# Consent Implementation Subcommittee

## Summary Progress Report

**January 25, 2012**

**Workgroup Staff:** Carol Robinson, Kahreen Tebeau, Chelsea Hollingsworth, Ronit Zusman, Chris Coughlin, Mindy Montgomery
**Report Prepared by:** Kahreen Tebeau and Ronit Zusman
**Meeting Date:** January 25, 2012
**Primary Meeting Focus:** Various models of HIE and the opt-out consent policy and implementation
**Panel Members Present:** Bob Thomson, Tim Timmons, Anne Greer, Gwen Dayton, Dr. Ronald Marcum, Lynne Shoemaker; **Via Phone**: Jerry Cohen, Glendora Raby, Chas Horner, Scott Seibert
**Panel Members Absent:** Shawn Messick, Dr. Thomas Yackel, Jason McNichol
**Other Attendees**: Shannon O'Fallon

**Progress Status Summary:** Members received a presentation on the four most prominent models of electronic health information exchange (HIE) currently in use, and discussed and further developed recommendations for HITOC on how to implement the opt-out consent policy for HIE.

**Discussion Highlights:**

- **Shared Understanding of Recommendations**
  - In response to a question presented by a member of the Subcommittee, members were informed that they are not required to reach a consensus; rather the goal is to have a shared understanding of what staff will present to HITOC pertaining to their recommendations.
- **Four Models of HIE**:
  - The Subcommittee received a presentation on the four main models of HIE currently in use.
  - Clarification and distinctions were made between application service provider (ASP) models , where an outside entity stores data for only one covered entity but does not aggregate it from multiple sources, and the centralized HIE model, where an outside entity stores data from multiple sources and makes it accessible to multiple entities.
  - The traditional legal principles of property ownership are not clear or necessarily applicable when it comes to the ownership of protected health data; it may be more helpful to think of it in terms of rights and responsibilities.
  - Questions were raised about the Publish/Subscribe model, such as whether it can be verified that a provider's system received the notifications. It was noted that there are different ways to configure and implement a Publish/Subscribe model and the details would depend on how it is configured and implemented. It was also noted that this model will become more widely used as more providers adopt and use mobile technology devices such as smartphones.
- **Implementing Opt-Out for HIE**
  - The Subcommittee members discussed the issue of control over access to data. It was noted that after any disclosure, whether it be to another covered entity or to a business associate such as an HIO, the disclosing provider no longer has control over re-disclosure. More clarification and definition on what was intended by the ONC's Privacy and Security Tiger Team recommendations on consent was needed by the Subcommittee to move forward, and much of the discussion focused on clarifying these concepts, including the concept of "control."

- **Consensus to Date on Opt-Out Recommendations:**
    - The Consent Implementation Subcommittee generally supported the following policy, but questions remain:
        - *Opt-out opportunity:*
        *If protected health information is disclosed into a queryable database managed/owned by a third party, which aggregates data on patients from multiple sources and makes that aggregate data available to multiple entities, then patients should be given the opportunity to opt-out of having their data disclosed into the database.*
        *The opportunity to opt-out would not apply to the disclosure of protected health information for the purposes of payment, public health reporting, health care operations, or any disclosure required by law.*

    - The question that remains is what would or should happen if the queryable database in question is used for both treatment and one or more other purposes for which the opt-out opportunity would not apply (payment, health care operations, etc.). There were questions and discussion about whether, for example, CCOs might combine patient data in a database that could be used for the purposes of treatment, payment, and quality improvement/healthcare operations. The question of mixed database use and its implications for opting-out will be discussed at the next meeting.

**Meeting Outcomes:**

- The Consent Implementation Subcommittee achieved a shared understanding of the timeline under which they are operating, consensus to date on the opt-out recommendation, and outstanding questions (see below).

**Next Steps:**

- **Timeline**: The Consent Implementation Subcommittee will reconvene in March 2012 after the legislative session is complete and all stakeholders have had adequate time to evaluate the finalized CCO legislation.
- **Outstanding questions to be addressed by the Subcommittee in their next meeting include**: The question of mixed database use (including within a CCO environment) and its implications for opting-out; the mechanisms/tools for providing notification to patients and for patients to opt-out; who should be responsible for informing patients and providing opportunity to opt-out; whether notification/opportunity to opt-out should be renewed and if so, how often. Additional questions may also be identified moving forward.
- **Challenges/Opportunities:** The Subcommittee noted the difficulty in developing a consent implementation policy that would be supportive of CCOs without knowing more about the structure of CCOs, and requested that information about CCOs be provided to them at their next meeting.

**Other Workgroup Interdependencies:** Nothing at this time.

**Public Comment:** Nothing at this meeting.

**Out of Scope, But Needs Attention:** Nothing at this time.

**Recommendations to HITOC:** Nothing at this time.