient information between parties with existing relationships to the patient, as currently allowed by HIPAA, is crucial to analyzing and proactively managing a patient’s medical condition, both in the long term and in emergent situations.”
- “1. Repeal MN Statute 144.292; 2. Defer to the established HIPAA Federal Regulations that health care providers are required to comply with. Administrative, physical, and technical security requirements are already in the HIPAA privacy and security regulations. [sic] 4. Allow the release of information for treatment, payment and operations without patient consent.”
- “[W]hile the MHRA is silent on issues of data security, secure transfer, and who may access a patient's medical records, it is in fact HIPAA that provides broad and strictly-enforced security standards, which comprise the bulk of the privacy protections patients receive. Under HIPAA, medical providers, insurance carriers and certain other entities already are required to follow significant privacy and security standards when using, accessing and disclosing protected health information. It is HIPAA that provides both the protections and enforcement that most protect patients' private health information.”

Considerations and Implications

The range of RFI responses from a patient/individual and a health care provider perspective suggest a number of considerations and implications for lawmakers as they weigh options related to the MHRA. In addition, the RFI identified several peripheral observations that are interrelated to the questions of impact or cost associated with the MHRA and relevant to the process of providing patient care.

The following considerations were reviewed and endorsed by the Minnesota e-Health Initiative’s Advisory Committee and are offered as part of this analysis.

1. The MHRA does not adequately support the majority of patients whose preference, as reported by providers, is to share their health information to ensure they receive the appropriate care. While MHRA supports patients who do NOT want to share their personal health information, information from providers indicates that these patients represent a very small percentage of all patients. Providers report that the vast majority of patients consent to have their information to be shared, and responses from patients to this RFI indicate a mix of preferences. In practice, the MHRA inhibits the ability of those who want their information to be shared to do so easily. Future statutory approaches should more easily enable information sharing for patients who prefer that their information be shared, using a simplified process, and enable patients to better understand their confidentiality rights.

2. If the consent requirements of the MHRA remain in place, some clarifications to operationalize the current MHRA intentions are needed. The responses to the RFI demonstrated a significant variation in the way that the consent requirements of the Minnesota Health Records Act are being implemented, indicating different interpretations of the law. Other, more extensive work of the Minnesota e-Health Initiative supports this conclusion. Clarifications include:

- Clarifying that consent does not require a wet-pen signature and that electronic signature should be allowed.
- Specifying how long a patient’s consent to share information remains in place before expiring.
- Using common language and definitions regarding health information exchange, compared to Minnesota’s HIE Oversight law (Minnesota Statutes §§62J.498-4982).

3. Education, resources and legal assistance related to the MHRA are needed by providers, especially providers in smaller practices. In addition to clarifications within the law itself, training, resources, and legal assistance are needed to help providers have a common understanding of the law and processes for implementation. Providers have many resources to support HIPAA, but very few to support MHRA. In addition to resources to support MHRA, it is equally important for a more common understanding on specific provisions of HIPAA, including requirements for treatment, payment, and health care operations as well as security requirements.

4. Education and resources are needed by patients. In addition to providers, patients are often uncertain, misinformed or confused about information such as:

- What rights they have regarding the disclosure of their information to providers, payers, and others.

- How their information is typically used and accessed in a health care setting, and how to understand an audit trail regarding access to their information.
- The security protections that are in place to keep their information confidential.

5. Implementing MHRA often requires a manual (work around) process for obtaining patient consent outside of the electronic health record system digital workflow. This implies more resources are needed for implementation of customized systems that are MHRA-compliant. Because the work around process requires more staff time/resources, many of which are hidden costs built into workflows, fewer resources are available for patient care. Providers that have the resources to try to electronically implement the process face expensive technology updates.

6. It will be difficult for Minnesota to achieve its goals related to coordination of care for complex patients, improved quality of care, and cost savings due to varied interpretations of the consent requirements in the MHRA. The aims of accountable care organizations (ACOs), Integrated Health Partnerships (Minnesota Medicaid ACOs), and other health care payment and delivery reform models (e.g., health care homes) are to lower costs while improving care and outcomes. Care coordination, including sharing relevant patient information among appropriate providers, is necessary to achieve these goals. Future statutory changes should realize the potential of ACOs, health care homes and other reform efforts to improve health care in Minnesota.

Conclusions

At a high level the responses to this RFI demonstrate frustration with and misunderstanding of current consent requirements in Minnesota. While providers report that the vast majority of patients provide consent for their information to be shared, the lack of consensus among patients who responded to the RFI is evidence that this topic is challenging to assess among the greater population. That said, two strong messages emerged: the desire of both providers and patients to easily coordinate care, and the desire to understand and decide who should have access to a person's health information.

Providers manage the consent requirements of the MHRA using a wide range of processes, often including manual workarounds that do not integrate into today's electronic workflow environment. There are costs associated with this, but providers more often described the confusion factor for their staff and their patients that results from these workarounds. Furthermore, they experience problems with timely sharing of patient information with other providers, and see a burden for patients in dealing with repeat testing and appointments. Providers also noted that they don't have easy access to "off the shelf" tools and training to support their implementation of MHRA, so developing these technologies and procedures is a resource issue. While the views of patients were mixed on whether the current law helps or hurts them, a clear majority of the providers supported changing Minnesota law to align with HIPAA to support care coordination, uniformity in interpreting the law, and efficient implementation of workflows and care delivery.

Appendix A: Request for Information



**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 24, 2016

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

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under the Minnesota Health Records Act**

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.

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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 24, 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.

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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 of 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.

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

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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	2	3	4	A great deal of burden	Do not know
	1				5	
a. To what extent is this effort a burden for you?	<input type="checkbox"/>	<input type="checkbox"/>				

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.
[Click here to enter text.](#) hours

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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): [Click here to enter text.](#)

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				Positively impact	Do not know
	1	2	3	4	5	
a. Receive quality care	<input type="checkbox"/>					
b. Receive timely care	<input type="checkbox"/>					
c. Make sure your health information is protected	<input type="checkbox"/>					
d. Receive coordinated care	<input type="checkbox"/>					
e. Avoid extra doctor visits, tests, x-rays, etc.	<input type="checkbox"/>					
f. Take care of your health	<input type="checkbox"/>					
g. Be satisfied with your care experience	<input type="checkbox"/>					
h. Other (please describe): Click here to enter text.						

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

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

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.

[Click here to enter text.](#)

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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/>.

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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)

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Term	Definition
Electronic Health Records (EHR)	<p>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</p> <p>MN e-Health Glossary www.health.state.mn.us/e-health/e.html</p>
Health Information Exchange (HIE)	<p>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</p> <p>MN e-Health Glossary www.health.state.mn.us/e-health/h.html</p> <p>"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)</p>
Health Information Technology (HIT)	<p>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</p> <p>MN e-Health Glossary www.health.state.mn.us/e-health/h.html</p>
Individual	<p>Individual means the person who is the subject of protected health information (HIPAA)</p>
Patient	<p>"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)</p>

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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	<p>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.</p> <p>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.</p> <p>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.</p> <p>(See Code of Federal Regulations Title 45, Section 164.501)</p>

Appendix B: Methodology

Introduction

The RFI responses are qualitative in nature. The analysis team applied a systematic and rigorous method to review and analyze the data, develop themes, and allow for transparency of process.

Analysis involved an iterative process of reviewing and categorizing (or organizing) the information provided in the RFI responses to identifying common themes. MDH-OHIT staff led the analysis of provider responses relating to costs (i.e., relating to questions A2 and A7), and all responses presented by or on behalf of individuals (all of section B). Department of Administration staff led analysis of provider responses not relating to cost.

After independent review the two teams (MDH and Admin) met to discuss themes and come to agreement on the themes and considerations. The themes and considerations were endorsed by the Minnesota e-Health Advisory Committee during their December 8, 2016 meeting.

Response profile

MDH released the request for information on September 16, 2016, with a 39-day response and used multiple distribution methods to promote the RFI. 86 responses were received by the October 24 deadline.

86 responses were received but excluded from this analysis

- 1 response was blank (email with no attachment)
- 1 response was a duplicate response
- 3 responses were modified form letters addressing payer Explanation of Benefit; therefore deemed out of scope for this analysis.

81 responses were reviewed for this report

- 22 responded as or representing both provider and individual
 - 21 responded to all or part of the RFI form
 - 1 responded with a letter or email and not the RFI form
- 57 responded as or representing providers
 - 47 responded to all or part of the RFI form
 - 10 responded with a letter or email and not the RFI form
- 46 responded as or representing individuals
 - 30 responded to all or part of the RFI form
 - 16 responded with a letter or email and not the RFI form