

COALITION FOR PATIENT PRIVACY

June 26, 2009

Office of the National Coordinator for Health Information Technology
200 Independence Ave, SW
Suite 729D
Washington, DC 20201
Attention: HIT Policy Committee Meaningful Use Comments

Also Submitted via email to MeaningfulUse@hhs.gov

The Coalition for Patient Privacy is a diverse, bipartisan group of organizations that represents millions of Americans. We promote health IT that strengthens consumer control over protected health information so that the United States' electronic health system will be trusted and used by patients. Consumer control also ensures that the data available for research is accurate and complete, rather than the inaccurate and incomplete data we have today on all sensitive or stigmatized illnesses.

We envision an ethical health system that reaps the benefits of technology while simultaneously protecting our children and grandchildren from discrimination based on their protected health information. Individuals can best ensure that personal data goes *only* to the 'right' places at the 'right' time. With control over PHI, consumers can prevent the most egregious violations of privacy and most destructive uses of our health information, including rampant electronic fraud and identity theft by limiting who can access our records.

The KEY CRITICAL FUNCTION needed in every EHR to enable "meaningful use" of EHR data is the ability for patients to control the uses and disclosures of all protected health information (PHI). We recommend adopting existing open source technology that enables detailed control over disclosures as a baseline model or floor for consent technologies. The millions of members in our organizations want granular control over disclosures of their electronic health records, analogous to the ethical principles that have long governed our control over disclosures from paper health records.

The Meaningful Use Workgroup recommended to the Health IT Policy Committee that proposed "meaningful use" functions in EHRs should be "ultimately **linked to achieving measurable outcomes** in patient engagement, care coordination, and population health."

We believe that only if patients are willing to participate in the healthcare system and trust doctors with their most sensitive concerns will they disclose complete and accurate information necessary to achieve measurable and reliable outcomes.

Accurate and complete information cannot be obtained by force. We know from the California HealthCare Foundation's National Consumer Health Privacy Survey of November 9, 2005 that 1/8 patients or 12.5% of the population avoids their regular doctor, asks doctors to alter diagnoses, pays privately for a test, or avoids test altogether. If we do not restore patient control over PHI, we can expect electronic health data to have error and omission rates of up to 12.5 %. The breakthroughs and benefits possible with technology-enhanced research will never be reached with such a high rate of errors and omissions.

- Absent and erroneous data = garbage in
- Garbage in = garbage out

- Garbage out = faulty research
- **Research using bad data won't produce reliable outcomes measures or generate answers about "comparative effectiveness". When so many patients get treatment off-the grid or avoid treatment altogether, no data is produced.**

See CHCF survey at: <http://www.chcf.org/topics/view.cfm?itemID=115694>

The Workgroup recommended 5 policy priorities, with goals and objectives to be achieved between 2011 and 2015, and methods to measure those achievements. The policy priorities are (1) improve quality, safety, efficiency, and reduce health disparities, (2) engage patients and families, (3) improve care coordination, (4) improve population and public health, and (5) ensure adequate privacy and security protections for personal health information.

Our recommendations focus on the Workgroup's Policy priority (5), because none of the *other* policy priorities can be achieved unless the public trusts doctors and consumer control over PHI is restored.

The Coalition's key recommendation to ensure "adequate privacy and security protections for personal health information" is to restore consumer control over PHI in electronic health records and systems. America will never get the data most needed for critical kinds of research like comparative effectiveness, P4P, quality improvement, population health, personalized medicine, and genetic research unless patients are certain that their sensitive health records will not be used without informed consent. Research ethics are based on informed consent for participation, which follow from the Hippocratic Oath requiring patient consent before secrets are shared.

Recommendations:

1) The Coalition for Patient Privacy recommends using the consent requirements in the existing federal regulation 42 CFR Part 2 for the release of information relating to alcohol and substance abuse be used as the policy standard for the release of all protected health information.

See Title 42: Public Health, PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS, Subpart C—Disclosures With Patient's Consent at <http://ecfr.gpoaccess.gov/cgi/t/text/textidx?c=ecfr&sid=fcebf9c9cc10f7fe148f6c1d2f0f5753&rgn=div8&view=text&node=42:1.0.1.1.2.3.1.1&idno=42>. See addendum to this document.)

The detailed consent provisions in this federal statute have been implemented very successfully by behavioral treatment centers that are members of the National Data Information Infrastructure Consortium (NDIIC). Electronic consent is used in over 22 regions in 8 states, for the disclosure of records of 4 million patients over the past 9 years. The NDIIC electronic consents include all consent elements in 42 CR Part 2, including the Prohibition on redisclosure, successfully enabling the electronic exchange of this highly sensitive data for years at low cost. See: <http://ecfr.gpoaccess.gov/cgi/t/text/textidx?c=ecfr&sid=fcebf9c9cc10f7fe148f6c1d2f0f5753&rgn=div8&view=text&node=42:1.0.1.1.2.3.1.2&idno=42>

Because these electronic consents are open source, they can easily be adapted and validated by the NDIIC and other communities that validate open source technologies. At the same time, 42 CFR Part 2

allows for disclosures in medical emergencies, research activities, and audit and evaluation activities.
See:

<http://ecfr.gpoaccess.gov/cgi/t/text/textidx?c=ecfr&sid=42bbb5435b731dae7ede9379cc97f76e&rgn=djv6&view=text&node=42:1.0.1.1.2.4&idno=42>

2) The Coalition for Patient Privacy recommends using the electronic open source consents developed by the NDIIC that meet the requirements of 42 CFR Part 2 for the release of information relating to alcohol and substance abuse be used as the minimum standard for electronic consent to release of all protected health information. See: <http://www.ndiic.com/> and contact <http://www.ndiic.com/staff.shtml> for further information on electronic consent modules.

Sincerely:

The Coalition for Patient Privacy

American Civil Liberties Union
Consumer Action
Electronic Frontier Foundation
Just Health
The Multiracial Activist
The National Coalition of Mental Health Professionals and Consumers
Patient Privacy Rights
Private Citizen, Inc.
United States Bill of Rights Foundation

Addendum: 42 CFR Part 2 “Form of written consent”.

(a) *Required elements.* A written consent to a disclosure under these regulations must include:

- (1) The specific name or general designation of the program or person permitted to make the disclosure.
- (2) The name or title of the individual or the name of the organization to which disclosure is to be made.
- (3) The name of the patient.
- (4) The purpose of the disclosure.
- (5) How much and what kind of information is to be disclosed.

(6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under §2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under §2.15 in lieu of the patient.

(7) The date on which the consent is signed.

(8) A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.

(9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(b) *Sample consent form.* The following form complies with paragraph (a) of this section, but other elements may be added.

1. I (name of patient) o Request o Authorize:

2. (name or general designation of program which is to make the disclosure)

3. To disclose: (kind and amount of information to be disclosed)

4. To: (name or title of the person or organization to which disclosure is to be made)

5. For (purpose of the disclosure)

6. Date (on which this consent is signed)

7. Signature of patient

8. Signature of parent or guardian (where required)

9. Signature of person authorized to sign in lieu of the patient (where required)

10. This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already taken action in reliance on it. If not previously revoked, this consent will terminate upon: (specific date, event, or condition)

(c) *Expired, deficient, or false consent.* A disclosure may not be made on the basis of a consent which:

(1) Has expired;

(2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;

(3) Is known to have been revoked; or

(4) Is known, or through a reasonable effort could be known, by the person holding the records to be materially false.