» *Andis Robeznieks*

Consent decrees

Patient control over access to their medical data often just a mouse-click away

Minnesota is typically in the "vanguard" when it comes to healthcare advances, says David Feinwachs, general counsel for the Minnesota Hospital Association, and the state recently took a couple of leaps forward in the area of electronic medical-records adoption. But at least one consumer advocate insists that the state also took a giant step backward in protecting patient privacy.

As politics and technology interests collide in Minnesota, it highlights the battle being fought between those who want unfettered access to patients' medical information and those who seek to stop their most private information from becoming public knowledge. Now, however, some companies are learning how the same technology being used to pry into people's personal data can also be utilized to block the view. As knowledge of these patient-consent applications become more known, there is more outcry that they be put to use.

ADVICE ON CONSENT

For EMRs, patient-consent declarations could include the following:

- Opting in or opting out: Privacy advocates like opt-in clauses, data collectors prefer opt-out. Both take all-or-nothing approaches.
- Certain information under certain conditions: Data about X can be viewed by physicians A and B, and also C—but only in cases of Y.
- In case of emergency, break glass: Barriers to patient data would be lifted when necessary. Patients are notified when this occurs.
- Dusting for prints: If someone opens a record, the patient gets to know who opened it, where and for what purpose.

Source: HIPAAT

Minnesota's $1.46 billion health and human services appropriation bill signed by Gov. Tim Pawlenty mandated that all hospitals and healthcare providers install interoperable EMR systems by Jan. 1, 2015, and the bill included $14 million to help small rural providers and clinics implement systems.

In addition, Minnesota Medical Association Chairman of the Board of Trustees Michael Ainslie says the state updated the Minnesota Health Records Act for the 21st century by clarifying EMR policies and laid the groundwork for the development of an electronic record-locater service, or RLS. An RLS is an index of patient-identifying information directing providers in a health information exchange, or HIE, to a patient's health records. But, according to consumer healthcare advocate Twila Brase, the RLS did so at the expense of the state's reputation of being a guardian of patient privacy.

Brase, who is a nurse and the president of the Citizens' Council on Health Care, says provisions calling for patient consent for inclusion of their records in the RLS were removed and, in so doing, people's personal medical information is being put at risk of being used by hackers, read by nosy healthcare workers and exploited by health plans.

"When they can take our data and put it online without our consent, what this says is our data is not ours," she says. "The whole idea is that data is gold and this is the 21st century version of the gold rush. It's about influencing medical decisions from outside the exam room and getting their hands on the data."

But Feinwachs says the RLS mentioned in the legislation is more concept than reality right now and he believes—if the state moves ahead slowly but surely—there will be time to work out any problems.

"A record locater service has the potential for abuse, but where we differ from Twila is that, clearly, we see electronic medical records are the wave of the future," he says. "It's unrealistic to believe that electronic medical records won't become the norm in the future, and it's unrealistic to believe that this form of rapid communication won't be used to make healthcare safer and more efficient."

While speeding up the process, Feinwachs says using the Web does have the side effect of making simple business transactions more complex. Nevertheless, Feinwachs says if participation in the RLS required an affirmative "opt in" by patients, "there probably wouldn't be enough participation to make it worthwhile." He adds that other consent provisions—such as making certain health information available to only certain providers at certain times—poses problems as well.

"It's possible, but I don't think it's practical," Feinwachs says, adding that consumers will have to make "global decisions" on the use of their information rather than having different choices for different situations.

Money vs. privacy

But Kelly Callahan, the head of business development for HIPAAT, a provider of "consent aggregation" software, disagrees. His Mississauga, Ontario-based company has been working on detailed "access controls" since 2002, but it's only been in the past six to eight months that interest has really been picking up, he says.

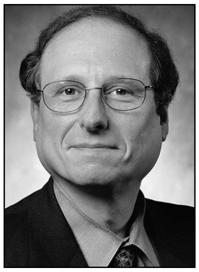
"If you get people pushing back and saying 'This is not possible,' we can show them it is possible," he says. "There's a misconception that it's more trouble than it's worth. It is a pain point, and it's painful because you have to spend more money, but what are the consequences if someone has their information exposed?"

Callahan's company takes its name from the Health Insurance Portability and Accountability Act of 1996, and he calls enforcement of HIPAA's privacy rules "negligible at best." He also acknowledges that "if it were not for the electronic exchange of information, there would be little need for what we do."

Callahan describes the HIPAAT program as a "call center" for an EMR system. If a healthcare provider within a regional health information organization, HIE or nationwide health information network wants to look up a patient's record, Callahan explains that the request would first go through HIPAAT's aggregation of organization privacy policies and patient-consent directives. Then, if these policies and directives allow that particular provider in that particular situation to view the information, "seamless" access will be provided.

InterSystems Corp., a Cambridge, Mass.-based IT company, developed its HealthShare product line specifically for RHIOs and other HIE applications. It consists of a browser-based viewer and a central index hub. In between is the HealthShare Gateway connection that filters physician information requests through the patient-consent declarations and security policies it has stored inside. A 2006 company white paper states that "every request is automatically checked by the appropriate Gateway for adherence to patient consent policies."

Feinwachs wasn't aware of how advanced the consent-management business had become, but he wasn't surprised either. "Every time you pass a law, there's a company somewhere developing a product to implement it," he says.


Feinwachs: **Patients need to make "global decisions" on their data.**

Callahan credits patient-consent mandates in the U.K. and the Canadian province of Ontario for the recent flurry of HIPAAT activity, and says it's only a matter of time before state and federal governments in the U.S. take notice that not only is patient-controlled access possible, but also it is necessary to gain public acceptance of EMR systems.

"It's being recognized that you can't invest loads of money into a national program if the public doesn't buy into it," he says. "In the U.K., they were five years into a national program and they had to pull back and address what they could do to get the public's confidence."

Let the patients drive

Writing in the *British Medical Journal* last July, John Halamka, a physician and chief information officer at CareGroup Health System in Boston, noted how important patient consent was to widespread adoption of health IT.

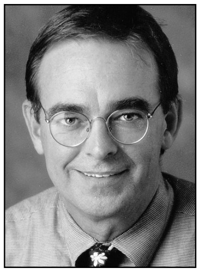
"We have only one opportunity to build a healthcare information superhighway that patients and providers can trust," wrote Halamka, who's also associate dean for educational technology at Harvard Medical School. "We should let the patients decide if they want to drive on it."

Last August, the American Psychiatric Association called for the Certification Commission for Healthcare Information Technology to add access-control functions to the panel's interoperability standards for ambulatory EMRs.

In September 2006, the U.K.'s National Health Service Care Record Programme Board agreed to a "sealed envelope" application where patients can decide if certain parts of their personal record could be blocked from general view, and estimated that the "sealing functionality" will become available sometime within the next two years. Ontario's Personal Health Information Protection Act calls for allowing patients to put such information in a "lockbox." In the U.S., such features are described as "break glass" applications with patients and others alerted if this "glass seal" is broken.

Callahan says that HIPAAT has been active with the Halamka-chaired Healthcare Information Technology Standards Panel, which was created in 2005 by the American National Standards Institute, and was awarded a $3.3 million contract to develop a process to harmonize standards for HIEs.

He adds that vendors that serve on HITSP and similar bodies are interested in what's happening in other countries because "you can grab things and modify them rather than having to create something new—and there's also the perspective that it would have been well-vetted already." Callahan also notes that the U.K. learned some hard lessons, and people around the world will try to avoid repeating other people's mistakes.


Pierson: **People will share information, but not everything.**

So, while technical and political barriers to allowing patients more control over who sees their data are falling, Callahan says, cultural obstacles remain.

"There are healthcare providers who feel they have the patient's best interest at heart, and would not want to have patients manipulate their diagnosis or not have full access to their information to provide or render care," Callahan says. "At the end of the day, people who used to be in control won't have as much control anymore."

And, the sooner physicians figure that out, says Marc Pierson, the better off everyone will be and the quicker health IT adoption will spread.

Pierson, who is the vice president of clinical information and special projects (but likes to use the title "community informatics") at PeaceHealth's 235-bed St. Joseph Hospital in Bellingham, Wash., says "a lot of people would share more information, but they don't want to share everything."

In 2002, St. Joseph joined with other healthcare organizations in Whatcom County to develop a communitywide Web-based personal health record financed by a $1.9 million Robert Wood Johnson Foundation grant. He said the PHR, called Shared Care Plan, is now used by about 1,200 people in his community of 173,000, and he maintains that patient-consent controls haven't led to problems.

"We have yet to see anyone say they don't want the ER doc to see anything," Pierson says. "They're not dumb. They want the ER doc to see everything—but why should their dermatologist know about the gonorrhea they had in their 20s?"

Pierson says he expects the use of the Shared Care Plan to multiply exponentially in the years ahead and much of that success is because it allows people to choose what people can see, who can see it and when.

"We got a bunch of people to say what they want—and they asked for that level of" detail, Pearson says. "When people get a choice, they're going to pick the choice that gives them the most control."

He adds that providers will still have their own individual patient records that they generate that patients will not have access to, but he also sees the time when copies of all laboratory results and diagnostic images will automatically be sent to a patient's PHR. Also, he says that it's his belief that widespread use of PHRs—which, on a large scale, will cost about $2.50 per person annually—will happen a lot faster than the development of a nationwide health information network.

"They could probably give every patient in the country a PHR for what it would cost to give every doctor in Chicago an EMR," Pierson says.

He adds that recent gains by consumer activists have made him more confident that the "powers that be" won't overrule the public's wishes for health IT.

"I'm so incredibly optimistic that the right thing is going to happen," Pierson says. "It's only a question of when and who's going to do it." «