

Advisory Committee on Genetic Privacy and Research

Meeting Minutes — August 3, 2005

Attendees:

Emily Harris (co-chair), Betsy Earls, Gayle Woods, Jane Van Ness, Delores Empey, Marc Morenco, Stuart Kaplan, Robert Nystrom, Kara Manning, Theodore Falk, Rita Aikins, Patricia Backlar, Michael Garland, Julie Koch, Ron Marcum, Staci Coy, Molly Burns-Hermann, Kiley Ariail, Summer Street, and Naomi Adams.

Welcome and Introduction

- Everyone introduced himself or herself.
- Summer Street announced that she has started working on a bibliography. She brought copies for the group to see.
- July minutes were not reviewed but will be sent out via email for approval.

Outcome:

Suggested changes to the July meeting minutes will be sent to Naomi Adams (naomi.adams@state.or.us or 971-673-0242).

SB 1025 B Engrossed Administrative Rules

The Governor signed Senate Bill 1025 B Engrossed on July 29, 2005.

Kiley she shared with the committee a timeline for implementing the rules that will become effective January 2, 2006. Both Emily and Kiley think the best scenario is to change the deadline for a complete draft of the rules from November 1, as shown on the timeline, to October 1. This is to ensure so there will be adequate time for a public hearing during the month of December before the implementation deadline in January. Because October 7 is only 7 or 8 weeks away, there will be a need for committee members and interested parties to work on the rules in between meetings. Volunteers were requested and asked to contact Kiley who will schedule some work group meetings.

The group was reminded that DHS is ultimately responsible for the rules and the ACGPR is simply acting in an advisory capacity.

The committee then discussed how the administrative rules should be written and what should be included with much emphasis on the notice requirement.

Overall, members and guests expressed a great deal of concern about the rules, stressing the need for flexibility, clarity, completeness, and ease of interpretation. Many specific issues were raised, including:

- Ensuring an opt-out request follows an individual from one institution to another
- Not placing all the burden of responsibility on institutions, but expecting that individuals will bear some of the responsibility for the implementation of their own wishes regarding opt-out
- Ensuring that the rules are consistent with statute and existing rules
- Protection of the rights and wishes of incompetent or incapacitated persons
- Circumstances involving emergency notification and death
- Clarification of who must receive notification, especially in cases of families, subscriber units, and minors
- Whether to require that the notification be included in HIPAA notice of privacy practices
- Issues surrounding tracking and documentation of notification and opt-out, especially in instances where medical records are not maintained for outpatients.
- The obligations of direct vs. indirect providers
- Whether biological specimens and sources of clinical individually identifiable health information will be labeled with opt-out preferences.

The Committee discussed developing model forms or a DHS informational website, and how DHS could help with the educational needs of institutions.

Kiley will collect committee feedback by e-mail, to address whether all the issues have been identified. Particular emphasis should be paid to issues the rules should address rather than questions of implementation. Working groups will then address the listed issues

The rule making process requires collecting public testimony on proposed rules. It was suggested that collecting input before public hearing might save time. Ted Falk suggested reaching out to a list serve that HIPAA experts read to gather this input. Various other ways of contacting stakeholders were suggested, including the Oregon Medical Association, caseworkers, Pharmacists, ambulatory surgery centers, and the South West Washington and Oregon HIPAA Forum, and private practice physicians.

Workgroup volunteers were requested. The committee suggested two working groups: one for notification and opt-out rules, and one for research-related rules. Kara Manning volunteered for the research rules group. Julie Koch and Stacy Coy both volunteered for the Notification group. Ron Marcum said he would be comfortable in either group.

Ted Falk volunteered to review the existing rules and see what will need to be changed.

Emily, Naomi or Kiley will send out a message with potential meeting times. There will be at least two meetings before the September regular meeting.

Outcomes:

- 1. Feedback will be sought from members and guests. An e-mail will be distributed asking what questions or issues the rules need to address. Responders will avoid addressing implementation issues.**
- 2. Kiley will consider seeking feedback from a HIPAA listserve.**
- 3. Small Work Groups form in August: A notification group, and a research rules group. Volunteers as indicated above.**
- 4. Ted Falk will review the existing administrative rules for needed changes.**
- 5. Emily, Naomi or Kiley will schedule working groups.**

Adjourn

Next Meeting September 7th, 2005

First Wednesday of each month

1:00 to 3:00 p.m.

Oregon Medical Association

5210 S.W. Corbett Avenue in Portland