Proposed ***Rules and Regulations Pertaining to the Regional Health Information Organization and Health Information Exchange (R5-37.7-HIE)***

Community Review Meeting Minutes

Friday, 7 November 2008

Persons in Attendance: See attached sign-in sheet.

The meeting was convened at 1:35 p.m. by Amy Zimmerman, MPH, Chief of Health Information Technology, Rhode Island Department of Health, who provided introductions, an overview of the regulatory process, and the purpose of the meeting.

Comments/issues are summarized below:

Source of the Comment	Section number	Comment Received or Issue Discussed
ACLU	Required by statute-not addressed in regulations	R.I.G.L. §5-37.7-4(c) "Patients and health care providers shall have the choice to participate in the HIE, **as defined by regulations**…" Nothing provided within the draft regulations describes a process for making patients or providers aware of the choice, nor how and when the choice is presented to patients. The proposal does not even appear to explicitly address whether this will be an opt-in or opt-out system. Also missing is any procedure to document the informed consent of those agreeing to participate.
ACLU	Required by statute-not addressed in regulations	R.I.G.L. §5-37.7-5(a) "The director of the department of health shall **develop regulations** regarding the confidentiality of patient participation…" However, the section of the regulations titled "Confidentiality Protections" consists almost exclusively of language mirroring the statute. In light of the significance of confidentiality to the implementation of an HIE, the absence of any clarifying regulations is striking and disconcerting.
ACLU	Required by statute-not addressed in regulations	R.I.G.L. §5-37.7-6 "The RHIO shall, **subject to and consistent with department regulations** and contractual obligations it has with the state of Rhode Island, be responsible for…" This is another area that prompted a great deal of discussion during the legislative process. Regulations were expected to cover minimum confidentiality and privacy practices and standards that the RHIO must be held to in accordance with any contractual agreement between the Department and the RHIO. Also discussed for inclusion through the regulatory process, but not addressed in this proposal, was the addition of mechanisms to

		address contractual violations of these standards by the RHIO. The goal of these mechanisms was to ensure meaningful accountability without leaving the Department with the sole choice of seeking revocation of the contract as the remedy for any violations.
ACLU	Required by statute-not addressed in regulations	R.I.G.L. §5-37.7-7(c) "The content of the authorization form […] shall be prescribed by the RHIO **in accordance with applicable department of health regulations**..." The proposed regulations, for the most part, simply regurgitate the statutory language. It would be both appropriate and useful to propose a draft authorization form – or, at a minimum, a detailed listing of what should be included on the form – in order to ensure it adequately addresses the statutory requirements and demonstrates true informed consent.
ACLU	Required by statute-not addressed in regulations	R.I.G.L. §5-37.7-8(a) "Authenticate the recipient of any confidential health care information disclosed by the HIE **pursuant to rules and regulations promulgated by the agency**." There is absolutely no authentication process spelled out within the proposed regulations.
ACLU	Required by statute-not addressed in regulations	R.I.G.L. §5-37.7-10(d) "To terminate his or her participation in the HIE **in accordance with rules and regulations promulgated by the agency**" This is also something absent from the draft rules, but that is very important to patient autonomy.
ACLU	Include additional requirement in regulations	Since the statute fails to limit the ability of health care providers to deny treatment to patients who refuse to participate in the HIE, we believe that, at a minimum, the regulations should require providers to notify the Department if they mandate patient participation in the HIE and require the Department to maintain a list of those providers for public access. In this way, patients concerned about their privacy will be able to make the most informed decisions about the health care providers whose services they wish to use.
ACLU	Include additional requirement in regulations	Section 4(e) of the statute requires that the HIE and RHIO be bound by HIPAA-compliant business associate agreements. The Department should include within its regulations the terms it considers necessary and appropriate to ensure HIPAA compliance.
Butler Hospital	Include additional requirement in regulations	Specific guidance regarding how to manage the health information of a patient who exercises his/her right to terminate his/her participation in the HIE is needed to address how the record holder is to manage that information
United Healthcare	Include additional definition in regulations	Add definition of "payer participant"[to allow access by a payer to HIE for case management purposes]
Community Review	Include additional	Add definition of "deidentified information"

	definition in regulations	
Partridge, Snow, and Hahn	§1.2(1)	"As established by this chapter" should probably read "as established by the Act"
Damale	§1.10	Electronic Mobilization, moving clinical information with accuracy is important but should also add security and confidentiality
Damale	§1.12	May want to add RNP and PA to list of "health Care Providers".
RI Academy of Physician Assistants	§1.12	Physician Assistants should be added to the list of professionals defined as "health care providers"
Partridge, Snow, and Hahn	§1.17	"department of health" in line 3 should be replaced with Department"
Damale	§1.20	pharmacy, laboratory, health care provider and may want to add health care facility.
Partridge, Snow, and Hahn	§1.20	Proposed regulations do not specifically address who the "provider participant" must execute an agreement with [*Includes detailed comment on other related issues and possible locations where this information would be appropriate*]
United Healthcare	§2.2(e)	Request additional clarification of term "public health purposes"
Partridge, Snow, and Hahn	§2.3	More specifics needed regarding oversight of RHIO, including annual review of required policies and procedures [*Includes detailed comment on why this issues need to be addressed*]
United Healthcare	§2.3(a)	Does "safeguarding" include opt-in/opt-out policies?
Community Review	§2.3(a)	Add "the Act and" before "these Regulations" in the 1st sentence.
Community Review	§2.3(c)(2)	Add "of enrollment" after "Participant withdrawal"
Community Review	§2.3(c)(8)	Check statutory language on identity theft
United Healthcare	§2.3(c)	We recommend adding a subsection (10) –Security standards pertaining to access, use and maintenance of the HIE
Partridge, Snow, and Hahn	§2.4(c)	Add "in accordance with HIPAA and the Act" at the end of the existing section.
Damale	§2.4(c)	This states that a patient participant can alter the medical record of a provider. This is not standard practice in the electronic or paper format. Provider's can amend their own work product, but not other

		providers or patients.
United Healthcare	§3.1	Request clarification of relationship between HIE Advisory Commission and RI Quality Institute HIE Oversight Committee
EDS RI	§3.2	HIPAA is spelled HIPPA rather than HIPAA
Partridge, Snow, and Hahn	§3.2	HIPAA is spelled HIPPA rather than HIPAA
Community Review	§3.2	A data supplier, such as a health plan, should be represented on the HIE Advisory Commission
Partridge, Snow, and Hahn	§3.2	Recommend removal of reference to individual with IRB experience. [*Includes detailed comment on why IRB and HIPAA experience are not interchangeable*]
Community review	§3.2	Include statutory citation for HIE appointment process
Community review	§3.2	An individual with experience in cyber security should be represented on the HIE Advisory Commission
ACLU	§3.5	Though purporting to simply mirror the statutory language, refers to HIE Advisory Commission reports as being "publicly available." In fact, the statute requires that the reports "be made public." The distinction between the passive availability of the reports provided by the regulations and the active mandate that the reports be public as contained in the statute is not a mere stylistic difference
ACLU	§4.1	This section should be further expanded to include the processes a patient would go through in subsections (a), (c), (e), and (f) to obtain records, terminate participation, etc. For example, whom do patients contact? What timeframe should they expect? Are there any forms required?
Damale	§4.1(b)	Should read "provider organization(s) or providers can access health care information".
Community Review	§4.1(b)	Replace "organization" with "participant" for consistency with previously defined terms
Partridge, Snow, and Hahn	§4.1(b)	Current wording appears to contradict other parts of statute and regulations. Recommend section be removed or modified to read "to identify in the authorization form which provider organization(s) have his/her consent to access his/her health care information". [*Includes detailed supporting rationale for this suggested change*]
Community Review	§4.1(b)	Specifically state who can be denied access; also add how "emergency only" option can be invoked
Community Review	§4.1(e)	Add "the Act and" before "these Regulations"
Damale	§4.1(f)	Again, it is not standard for the patient to be able to amend a provider

		medical record.
ACLU	§4.1(f)	The language herein is taken directly from statute. However, R.I.G.L. §5-37.7-4(e) makes clear that the RHIO also must respond directly to patient requests to amend their health care record. The regulations should propose some standards for RHIO compliance with this obligation
United Health Care	§4.2(a)	Does use of "sign" only mean ink on paper? Regulations should also allow electronic signature, with appropriate verification .
Butler Hospital	§4.2(b)	The language should be re-worded to insure compliance with the Rhode Island Mental Health Law (as the "or use for clinical care" implies that this reason would be an exception), yet the Rhode Island Mental Health Law and federal substance abuse statutes are more stringent in this regard
EDS RI	§4.3	I assume under the Exception from Confidential Protection, release without Authorizations as permitted by HIPAA for payment and healthcare operations were purposely omitted due to the nature of the system and its intended use?
Butler Hospital	§4.4	Suggest incorporation of the principle of minimum necessary in terms of re-disclosure of information from one provider to another
ACLU	§4.5	We would like the language related to "proposed uses" (§4.5(a)(1)) to be clearly outlined. It is our understanding that the HIE was established primarily for the benefit of treatment and care coordination. It is ambiguous to a worrisome degree not to give further definition of what other uses would be allowed and to ensure that patients will know if they are agreeing to sharing information for non-treatment purposes. In this regard, we also believe the regulations should provide for the use of two separate forms: one for treatment situations and a separate form to authorize patient information for other purposes approved by the Department, such as marketing or research. This would help to ensure a patient's informed consent to participate in the latter to the extent that the Department is agreeing that these uses are permissible.
EDS RI	§4.5	Also does not seem to require all the elements as are required under the HIPAA Privacy rule. Again I'm not sure if that was purposeful.
ACLU	§4.5(a)	In order to protect patient privacy, we would urge that the regulations, similar to HIPAA, contain a minimization requirement when it comes to the transfer of information for non-treatment purposes. That is, only the minimum necessary medical records information should be provided to non-provider third parties for whom consent authorization has been provided by the patient.
United Health Care	§4.5(a)	Does use of "sign" only mean ink on paper? Regulations should also allow electronic signature on authorization form, with appropriate verification .

ACLU	§4.5(b)	This section makes reference to a non-existent statute section, R.I.G.L. §5-37.3-4(4)(d)
Community Review	§4.5(b)	Remove reference to RIGL §5-37.3-4(4)(d)
Damale	§4.5(4)(ii)	Item 4.4 Secondary Disclosure would not be allowed if this item is followed, since it only designates specific health care providers. This needs further clarification, since it is inconsistent.
Partridge, Snow, and Hahn	§4.6(c)	This subsection does not belong under §6.4. [*Includes detailed rationale to support this contention*]
Community Review	§4.6(c)	Comment similar to Partridge, Snow & Hahn. Also suggested that relocation to §2.5 would be appropriate.
United Healthcare	§5.2(a)	Replace "hold confidential health care information" with "hold **or access** confidential health care information" at the end of the second sentence
United Healthcare	§5.2(b)(4)(i)	Add "**and report results publicly**" at the end of the subsection.
Damale	§7.2	These penalties are onerous and should be clear to all participants before signing on to the HIE. I assume this would not apply to honest oversights? It does say knowingly and intentionally.

Ms. Zimmerman indicated that all of the comments received related to these regulations will be reviewed with staff. There will be another community review scheduled as the next step in the rule-making process.

The meeting adjourned at 2:00 p.m.

Respectfully submitted,

M. Elizabeth Shelov, MPH, MSSW
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Division of Environmental and Health Services Regulation
November 19, 2008