

Minnesota Privacy and Security Project
Patient Consent Subgroup
Meeting Notes
Dec. 20, 2006

Attending: Billie Zippel, Co-Chair – Blue Cross of Minnesota, Laurie Beyer-Kropuenske, Co-Chair – Department of Administration, Darrell Shreve – MHHA, Beth Spohn – Fredrikson & Byron, Dan Routhe – U of MN, Eric Klavetter – Mayo Clinic, Pat Carter – HealthPartners, Todd Vollmers – Department of Commerce, LaVonne Wieland – HealthEast, Deb DeBruin – U of MN, John Gross – Department of Commerce, Lois Dahl – Fairview, Tess Settergren – SMDC

Staff: Jim Golden – Department of Health, Dave Orren – Department of Health, Mike DeWane – Rx2000, Christina Wen – Department of Health, Katie Engler – Department of Administration

1. Call to order

Billie Zippel called the meeting to order and reviewed the meeting objectives.

2. Updates

Jim Golden reviewed the updated schedule that was included in the meeting materials. If we begin to discuss the issue of informed consent, it will be continued at the January 3rd meeting and additional materials will be provided before that meeting. A preliminary draft of the report will also be on the agenda on the 3rd with a review of the more complete document at the January 17th meeting. Both January meetings will be held at the Health Department's conference center at Snelling Office Park (near the State Fairgrounds).

3. Meeting Notes for Dec. 6 Meeting

There were no comments on the meeting notes from the December 6th meeting. If any items are discovered, please send them to Jim.

4. Related Health Care Entity

The group had previously discussed the need for a definition of the term “related health care entity.” Because “common ownership” does not work for nonprofit corporations, Beth Spohn had suggested a definition.

Katie Engler was able to find a definition of “affiliate” in Chapter 144 and so revised Beth's suggestion to incorporate that existing definition.

The revised language reads:

New definitions in section 144.335, subdivision 1:

“Related health care entity” means an affiliate of the provider releasing the health information.

“Affiliate” has the meaning given in section 144.6521, subdivision 3(b).

Group members were satisfied that the revised definition addressed their concerns about nonprofit corporations.

5. Provider Ability to Rely on another Provider’s Representation/Allocation of Liability

When dealing with a patient consent, current law has caused a human-intensive process to be developed. For example, once a written, signed consent is obtained from a patient, it is sent via U.S. mail or facsimile to the provider who holds the records. An employee of the disclosing provider reviews the written consent to be certain all legal requirements have been met. Once the legal requirements have been satisfied, the patient’s health records are then pulled, reviewed, any needed redactions are made in order to comply with the consent, and then the records are sent to the requester.

If one of the goals of e-health is to enable automated, real-time exchange of health information, then changes may be necessary to make it possible to reach the goal.

To facilitate the discussion, the following scenario was offered.

The patient has waited several months to see the dermatologist and it is the day of the patient’s appointment. The dermatologist identifies information that would be helpful to have from the patient’s primary care provider so that a course of care can be determined. The patient is willing to consent to the release by the primary care provider immediately so that the dermatologist can get the needed information while the patient is still in the dermatologist’s office. What needs to be changed to facilitate this real-time exchange?

Option One: Current statutory language – responsibility on disclosing provider

From Minnesota Statutes, section 144.335, subdivision 3a:

(e) A person who negligently or intentionally releases a health record in violation of this subdivision, or who forges a signature on a consent form, or who obtains under false pretenses the consent form or health records of another person, or who, without the person's consent, alters a consent form, is liable to the patient for compensatory damages caused by an unauthorized release, plus costs and reasonable attorney's fees.

Pros:

- At least one group member sees the current language above as conferring some liability on a person who obtains consent under false pretenses. However, other group members said that the language does not provide much protection for the disclosing provider. This is because the disclosing provider intentionally releases the health records based on the consent and so falls squarely within the statutory language.

Cons:

Option Two: Opposite of current statutory language – responsibility on requester

New language for Minnesota Statutes, section 144.335, subdivision 3a:

(e) A person who negligently or intentionally ~~releases~~ requests a health record in violation of this subdivision, or who forges a signature on a consent form, or who obtains under false pretenses the consent form or health records of another person, or who, without the person's consent, alters a consent form, is liable to the patient for compensatory damages caused by an unauthorized release, plus costs and reasonable attorney's fees.

Pros:

Cons:

- This doesn't improve the situation providers find themselves in.

Option Three: Division of responsibility/liability

A third option is to provide a mechanism to use to allocate liability. As this option has several parts, the pros and cons of each piece are noted separately.

A. Add a definition to Minnesota Statutes, section 144.335, subdivision 1:

"Request" means a patient consent or a communication of a patient's permission to release health information.

Pros:

Cons:

- The definition of "request," as written, includes oral communication. Group members recognize that oral communication occurs, particularly between physicians. There was concern about this practice, but group members were uncertain whether the practice could be effectively banned. There was also discussion about whether there should be documentation of oral communications, what would be sufficient documentation, and how providers could minimize their risk.
- A patient's ability to limit the health records that are disclosed can have a negative impact on the care that the patient receives. Incomplete disclosure also may expose providers to malpractice claims. This issue could be addressed by a statement in the consent that partial release of records will affect care.

B. Amend Minnesota Statutes, section 144.335, subdivision 3a:

Subd. 3a. **Patient consent to release of records; liability.** (a) A provider, or a person who receives health records from a provider, may not release a patient's health records to a person without

(i) a signed and dated consent from the patient or the patient's legally authorized representative authorizing the release;

(ii) unless the release is specifically authorized by specific authorization in law; or

(iii) a representation from a provider that they hold a request.

Except as provided in paragraph (c) or (d), a consent is valid for one year or for a lesser period specified in the consent or for a different period provided by law.

Pros:

- A technology-based system can be set up to capture the data needed to document the representation that permission was given and to set up the ability to verify compliance.
- A standard form could be created that would offer all participants a “safe harbor” to assist in managing risk.

Cons:

- This amendment that acknowledges the ability to rely on a representation is limited to providers and so to treatment situations. There are some situations where a health plan has information that would be helpful in providing care (i.e. filled prescriptions). Broadening this provision to include health plans/payers/group purchasers was discussed. If “person” is substituted for “provider,” then the HIPAA provisions would have effect and so would prevent requests by third parties such as attorneys. Adding “for treatment, payment or health care operations” may be too broad and raise privacy concerns.
- By maintaining existing language stating that consents must be written and signed, the oral communication issue is not addressed.

C. Add to Minnesota Statutes, section 144.335:

Subdivision 3e. In adjudicating a dispute involving the disclosure of patient health records, a court will use the following in determining how liability will be allocated.

(a) By issuing a request for health records, a person warrants to the disclosing provider that:

- (1) the request contains no information known to the person to be false;
- (2) the request accurately states the patient’s desire to have health records disclosed or that there is specific authorization in law; and
- (3) the request does not exceed any limits imposed by the patient.

(b) By complying with a request, a provider warrants that:

- (1) the provider has complied with the requirements of this subdivision regarding disclosure of health records;
- (2) the request contained no information known to the provider to be false; and
- (3) the provider has complied with the limits set by the patient as stated in the request.

(c) No person or provider may disclaim or contractually limit the application of this subdivision, nor obtain indemnity for its effects, if the disclaimer, limitation, or indemnity restricts liability for misrepresentation as against persons reasonably relying on the request or disclosure.

(d) A court of this state presumes that:

(i) A request made by a person that complies with the provisions of this subdivision is valid and represents the wishes of the patient.
(ii) The information listed in a request is accurate.
(iii) The recipient of a request has no knowledge or notice that the person making the request:

(A) breached a duty to the patient; or
(B) does not rightfully have a request.

(e) A court of this state shall give effect to liability allocations between the parties provided by contract to the extent not inconsistent with the requirements of this chapter.

Pros:

- Would a penalty be a helpful addition to this subdivision? Would a criminal penalty be appropriate?
- Clauses (a)(3) and (b)(3) may be clearer if they state that compliance is with “any limits contained in the consent.”
- There were questions about how (b)(2) would work in an automated environment. This language would be an incentive for providers to quickly and accurately record revocations and other statements of limitation so that the system could identify potential problems.

Cons:

- The language in paragraph (e) does not go far enough; parties should not be allowed to allocate liability to the detriment of the patient. For example, the “deep pocket” provider cannot assign all liability to the small provider making it impossible for a patient who has been harmed to be compensated.
- If subdivision 3a(a)(iii) is limited to providers, it was suggested that subdivision 3e(a) should also be so limited so that the provisions are consistent.

Other Issues – all parts of Option Three

It was noted that if “current treatment interpretation 1” is followed (broad, general consent), then this is not really an issue. There was some discussion about whether patients would sign a consent if they understood the impact of interpretation 1 and if it would be possible to write a general consent that informed the patient sufficiently to make the consent valid. There was concern about operational issues that would result from fewer patients signing a broad, general consent and how those would be managed.

There was some discussion about the need for a public conversation about consent, what it means and how patients achieve choice in the process. More clarity on the consent form is one option as is education to help patients understand that they don’t have to sign the consent on order to see the provider.

Currently, some patients use the ability to limit the disclosure of health records for “inappropriate” purposes. For example, patients who are seeking drugs will not authorize complete disclosures to assist them in obtaining drugs. Others ask that their records be changed

to show a longer history of a particular condition to make them eligible for some kinds of care (e.g. through the Veteran's Administration). There was concern that enabling electronic health information exchange will exacerbate this situation.

It was also noted that the ability of a patient to limit what can be disclosed may cause an increase in these limitations. That happened when HIPAA was implemented; there was an increase in the requests for amendment and restriction because there was information explaining those rights. There was some discussion, with no recommended solution, on whether providers should be allowed to refuse to accept limits contained in a consent. It was also noted that it will be difficult to implement an automated response to a limited consent because health records are not segregated by type or topic. Human intervention will be needed to review requests to ensure compliance with the limitations.

On a related note, it was recognized that there is no current statutory authority for providers or health plans to provide information to the appropriate authorities about certain behaviors like those of drug-seekers.

Will this language have a negative impact on the ability of clinicians to use de-identified data to inquire about best practices for a particular condition? Many clinicians now use the Internet to conduct a literature search to help them care for a specific patient.

A broad, contract-based interpretation of "related health care entity" would also reduce the impact of this issue.