

Advisory Committee on Genetic Privacy and Research

Meeting Minutes — October 6, 2004

Attendees

Emily Harris (Co-Chairperson), Gwen Dayton (Co-Chairperson), Barry Anderson, Kara Manning, Dolores Empey, Gayle Woods, Kate Oetzel, Rebecca Burdg, Kim Wirtz, Pam Lally, Diane Priebe, Bob Koler, Ted Falk, Kara Manning, Greg Fowler, Desiree Hollemon, Patricia Backlar, Jon Zonana, Michael Garland, Laura Zukowski

Introduction and Announcements

- Welcome and Introductions — Everyone introduced himself or herself.
- Review of Draft Minutes from Last Meeting (September 1, 2004)
Draft minutes from September 1, 2004, had been circulated in the e-mail prior to this meeting. No one present had any requests for corrections or additions.
Outcome: Co-Chair Emily Harris directed that the minutes from September 1 were approved with the understanding that they may be corrected. Contact Laura Zukowski (laura.a.zukowski@state.or.us or 503-731-4021) if you would like to request changes.

Update: Public Input Survey

Barry Anderson presented results from Geneforum's public input survey on genetic privacy. He passed out copies of a written analysis and discussed some of the key findings. Among the key points of his presentation were the following.

- More respondents "strongly agreed" that they were concerned about genetic privacy for its own sake than were concerned about potential discrimination based on their genetic information (60% versus 39%). Among respondents without health insurance, concern about potential discrimination based on genetic information was higher than among those with health insurance.
- The majority of respondents did not indicate greater concern for the privacy of genetic information versus other types of medical information (88% versus 12%). The more knowledgeable about genetics, the less likely the respondent was to express greater concern for genetic information versus other medical information.
- Respondents expressed greater concern regarding loss of privacy when their tissue samples were used for genetic research versus for other kinds of research (71% versus 29%). They also expressed greater concern about genetic privacy regarding the use of tissue than about the privacy of their genetic information.
- When respondents rated the importance of protections for various types of information (three different non-genetic diagnoses and the fact of having sought genetic counseling), they did not express more concern over protecting the fact of having sought genetic counseling. Concern over the privacy of a diagnosis of HIV

infection was greater than concern over the privacy of having sought genetic counseling.

- Respondents expressed more concern about information from a genetic test than about family history. Those respondents who knew about Oregon genetic privacy laws were less likely to express more concern over genetic test results than about family history.
- Respondents expressed greater concern over privacy of genetic information with regard to health insurance versus disability or life insurance.

Outcome 1: Laura Zukowski will e-mail the public input survey reports to the committee and interested parties.

Outcome 2: Everyone should read the public input survey reports and bring back any questions or comments to the November 3 meeting.

Potential Amendments to DHS Legislation

Gwen Dayton led this lengthy section of the meeting. Five guests from Kaiser Foundation Health Plan of the Northwest and Regence Blue Cross/Blue Shield of Oregon presented information about what comprises “health care operations” in their organizations. Member Gayle Woods also presented information about existing restrictions in the insurance code. Discussion was woven throughout these presentations. The purpose of the presentations and the discussions was to lead members to an understanding of the meaning of “health care operations” and to come to an agreement of whether or not these “health care operations” should be included in the carve-out for all health insurers, along with treatment and payment activities.

Dolores Empey (Privacy Officer), Kate Oetzel (Quality Resource Manager for Ambulatory Care and Networks), and Rebecca Burdg (Quality Resource Manager for Credentials) discussed health care operations of Kaiser Foundation Health Plan of the Northwest, which is part of an Organized Health Care Arrangement (OHCA) organized under HIPAA. The OHCA designation allows the integration of activities between what are normally separate covered entities under HIPAA. Kaiser “integrates” the functions of these entities, and, as an OHCA, has fewer preliminary steps with which it must comply before members’ personal health information may “flow” between the provider, hospital, and insurer entities within the arrangement.

The Kaiser representatives emphasized that employees within their organization have access to health information on a “need to know” basis only and are bound by confidentiality agreements. Much of the exchanged health information is deidentified or compiled in aggregate. Kaiser employees access information through the electronic medical record system, and the various entities within Kaiser have access to different information fields. Health care operations in the OHCA include quality assessment and improvement; provider review, credentialing, etc.; underwriting and related activities; medical review, legal services, audits, etc.; business planning and development, business management and administration activities, such as customer service, internal grievance resolution, fundraising, etc.

Kim Wirtz, Pam Lally, and Diane Priebe discussed health care operations of Regence Blue Cross/Blue Shield (Regence BC/BS), which is a health insurance underwriter. This organization is a covered entity (“health plan”) under HIPAA, whose main business is paying claims under group health plans for employees and individual health plans. The representatives reported limited access and other systems protections around personal health information and stated that the Regence BC/BS does receive information from providers to process claims, which may include genetic information.

In response to questions from members regarding information included in preauthorization requests, the representatives stated that Regence BC/BS does not request genetic information for preauthorization for treatment or testing and does not see the results of genetic tests for which it pays claims. CPT codes used for genetic testing are reported to be generic. Requests for preauthorization for BRCA 1 & 2 testing or prophylactic oophorectomy and /or mastectomy (with positive result of BRCA 1 & 2 testing) would be documented in a preauthorization file. No results of the testing would be in the file, and access to this stored information is limited.

Gayle Woods from the Insurance Division reported that she had reviewed the insurance code and administrative rules, along with the Oregon Standard Health Statement that is used by individual policy health insurance applicants. She distributed copies of all these documents. For group policy applicants, health insurers may look at individual information for late enrollees only. For applicants of individual policies, insurers may only request information for any “yes” answers on the Oregon Standard Health Statement, although the insurer may look at any and all information that is sent from a physician (never another health insurer), even information that is sent in error.

Outcome 1: Gayle Woods will follow up on the issue of the breadth of question 52.a. on the proposed replacement for the Oregon Standard Health Statement. She will share members’ concerns with Lewis Littlehales of the Oregon Insurance Division. This question, as written on the proposed form, would require an applicant to report any “medical advice, diagnosis, care, or treatment” within the last five years, which would include genetic services.

Outcome 2: The committee members agreed to request amendment of LC 298 to include Health Care Service Contractors. In addition, members decided to maintain LC 298’s carve-out for health care operations, in addition to treatment and payment activities, for both medical providers and health insurers.

Outcome 3: Dolores Empey, the Kaiser Privacy Officer, invited the committee to contact her with any additional requests for information or clarification. Her phone number is (503) 813-4804.

Use of Genetic and Family History Information

There was a brief discussion as to whether there are adequate protections against using genetic and family history information in insurance underwriting and employment. Insurance underwriters may use an individual’s medical history for individual health policies, but no insurers (of any type) may consider family history in underwriting. The

seeking of genetic counseling does not appear to be addressed at all in any of the genetic privacy statutes, whether for insurance underwriting or for employment.

Outcome 1: *The committee will continue to discuss the use of genetic and family history information at the November 3 meeting. The following questions will guide the discussion: Is there truly a barrier for the seeking of genetic services or the full disclosure of family history, or is consumer perception the barrier? Does the current law protect from discrimination in insurance underwriting those individuals who seek genetic counseling? Does the current law address protection against discrimination in employment? Should the law protect the seeking of genetic counseling or testing?*

Outcome 2: *Gwen Dayton will review the employment code in terms of protection against discrimination based on genetic and family history information.*

Outcome 3: *Emily Harris will ask Gayle Woods to address the question, “Does the current law protect from discrimination in insurance underwriting those individuals who seek genetic counseling?” at the November 3 meeting.*

Update: Research Subcommittee

Emily Harris shared a handout that she wrote with input from Kara Manning. The handout compares Oregon’s consent requirements for genetic research to HIPAA’s authorization requirements for medical research by a covered entity. (HIPAA does not address genetic research specifically.) There are differences in the requirements under the two laws, specifically in relation to Oregon’s opt-out clause and for use of historical samples.

Without Oregon’s genetic privacy regulations, genetic researchers who do not receive federal funding and are not covered entities would be subject only to FDA review. There is concern that these types of researchers are increasingly common, especially among drug companies.

If the committee were to decide to pursue research legislation, it would be separate from the legislative concept on genetic and family history information and the legislative concept on medical providers and insurers. Timing and sponsorship could be an issue as well, although expanding economic opportunity for research in Oregon could be a selling point. Another consideration is that restricting use of genetic and family history information in the same legislative session could also help sell the legislation for loosening restrictions on researchers.

Outcome 1: *This committee will continue to discuss authorization and consent requirements for genetic research at the November 3 meeting. More input is needed from members who were not present today or who already had left the meeting.*

Outcome 2: *Emily Harris will send Carol Pratt an electronic copy of the document she brought to this meeting and ask for input, especially regarding tissue banking. Emily will also send Laura Zukowski an electronic copy for distribution to the committee and interested parties.*

Outcome 3: Patricia Backlar will send Laura Zukowski an electronic copy of an article on HIPAA and research to e-mail to the committee and interested parties.

Report to the 73rd Legislature: Strategy and Timeline

Outcome 1: Gwen Dayton and Emily Harris will look at the 2003 Legislative Report and assign members to write each section.

Outcome 2: Writing the legislative report as an update or addendum to the last report is a possibility. There is general agreement to write a shorter report than what was written for the 2003 Legislature.

Meeting Schedule

November 3, 2004	January 5, 2005	July 6, 2005
December 1, 2004	February 2, 2005	August 3, 2005
	March 2, 2005	September 7, 2005
	April 6, 2005	October 5, 2005
	May 4, 2005	November 2, 2005
	June 1, 2005	December 7, 2005

First Wednesday of each month
1:00 to 3:00 p.m.
Oregon Medical Association
5210 S.W. Corbett Avenue in Portland