Health IT Policy Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

Privacy and Security Workgroup

Interoperability Roadmap Comments

Deven McGraw, chair
Stanley Crosley, co-chair

April 7, 2015

Agenda

1. Overarching Comments
2. Section H Comments
3. Section G Comments

PSWG Members

- **Deven McGraw**, Chair, Manatt, Phelps & Phillips, LLP
- **Stanley Crosley,** Co-Chair, Drinker Biddle & Reath LLP
- **Donna Cryer,** Member, CryerHealth
- **Gayle B. Harrell**, Member, Florida State House of Representatives
- **Linda Kloss,** Member, Kloss Strategic Advisors, Ltd.
- **David Kotz,** Member, Dartmouth College
- **Gilad Kuperman,** Member, NewYork-Presbyterian Hospital
- **Manuj Lal,** Member, PatientPoint Enterprise
- **David McCallie, Jr.,** Member, Cerner Corporation
- **Micky Tripathi,** Member, Massachusetts eHealth Collaborative
- **John Wilbanks,** Member, Sage Bionetworks
- **Kristen Anderson,** Ex Officio, Federal Trade Commission
- **Sarah Carr,** Ex Officio, NIH Office of Science Policy
- **Adrienne Ficchi,** Ex Officio, Veterans Health Administration
- **Stephania Griffin,** Ex Officio, Veterans Health Administration
- **Cora Tung Han,** Ex Officio, Federal Trade Commission
- **Taha Kass-Hout,** Ex Officio, Food and Drug Administration
- **Bakul Patel,** Ex Officio, Food and Drug Administration
- **Linda Sanches,** Ex Officio, Office for Civil Rights-Health and Human Services
- **Kitt Winter,** Ex Officio, Social Security Administration

Overarching Comments

Overarching Comments, continued

Comments

Clarify language regarding the relationship between "basic choice" and existing health or medical privacy laws that permit the sharing of health information for some purposes (such as among health care providers for treatment and care coordination) without the requirement to first obtain patient permission.

- For many readers, the draft Roadmap was unclear on what was intended in the discussion of basic choice. Some interpreted the discussion as requiring basic choice even in circumstances where the law permits data to be shared without first requiring an individual's express permission (for example, the draft Roadmap describes the laws that permit sharing as being the default when an individual has not expressed basic choice, which could lead to an interpretation that some level of basic choice is either required or preferred).

Overarching Comments, continued

Comments

- ONC should make sure the final Roadmap clearly and unambiguously articulates the following national near-term goals (which were presented to the PSWG by ONC during one of our public sessions on the Roadmap):
  - Exchange is permitted for certain purposes without an individual's permission;
  - Basic choice, *if offered to individuals,* is offered in a technically standard way and individuals can more easily make choices electronically and online; and
  - Harmonize categories/conditions legislatively defined under federal and state law (e.g., mental health).

Overarching Comments, continued

Comments

With respect to exchange among providers, the Interoperability Roadmap should focus first on removing the roadblocks to exchange pursuant to existing laws, to achieve more consistent interpretations of these laws and assure greater interoperability.

- Policy debates about the degree of control that patients should have over personal health information are ongoing and will continue into the future, particularly as technology and cultural norms around privacy evolve and as the exchange and use of health information extends beyond the boundaries of traditional healthcare.
- ONC should focus the Roadmap first on promoting/assuring interoperability within traditional healthcare providers in the face of the existing legal and regulatory framework, enabling existing laws and practices around patient choice to be honored, but also considering the dynamic environment of greater patient engagement that is rapidly evolving outside of these traditional borders.
- It would help to clarify whether, when a provider makes a disclosure permitted by federal law, the discloser is liable for any bad or careless acts of the receiver. Clarity on this point would reduce uncertainty and depending on the answer, might help remove obstacles to interoperability.

Comments – Section H

Consistent representation of authorization to access health information

When coupled with identity verification, this allows consistent decisions to be made by systems about access to information.

Section H - Consistent representation of authorization to access health information, continued

Specifically Charged Question	Comments
H1. Who should ONC convene to develop policy recommendations and a framework to enable consistent decisions about authorized access to health information?	**ONC should gather information from a broad array of stakeholders trying to exchange, or facilitate the exchange of, health information (providers, patients, HIEs, federal and state entities, etc.) to determine what are common obstacles with respect to demonstrating legal authority to access a record, particularly for treatment and care coordination purposes, and starting with circumstances where consent is not required.**

Section H - Consistent representation of authorization to access health information, continued

Specifically Charged Question	Comments
H2. Is there agreement that the issue of "rules confusion" should be addressed from a policy perspective at the state level to advance the goals of a learning health system? If no, why not? If yes, what would be three priority areas for additional clarification?	**Clarification from state and federal regulators (ideally with specific examples) about what is acceptable for demonstrating legal authority to access information would be enormously helpful.** Focus should be on specific, high impact use cases that achieve the Interoperability goals of years 1-3 of ONC's 10-year vision. • ONC should work with stakeholders to define these examples that might serve as a basis for additional regulatory guidance; achievement of meaningful use objectives and sharing within accountable care organizations pursuant to other alternative payment models are two suggestions.

Section H - Consistent representation of authorization to access health information, continued

Specifically Charged Question	Comments
H2. Is there agreement that the issue of "rules confusion" should be addressed from a policy perspective at the state level to advance the goals of a learning health system? If no, why not? If yes, what would be three priority areas for additional clarification?	• Suggested priority areas: demonstrating the existence of a direct or indirect treatment relationship; requirements to share data for treatment or care coordination (both privacy and security); the impact of consent or authorization of the patient to share information, both in circumstances where it is required and in circumstances where it is not. • For example, the HITPC approved recommendations from the Tiger Team that included best practices for demonstrating legal authority to access a record in an environment governed by HIPAA. These and other approaches deemed acceptable should be broadly disseminated, if necessary in conjunction with the Office for Civil Rights (OCR) or other regulatory agencies. • There is also confusion with respect to other federal laws (42 C.F.R. Part 2) as well as state laws, where even providers operating within states do not fully understand their own state laws with respect to authorized sharing of identifiable health information.

Section H - Consistent representation of authorization to access health information, continued

Specifically Charged Question	Comments
H3. For role-based access, how should role categorization proceed across the healthcare system?	**ONC should focus on facilitating entity-to-entity exchange; who is permitted to access that information within the entity – role-based access – should be left to internal policies.** • Role-based access (RBA) is typically determined within an organization or institution. One organization's RBA controls – which are often very complex and under constant reevaluation – should have little or no bearing on whether another organization will decide to engage with it in health information exchange. A receiving organization is expected to facilitate how information is "triaged" within that organization. This includes ensuring health information (1) is delivered to the person to whom it is specifically addressed/directed, in circumstances where a particular person is designated as the recipient, and (2) is accessed only by persons who have legal authority to access that record and have the properly assigned role within their organization or institution. These latter two decisions are made at the organization/institution level.

Section H - Consistent representation of authorization to access health information, continued

Specifically Charged Question	Comments
H3. For role-based access, how should role categorization proceed across the healthcare system?	• Clarification that sending organizations are not legally responsible for how a receiving organization routes communication could help resolve uncertainty. • The Interoperability Roadmap could reinforce the need for organizations to embrace best practices with regard to structuring these internal policies.

Section H - Consistent representation of authorization to access health information, continued

Specifically Charged Question	Comments
H4. Is there a basic set of defined roles that can be agreed upon and built on?	**Granular consent requirements may necessitate some role standardization. As ONC further explores harmonization of more granular consent laws, it should consider whether role standardization, at least a high level, would help resolve interoperability obstacles posed by granular consent requirements.** • Note – granularity with respect to role standardization will need to be constrained in order to assure interoperability (example of open source software).

Section H - Consistent representation of authorization to access health information , continued

Specifically Charged Question	Comments
H5. Are existing standards to support authorization in healthcare sufficient to meet the needs of an evolving nationwide learning health system? H6. What are the reasons for the relatively low uptake of existing standards?	**These are questions more appropriate for the Standards Committee to resolve.**

Comments – Section G

Consistent representation of permission to collect, share and use identifiable health information

Though legal requirements differ across the states, nationwide interoperability requires a consistent way to represent an individual's permission to collect, share and use their individually identifiable health information, including with whom and for what purpose(s).

Section G – Consistent representation of permission to collect, share and use identifiable health information

Specifically Charged Question	Comments
G1. Are states ready to collaborate on the issue of permission? Why or why not?	**We do not know the answer to the question. We agree collaboration would be helpful and hope there is a willingness on the part of the states to come to the table, but states are addressing many issues and there may be limited bandwidth to take this on, particularly given its complexity. There will need to be a federal "convenor" to support this effort.**

Section G – Consistent representation of permission to collect, share and use identifiable health information, continued

Specifically Charged Question	Comments
G1. Are states ready to collaborate on the issue of permission? Why or why not?	• An early focus could be on developing standard definitions, so that consent can be more consistently represented. • As the imperatives to exchange grow stronger (due to payment reform and increased adoption of telemedicine, for example), the distress levels felt by providers who are unable to exchange due to lack of understanding of legal requirements and lack of technical mechanisms for achieving compliance will increase. This may help bring people to the table. • States could consider whether the framework recommended by the National Committee on Vital and Health Statistics (NCVHS) – which established specific, defined categories for granular consent – would help them achieve some consensus on how to harmonize. Consider also whether the Uniform Law Commissioners could help in drafting harmonized approaches. The Development of standards on granular choice should focus on circumstances where a patient's consent is required by law to improve provider confidence that they are exchanging data in compliance with law, and therefore to remove barriers to interoperable exchange.

Section G – Consistent representation of permission to collect, share and use identifiable health information

Specifically Charged Question	Comments
G2. What other methodologies, including technical solutions, should also be considered to address this concern?	**1. Although this is not a "technical" solution, ONC should evaluate the work done by the Social Security Administration (SSA) in formulating a universal authorization to share data that has enabled them to access data across states for consideration in disability determinations.** **2. ONC should also investigate the successful nationwide implementation of simple consumer preferences (akin to "basic choice") through the FTC's "Do Not Call" Registry.** **3. ONC should also look at successful existing exchange models to explore whether their approaches can be scaled.** **4. Use of consent repositories is another approach worth considering.**

Section G – Consistent representation of permission to collect, share and use identifiable health information, continued

Specifically Charged Question	Comments
G3. The Draft Interoperability Roadmap assumes that consent should persist with patient information; is this a valid assumption? What would be the impact of non-persistence on the interoperable movement of data?	**Achieving technical ability to "persist" consent or authorization is desirable – but likely only in those circumstances where there is either a legal obligation for consent to be persisted and honored across settings, or in the circumstance of data shared directly by, or at the request of, the patient.** • For some circumstances, having consent persist with the information is either legally required (e.g., pursuant to 42 C.F.R. Part 2 or other more granular consent laws) or would be desirable, although it is technologically very difficult to accomplish.

Section G – Consistent representation of permission to collect, share and use identifiable health information, continued

Specifically Charged Question	Comments
G3. The Draft Interoperability Roadmap assumes that consent should persist with patient information; is this a valid assumption? What would be the impact of non-persistence on the interoperable movement of data?	• At a minimum, consents need to be clearly communicated in circumstances where law or policy requires consent for sharing. In our work on query for patient records, as well as on granular consent and data segmentation, we have repeatedly recommended having a standard way of communicating consent to share where such consent is required. • There is concern that in the absence of a legal obligation to obtain the consent of the patient, it may not be possible for that consent to be honored downstream – and individuals providing that consent need to understand this. Does persistence of a consent trigger an obligation (either in reality or perception) that the consent must be honored? In addition, if we require consent to be persisted, do we risk creating an environment where consent becomes a de facto requirement because the absence of consent communicates that such sharing is not permitted?

Section G – Consistent representation of permission to collect, share and use identifiable health information, continued

Specifically Charged Question	Comments
G4. Is there agreement on approaching consent through basic choice as it relates to TPO followed by granular choice supported by a set of nationwide harmonized rules? G5. What are the alternatives we should be considering? G6. What areas of health information should be addressed first for granular choice? G7. What are realistic timeframes?	**1. ONC should make sure it also focuses on assuring that exchange can occur in circumstances governed by HIPAA (where choice is not necessarily required), in addition to focusing on choice circumstances. For example, ONC should look at the recommendations on "directed exchange" adopted by the HITPC in August 2010.** **2. ONC should also consider how to enable patients – such as through basic choice – to require that their data be shared for treatment purposes; in other words, ONC and applicable regulators could clarify whether a provider is permitted to refuse to exchange data when a patient requests exchange. This should be a fundamental use case for the Interoperability Roadmap and an example for which additional regulatory guidance could be promulgated. Consideration needs to be given to the risk associated with making certain system connections such that providers have the ability to reject system requests that may pose risk or onerous burden to systems.**

Section G – Consistent representation of permission to collect, share and use identifiable health information, continued

Specifically Charged Question	Comments
G4. Is there agreement on approaching consent through basic choice as it relates to TPO followed by granular choice supported by a set of nationwide harmonized rules? G5. What are the alternatives we should be considering? G6. What areas of health information should be addressed first for granular choice? G7. What are realistic timeframes?	**3. Basic choice has been implemented in one form or another by a number of HIEs and other exchange settings – and achieving exchange among HIEs is a desirable near-term goal, which bolsters the argument for early focus on basic choice.** **4. Because granular choice harmonization requires some significant work on the policy front, and work with multiple states, efforts to bring states together to begin the dialogue could be launched even while the standards focus is on enabling basic choice.** **5. Consider whether there are intermediate options between basic and granular, because granular is typically defined as applying to types of data. Consider enabling choice at the level of provider or provider organization, and enabling patients to make more global choices (for example, all treating providers vs. being required to specifically name them) should they choose to do so.**

Section G – Consistent representation of permission to collect, share and use identifiable health information

Specifically Charged Question	Comments
G8. How should success be measured when addressing the complexity of the rules environment?	**Success metrics should be linked to Interoperability goals, and, as noted above, focused on removal of obstacles to achieving high impact use cases. Some possible examples are set forth below:** • Convene a dialogue with states with respect to harmonization. (1 year) • Issuance of more guidance on acceptable mechanisms for assuring legal authorization to share information. (within 1-2 years, at least at the federal level) • Achievement of consensus on definitions for basic choice. (within 2-4 years) • Greater exchange of information for treatment and care coordination, particularly in circumstances where HIPAA governs (or there are no state laws that restrict sharing of information for those purposes). (1-5 years) This is already occurring with respect to e-prescriptions.