



Meeting #2

Date: November 8, 2016 9:00 AM

Location: School of Public Health, 1 University Place, Rensselaer NY 12144

Attendees:



PC Workgroup
Attendance_11.8.16.xl

Overview

This was the second meeting of the Value Based Payment (VBP) Patient Confidentiality workgroup. The purpose of meeting #2 was to discuss technical and data sharing issues related to patient confidentiality in a VBP context.

The Agenda for this meeting included:

1. Welcome and Introductions
2. Patient Confidentiality Rules and Regulations
3. Patient Confidentiality Relevant Consent Forms
4. Patient Confidentiality Issues and Considerations
5. Development of Draft Recommendations

Key Discussion Points (reference the slide deck “110716 Patient Confidentiality Workgroup Presentation”)

1. Welcome and Introductions

The Patient Confidentiality workgroup co-chairs and DOH sponsor opened the meeting with a roundtable introduction of participants as well as a high-level discussion concerning the goals of the meeting. The overarching goal would be to develop recommendations around rules and regulations governing patient confidentiality in regards to data sharing for the purposes of VBP.

2. Patient Confidentiality Rules and Regulations

The meeting began with an overview of federal and state regulations relating to patient confidentiality. Also addressed were the categorical difference between state and federal law, and general and special circumstances.

Regarding federal law, the policy goals and regulatory background of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) were described. Particular attention was given to the exception to HIPAA's general rule allowing for data dissemination to the minimal extent required to permit the treatment, payment and execution of healthcare operations.

Regarding state laws, a distinction was drawn between laws that apply to patient confidentiality more generally, agnostic of any special circumstances, and those which address patient confidentiality more narrowly within the context of special circumstances. Regarding generally applicable laws, Public Health Law (PHL) § 18 and Education Law § 6530 were addressed. It was agreed that both PHL § 18 and Education law § 6530 had the potential to be interpreted more narrowly than HIPAA.



Regarding PHL § 18, the workgroup discussed the law's policy and regulatory background. The group agreed that PHL § 18 requires written patient authorization for information sharing that is narrower than HIPAA, but it had the potential to be interpreted more broadly. However, PHL § 18 was still pending judicial interpretation. Regarding Education Law § 6530, the workgroup discussed the law's policy and regulatory background. Education Law § 6530 relates to professional misconduct as a result of the unauthorized dissemination of protected health information (PHI). The group agreed that both laws are implemented per DOH interpretation but more clarity from DOH would be useful. The group agreed that ultimately these regulations could be interpreted in a manner to align with HIPAA if the workgroup choose to make that a direct recommendation.

Regarding special circumstances, PHL § 2782, NYS Mental Hygiene law § 33.13, NYS Mental Hygiene Law § 22.05, and PHL § 17 were addressed. The policy and regulatory background of each was discussed. Regarding the disclosure of HIV information (NYS Public Health Law § 2782), it was agreed that DOH has interpreted this law to its broadest allowance.

The workgroup discussed particulars regarding the sequence of consent. While agreed that consent is not required for the health information exchange (HIE) connection itself, once HIV information is made available to the HIE, consent is required in the form of a Business Associate Agreement (BAA) to access this information. Similarly, regarding mental health, it was noted that the NYS Office of Mental Health (OMH) is currently working on an interpretation of NYS Mental Hygiene Law § 33.13 to include Performing Provider Systems (PPS).

The discussion turned to care management. Specifically, the group raised the issue of how a care management agency would be able to disseminate information. The current interpretation in this area is narrow. The group's consensus was that if these entities could not disseminate information, conducting the activities that are part of a highly integrated system or VBP environment would be difficult.

Next discussed was the Federal Medicaid confidentiality rule (§1902(a)(7) of the Social Security Act (42 USC §1396a(a)(7)). The group agreed that the Federal Medicaid confidentiality rule applies only to state-originated data. The group noted that through this federal law, only Medicaid professionals may use and disclose state-originated data. The group further noted that state-originated data must be used exclusively for the administration of the Medicaid program. The Social Security Act of 1972 defines what "administration" is in this context. It was also agreed that that the HIPAA rule and the Medicaid Confidentiality rule must be satisfied simultaneously where the data at issue are both state-originated data and contain personally identifiable health information. To the extent to which a mainstream managed care organization is sharing information directly through a RHIO for a PPS arrangement, it was agreed that generally such action does not concern state-originated data and falls outside of the scope of the Federal Medicaid confidentiality rule. For DSRIP, it was agreed that the Medicaid Rule was addressed with the DSRIP opt-out consent process.

The group also defined "health data" as the 18 elements of personally identifiable information (PII) outlined through HIPAA when associated with medical data (the "substance" of the medical record). These 18 elements include names, social security numbers (SSN), medical record numbers (MRN), account numbers, license numbers, vehicle identifier numbers (VINs), device identifiers, biometric identifiers, and full face photographic images.

The workgroup discussed what level of information sharing is possible without consent. Ultimately, consent will always be necessary for PHI related to substance use disorders 42 USC § 290dd-2 (Part 2 data). It was agreed that the current legal interpretation posits that Part 2 data cannot be shared for the purposes of analytics solely. This point is important for prioritization of care coordination efforts within a VBP model. Ultimately in the forthcoming recommendations, this workgroup must accommodate the most restrictive rule and/or create an exception to allow for necessary data sharing.



3. Patient Confidentiality Relevant Consent Forms

The Medicaid Consent form is a broader form of consent documentation that takes into consideration special circumstances. The group discussed that DOH legal could interpret its coverage more broadly and maintain alignment with HIPAA. Therefore, it was agreed that if DOH legal took a broad interpretation of the Medicaid Consent form it would facilitate dissemination of PHI in a manner supportive of the VBP effort if no other laws conflicted with the legality and coverage of the Medicaid Consent form.

Regarding the relationship of PHLs § 17 and § 18 to the Medicaid Consent form: It was generally agreed that DOH has interpreted PHL § 17 to mean that additional consents, beyond the Medicaid Consent form, must be in place to specifically identify the party receiving information. This would require additional consents beyond the Medicaid Consent form. It was noted that by achieving consent at the time of enrollment, there is an implication that at a minimum, PHL § 18 was fulfilled. However, it was noted that PHL § 18 also stipulates that when information is shared, those consents – either written or oral – specific to the information being shared must be placed in the patient's chart.

Ultimately, it was agreed that there is a general lack of clarity concerning the legality of sharing data between providers and the interplay between the Medicaid Consent form and PHLs § 17 and § 18.

4. Patient Confidentiality Issues and Considerations

A logic flow was presented concerning the broader options for disseminating data, including the particularities and existing interpretations of each consent form and applicable regulation. It was agreed that the Medicaid Consent form would cover almost all circumstances with a broad interpretation within the confines of HIPAA and for PHI related to substance use disorders 42 USC § 290dd-2 (Part 2 data). However, it was agreed that in most instances, parties default to the most conservative interpretation which limits disclosure of information necessary for VBP purposes.




HIPAA related issues also pose particular challenges. HIPAA limits the disclosure of that data because to be HIPAA compliant, entities must have a direct relationship with the patient (past or present), must only disclose the minimum necessary information, and must not disclose data for healthcare operational purposes that would otherwise be required by the VBP system beyond HIPAA's exception for treatment, payment and health operations. A BAA can help to bridge the gap in these specific instances. However, it was agreed that a BAA cannot always be put into place. Ultimately, it was agreed that a novel statute needs to be created for the purposes of SHIN-NY/RHIO and for care coordination.

The workgroup discussed the expiration of data. Currently, consent contemplates no expiration of data. Instead, individuals must actively change consent status. The group discussed requesting further DOH legal interpretations of the state laws and regulations of interest, and ultimately decided to pursue the potential for reinterpretation as well as developing alternative recommendations. Workgroup members requested specific guidance on the limitations on the release of data to other parties as well as receipt of data, along with options within each of those two categories. The group also requested a list of limitations so that end users could be made more comfortable with data sharing integral to VBP.

5. Development of Draft Recommendations

The group began a discussion of creating draft recommendations to facilitate data sharing within existing and/or updated patient confidentiality provisions. Fully vetted recommendations will follow this meeting.

Materials distributed during the meeting:

Document	Description
<p>VBP Patient Confidentiality Issue Brief</p>  <p>Patient Confidentiality Workg</p>	<p>This document details the high level policy questions related to patient confidentiality.</p>
<p>Patient Confidentiality Workgroup – Meeting #2</p>  <p>110716 Patient Confidentiality Workg</p>	<p>A presentation deck of policy questions and options for consideration as it relates to VBP patient confidentiality.</p>
<p>Patient Confidentiality Supplemental Materials</p>  <p>Patient Confidentiality Workg</p>	<p>This document includes links to relevant consent forms and regulatory background.</p>

Key Decisions

The Workgroup made decisions on the following key points during meeting #2:

- ✓ Further develop draft recommendations advanced during the meeting
- ✓ Request that DOH revisit their interpretations of state law in regards to patient confidentiality

Action Items:

- Further investigation on the Medicaid Confidentiality Rule including to gain clarity regarding whether the rule only pertains to data originating from the state.
- Provide a synopsis on state versus non-state originated data for the purposes of understanding the application of the Medicaid Confidentiality Rule.

Conclusion

The next workgroup meeting will be held in Albany on Tuesday, November 22, 2016 and will include:

- 1) Finalizing data sharing recommendations
- 2) A discussion of non-data sharing issues, including vital statistics