patientprivacyrights

February 25, 2011

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attn: Joshua Seidman
Mary Switzer Building
330 C. Street, SW, Suite 1200
Washington, DC 20201

Re: HIT Policy Committee Meaningful Use Workgroup Request for Comments Regarding Meaningful Use Stage 2

Thank you for the opportunity to comment on the Meaningful Use (MU) Stage 2 criteria.

Patient Privacy Rights is the leading consumer voice for building ethical, trustworthy health IT systems. We have over 12,000 members in all 50 states and lead the bipartisan Coalition for Patient Privacy, representing 10.3 million Americans. We seek to restore the right to informed consent, and the right to health information privacy in electronic systems. Individual consent and control are imperative for patients and consumers to willingly participate in electronic systems and data exchanges.

Like the criteria for Stage 1, the criteria for Meaningful Use Stage 2 and 3 are missing the key elements Americans expect from electronic systems: the ability to control who can see and use personal health information[1] and the ability to segment information so they can selectively share information. Segmentation is essential to protect sensitive information, but also is absolutely critical for patient safety, so that erroneous health information can be kept from disclosure.

In 2009, the bipartisan Coalition for Patient Privacy recommended that HHS ensure "adequate privacy and security protections for personal health information" by requiring EHRs to comply with the consent requirements in the existing federal regulation 42 CFR Part 2 for the release of information relating to alcohol and substance abuse. We recommended that those consent requirements should be extended broadly to apply to disclosures of all protected health information (PHI) for MU Stage 1. See: http://patientprivacyrights.org/media/L-Coalition_to_HIT_PC_Meaningful_Use.pdf. HHS ignored the coalition's recommendations and did not address the need for privacy, segmentation, or patient control over secondary uses of data in MU Stage 1.

[1] http://patientprivacyrights.org/patient-privacy-poll

Recently the Federal Trade Commission (FTC) released a report titled "Protecting Consumer Privacy in an Era of Rapid Change."[2] In this report, the FTC recommended a framework for all entities that collect or use consumer data. The framework included:

- Privacy by Design: including data security, reasonable collection limits, sound retention practices, and **data accuracy.**

- Simplified Choice: when data is not being used for common practice such as data fulfillment, the consumer should be offered a choice at a time and in a context in which the consumer is making a decision about his or her data.

- Greater Transparency: including improving privacy notices, providing access to consumer data they maintain, and **obtaining express consent before any secondary use of consumer data.**

The FTC officially recommended consumers have control over what personal information is collected and disclosed. The entire 122-page FTC report is really about the 'meaningful use' of consumer data. Shouldn't the same, or even more stringent criteria, apply to entities holding our personal health information?

Further, a key recommendation in the recent report by the President's Council of Advisors on Science and Technology to HHS[3] was to use a meta-tag architecture to provide the foundation for building a secure, private, and consent-based electronic health infrastructure. Not only does the majority of the public agree that data privacy protections must be engineered into health IT systems up front, but the President's key scientific advisors also agree.

Yet the Health IT Policy Committee's Privacy & Security Tiger Team has failed to make any recommendations about privacy and security for MU Stage 2. Clearly it is disappointing to see the HIT Policy Committee ignore key measures the public expects once again.

It is also puzzling to see the HIT Policy and Standards Committees continue to ignore the Administration's strong policy position on privacy and patient control over PHI. On July 8, 2010, Secretary Sebelius first announced the "Administration-wide commitment to make sure no one has access to your personal information unless you want them to." Dr. Blumenthal stated in support at the press conference that, "we want to make sure it is possible for patients to have maximal control over PHI."[4] Both the Secretary and Dr. Blumenthal have often reiterated the policy position that individuals should control their health data since the announcement.

Finally, implementing Meaningful Use criteria without simultaneously laying down a comprehensive and meaningful privacy framework for data use and exchange will lead to disaster. Requiring the use of EHRs that do not have informed consent tools and privacy protections will lead to widespread data exchange and violations of patient privacy. The MU criteria must be revised to explicitly require design for privacy at the outset.

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[2] http://www.ftc.gov/os/2010/12/101201privacyreport.pdf , p. 13

[3] http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf

[4] http://patientprivacyrights.org/2010/07/ppr-impressed-with-hhs-privacy-approach/

The MU criteria and work by the HHS advisory committees for Health IT Policy and Standards do not match either the public's expectations or longstanding rights to health information privacy and consent.

The foundation for regulations (including the MU criteria) must be based on the strong national consensus about the right of consent:

> Every state has developed a body of law and common law requiring consent before health information is disclosed. The nation has a very consistent national framework requiring consent and special protections for sensitive information (genetic, mental health, STDs), developed over more than a century. Americans have strong Constitutional rights to health information privacy. We are NOT starting with a blank slate on the issue of consent; rather ***the public expects consent and control over disclosures of health information for all routine uses and for research***.

The HIT Policy Committee should recognize that HIPAA is a 'floor' for privacy:

> HHS stated when issuing the Amended Rule: "The Privacy Rule provides a floor of privacy protection. State laws that are more stringent remain in force. In order to not interfere with such laws [affording a right of consent] and ethical standards, ***this Rule permits covered entities to obtain consent***. Nor is the Privacy Rule intended to serve as a 'best practices' standard. Thus, professional standards that are more protective of privacy retain their vitality." 67 Fed. Reg. at 53,212 (August 14, 2002).

<u>Patient Privacy Rights' Recommendations for Stage 2 MU:</u>

On June 29th, 2010, HHS/ONC held the Consumer Choices Technology Hearing, so existing and new consent and segmentation systems could be demonstrated 'live'. The consent and segmentation tools shown that day prove that these essential protections for HIT systems and data exchanges can be used and required across the healthcare system now.

The following ***existing*** legal and ethical privacy protections must be addressed now in Stage 2:

- 42 CFR Part 2—requires consent before addiction treatment records are disclosed
- 7332—requires consent before sensitive information is disclosed from the military health system to outside physicians and providers
- HIPAA
    - Physicians and covered entities ***are permitted to obtain consent***
    - Disclosures of "psychotherapy notes" require consent
    - Only the "minimum necessary" data should be disclosed (requires consent and the ability to segment/hold back information)

- Medical Ethics/Ethical Codes of all health professions:
    - Adherence to ethical codes is required in many state licensure laws
    - Obtaining consent to disclose health information is the standard of practice across the nation
- The lack of the ability to segment erroneous data before disclosures from EHRs is a major patient safety issue. Today, there is no existing way to stop erroneous information from being disclosed endlessly from EHRs certified for MU.

The following ***new*** HITECH privacy protections must also be addressed now in Stage 2:

- Segmentation has been delayed. No date has been set for regulations. HHS issued a white paper[5] that ignores the fact that existing systems for mental health and addiction have used robust segmentation functionalities for over 10 years[6] and mistakenly claims that adding segmentation functionalities would take years.
- Consent technologies have been delayed. The HIT Policy Committee MU WG is relying on the Tiger Team for all privacy and security recommendations. But there is no expected date for the release of their recommendations. The MU criteria rollout schedule originally scheduled the public's core privacy protection, the right of consent, for 2014, dead last.

Conclusions:

I. The current MU Stage 2 criteria and schedule for MU Stage 3 criteria completely ignore/omit privacy rights and protections in existing privacy law, common law, Constitutional decisions, and professional ethics. Worse, by not building in the protections the public expects, patient trust in physicians, electronic systems, and data exchanges will further erode, causing millions more people/year to avoid treatment for cancer, mental illnesses, STDs[7].

II. The new HITECH consumer data privacy protections are being weakened, delayed, or ignored in the current MU criteria.

III. The current MU criteria violate Americans' rights and expectations of control over health information in electronic systems and data exchanges.

IV. The current MU criteria require doctors and health professionals to violate medical ethics.

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[5] http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_950145_0_0_18/gwu-data-segmentation-final.pdf

[6] See transcript and testimony from the Consumer Choices Technology Hearing June 2010: http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=2833&PageID=19477#062910

[7] HHS found that 586,000 people/year avoid early diagnosis and treatment for cancer, 2 millions avoid early diagnosis and treatment for mental illness, and millions avoid treatment for STDs because of privacy concerns (65 Fed. Reg. at 82,779, 65 Fed. Reg. at 82,777, and 65 Fed. Reg. at 82,778)

V. The federal requirements in 7332, in 42 CFR Part 2, and for "psychotherapy notes" and "minimum necessary" in HIPAA are not addressed in the current MU requirements.

VI. Currently there is no way to prevent errors in EHRs from being endlessly disclosed. This is an urgent matter for patient safety and data accuracy, especially because electronic systems and data exchange facilitate the crime of medical identity theft. EHRs must enable segmentation of EVERY kind of health data, NOT just "sensitive" health data, so that errors cannot be propagated endlessly. Both patients and doctors should be able to segment erroneous data so patients can be sure that what is shared about them is accurate.

VII. Covered entities that use EHRs certified for MU Stage 1 and use EHRs that comply with the proposed MU criteria for Stages 2 and 3 will violate state and federal laws, as well as professional codes of ethics.

The public cares very deeply about privacy, and failure to protect privacy will impair adoption of HIT systems and data exchanges. Survey after survey shows the vast majority of the public wants to control the use and dissemination of their health information. More importantly, people act like they care; extensive evidence demonstrates that patients will put their health at risk to ensure that sensitive health information is private.

The MU Stage 2 criteria must enable each individual to selectively share parts of their health information ONLY with the people they choose and prevent those they do not want to see their data from having access (with rare exceptions under the law). The public expects their legal and ethical rights to be built into health IT systems and data exchanges now.

We urge the HIT Policy Committee Meaningful Use Workgroup to revise the Stage 2 and 3 criteria and proceed cautiously to realize the public's expectation of individual control over health information and make robust data privacy, consent, and segmentation a reality.

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