CONSUMER CONSENT OPTIONS FOR ELECTRONIC HEALTH INFORMATION EXCHANGE: POLICY CONSIDERATIONS AND ANALYSIS

March 23, 2010

Prepared for:

Jodi Daniel, JD, MPH, Director
Steven Posnack, MHS, MS, Policy Analyst
Office of Policy and Planning
Office of the National Coordinator for Health IT
200 Independence Avenue, SW, Suite 729D
Washington, DC 20201

Prepared by:

Melissa M. Goldstein, JD
Associate Research Professor
Department of Health Policy, School of Public Health and Health Services
The George Washington University Medical Center
2021 K Street, N.W., Suite 800
Washington, DC 20006

Alison L. Rein, MS
Director
AcademyHealth
1150 17th Street NW, Suite 600
Washington, DC 20036

With research assistance from:

Penelope P. Hughes, JD
Julie K. Lappas, JD
Scott A. Weinstein
Benjamin Williams

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EXECUTIVE SUMMARY

The issue of whether, to what extent, and how individuals should have the ability to exercise control over their health information represents one of the foremost policy challenges related to the electronic exchange of health information. The current landscape of possible consent models is varied, and the factors involved in choosing among them are complex. States and other entities engaged in facilitating the exchange of electronic health information are struggling with a host of challenges, chief among them the establishment of policies and procedures for patient participation in their exchange efforts. While some have adopted policies enabling patients to exercise individual choice, others have prioritized the needs and concerns of other key stakeholders, such as providers and payers. The purpose of this paper is to discuss in detail the issues, nuanced considerations, and possible tradeoffs associated with the various consent options to help facilitate informed decision making.

Core consent options (abbreviated) for electronic exchange include the following:

- *No consent*. Health information of patients is automatically included—patients cannot opt out;
- *Opt-out*. Default is for health information of patients to be included automatically, but the patient can opt out completely;
- *Opt-out with exceptions*. Default is for health information of patients to be included, but the patient can opt out completely or allow only select data to be included;
- *Opt-in*. Default is that no patient health information is included; patients must actively express consent to be included, but if they do so then their information must be all in or all out; and
- *Opt-in with restrictions*. Default is that no patient health information is made available, but the patient may allow a subset of select data to be included.

As these definitions illustrate, a range of consent models can be applied in different contexts of electronic exchange in the U.S., and it is possible for there to be further permutations depending on the level of choice granularity allowed. There is also considerable variation in the type of information exchanged, ranging from the more basic (*e.g.*, lab results) to the more mature and complex (*e.g.*, a wide array of health information).

The consent model selected for electronic exchange, as well as the determination of which types of health information to exchange, affects many stakeholders (*e.g.*, patients, providers, and payers). These decisions also have consequences for national policy goals, such as improving the quality of healthcare, promoting public health, engaging patients in their health care, and ensuring the privacy and security of personal health

information. This discussion requires not only an appreciation of the sometimes competing interests of various stakeholders, but also consideration of the interests of the individual relative to those of society as a whole.

Provider and patient participation in electronic exchange have been identified as key challenges—both patient and provider participation are desired to facilitate better care delivery and advance other societal goals (*e.g.*, improved public health), as well as to ensure the viability and utility of the exchange. To enhance patient participation, numerous electronic exchanges have employed one or more of the following tactics:

- Active engagement of patients in the development of the exchange entity;
- Vigorous marketing of exchange efforts through effective channels;
- Initial and ongoing education (largely from providers) about the effort; and
- Adoption of an *opt-out* or *no-consent* model, in concert with tight restrictions on data access and / or use, including stringent penalties for misuse.

In addition, these electronic exchanges have employed the following methods of ensuring adequate provider participation:

- Minimization of administrative burdens, sometimes coupled with financial or other incentives;
- Maximization of value (*i.e.*, access to as much useful information as possible, as often as is needed); and
- Provision of key infrastructure and service components (*e.g.*, a record locator service or consent management tool).

Other issues of particular significance with regard to progress (or lack thereof) toward the greater proliferation of electronic exchange include:

- Numerous and sometimes inconsistent federal and state laws regarding patient consent generally, and disclosure of sensitive information specifically;
- Provider workflow challenges associated with obtaining and managing consent;
- The lack of (or difficulty in achieving) technical and procedural capacity to segment and manage data in the manners desired by various constituents;
- The concern that existing security and privacy provisions are inadequate; and
- The need to balance multiple and often conflicting stakeholder interests to ensure adequate participation.

At present, the evidence from emerging electronic exchanges is insufficient to determine the consequences associated with policy decisions that allow for greater or lesser levels of patient choice with regard to the electronic exchange of their data. There are early signs that consent models at both ends of the spectrum can generate sufficient patient and provider participation to achieve the critical mass necessary for system function and the realization of key goals. However, in any consent model the role of other factors, such as the accompanying level of dedicated human and financial resources, policy development, and other necessary supports, must also be considered. Due to the complexity of issues

involved in selecting and applying a particular consent model, appropriate guidance in the form of higher-level principles or recommendations is critical to moving forward. While this document represents a starting point for discussion related to consent, it is imperative that future deliberations are informed by further research regarding the effectiveness and impact of various consent options, consideration of the broader policy landscape, and assessment of the needs of those most affected by the consent decision. Until the time when we are confident that we can protect health information in a systematic and thorough way, prudent use of the mechanism of consent appears to be one of the most reliable ways to pursue that goal.