

Advisory Committee on Genetic Privacy and Research

Meeting Minutes — April 7, 2004

Attendees

Gwen Dayton (Co-Chairperson), Emily Harris (Co-Chairperson), Rita Aikins, Marc Marengo, Carol Pratt, Bob Koler, Patricia Backlar, Nan Newell, Robb Moses, Kiley Ariail, Ted Falk, Jon Zonana, Michael Garland, Astrid Newell, Andrea Meyer, Margaret Everett, Laura Zukowski

Introduction

- Welcome and Introductions — Everyone introduced himself or herself.
- There was a round of applause to thank Astrid Newell for her years of service with this committee. She is moving to northern Washington with her family, and so today's meeting will be her last. The committee acknowledged and thanked her for her contribution, especially for the two years she served as co-chairperson.
- Review of Draft Minutes from Last Meeting (March 3, 2004)
Draft minutes from March 3, 2004, had been circulated in the e-mail prior to this meeting. No one present had any requests for corrections or additions.

Outcome: *Gwen Dayton moved that the draft minutes of March 3, 2004, be approved. Carol Pratt seconded the motion. The minutes were approved with the provision that they could still be corrected. Direct comments and/or corrections to Laura Zukowski, laura.a.zukowski@state.or.us or (503) 731-4021.*

Opening Question — Oregon's Genetic Privacy Law: Is It Still the Right Thing?

Presentations: Current Legal Context

- Clinical Genetic Information — Gwen Dayton gave an overview of Oregon genetic information disclosure laws and HIPAA regulations that regulate the clinical setting. She talked about what a clinical provider in Oregon is required to do and not to do, and compared where state and federal laws are different.

In comparison to HIPAA, Oregon law is not always stricter, addresses different situations, covers different entities, and differs in terminology. HIPAA addresses the use and disclosure of personal health information by covered entities and does not address genetic information separately. It requires patient authorization for use and disclosure of personal health information, but exempts covered entities (health plans, providers, healthcare clearinghouses) from authorization requirements in situations of treatment, payment, and routine healthcare operations. Specific exceptions are made for coroners, funeral home workers, law enforcement, and court orders. Unlawful

disclosures made in good faith are still considered violations. Redisclosure is addressed only when it concerns redisclosure by a covered entity or a covered entity's business associate, and is not restricted.

Oregon genetic privacy law differs in many ways. It addresses genetic information specifically, that is, separately from other medical information; requires consent before genetic information can be obtained; requires authorization for use and disclosure of genetic information. (Certain situations, which include criminal investigation, court order, paternity testing, medical diagnosis of family members of a decedent, and identification of a dead body, are exempted from requirements for consent and authorization.) The law addresses genetic information of everyone in Oregon and does not apply only to the covered entities defined under HIPAA. It also applies to both the abstract object (genetic information) and the object (the DNA sample). Unlawful disclosures made in good faith do not violate the state statute.

HIPAA does not: address genetic information specifically; address the concept of consent or informed consent; address obtaining or retaining genetic information; cover non-health insurance companies, schools, employers, adoption agencies, etc. Areas for the committee to consider special protections include: family history; routine collection of DNA for an expanded number of criminal offenses; privacy; potential discrimination; proliferation of databases.

- Genetic Research — Carol Pratt compared HIPAA and Oregon genetic privacy law protections for genetic research. She reminded everyone that any use or disclosure of personal health information is subject to Oregon law, federal Common Rule, and federal HIPAA regulations.

HIPAA does not distinguish between genetic information and other health information, does not protect DNA samples specifically, only applies to individually identifiable health information that is received or maintained by a covered entity or a covered entity's business associate, and offers less protection for decedents as compared to the living. Oregon law addresses genetic research specifically and refers to genetic information in the context of obtaining or retaining genetic information, and recontacting research subjects; HIPAA applies broadly to health research and addresses use and disclosure by covered entities and their business associates.

The Oregon genetic privacy law distinguishes between these types of data: identified; identifiable; deidentified; coded; unidentified; anonymous. In contrast, HIPAA refers to personal health information (identified or identifiable under Oregon law), limited data set (identifiable under Oregon law), deidentified (deidentified, coded, unidentified, or anonymous under Oregon law). Both laws refer to deidentified data, but Oregon genetic privacy law places an additional requirement that a data repository also must deidentify source data and also distinguishes between coded, unidentified, and anonymous data.

HIPAA does not address consent, but requires authorization to collect, analyze, and store personal health information (and tissue). Oregon law has detailed requirements around specific informed consent to participate in research (if genetic sample collected after June 12, 2003), blanket consent (if sample collected before June 25, 2001), and notification with choice to opt out of research.

In general, Oregon genetic privacy law is stricter than HIPAA in regards to genetic research, and therefore it regulates genetic research.

- Discrimination: What Protections Exist Outside Oregon Law? — Kiley Ariail summarized pending federal legislation and current federal protections against discrimination based on genetic information.

Current federal protections against discrimination include Executive Order 13145 (which prohibits genetic discrimination against federal employees in the federal workplace and includes family history, genetic test information, and information about request or receipt of genetic services), American with Disabilities Act — Title I (prohibits discrimination in any aspect of employment based on disability, but remains untested in relation to genetic conditions or information and is administered under the Equal Employment Opportunity Commission, which can only offer interpretation with no force of law), and Civil Rights Act — Title VII (prohibits discrimination in employment based on race, color, religion, gender, or national origin, but remains untested against genetic discrimination).

There are some additional protections under federal law against discrimination in group health insurance based on health status, which includes genetic information: an individual may not be excluded from group coverage based on past or present medical history (including genetic information) and an individual may not be required to pay a higher premium than other group health insurance participants. There are no federal protections against genetic discrimination regarding other types of insurance.

Pending federal legislation would prohibit employment discrimination based on genetic information (S 1053/Non-Discrimination Act of 2003, Title II). Specifically, employers would be prohibited from engaging in adverse employment actions on the basis of protected genetic information; requesting, requiring, collecting, or purchasing protected genetic information about employees, with limited exceptions; maintaining protected genetic information in general personnel files; disclosing protected genetic information about employees, except in limited circumstances. Violations under this proposed legislation would be available under Title VII of the Civil Rights Act.

Oregon law does prohibit employers from requiring genetic testing unless there is an occupational qualification and only with informed consent. Oregon law also restricts the use of genetic information in (health) insurance underwriting. Applicants for insurance may be asked to take a genetic test (purpose of test must be revealed and consent/authorization obtained), but genetic information may not be used to reject,

deny, limit, cancel, refuse renewal, increase rate, or affect any terms and conditions of a health insurance policy.

Outcome 1: Discussion framework for the future will be use and disclosure of genetic information within clinical and research settings, with special consideration of potential discrimination.

Outcome 2: Members also will use the alternate framework of covered entities versus non-covered entities.

Outcome 3: Members will keep in mind that the term “discrimination” may not be the correct concept or word.

Outcome 4: Clinical setting will be the focus of the May 5 meeting.

Process and Timeline for DHS-Sponsored Legislation

Astrid Newell reported that DHS has decided to move forward with the legislative concept she submitted to administration for changes to the current genetic privacy statute. The concept would:

- allow DHS to write administrative rules that would exempt Oregon clinicians from the requirement for authorization to retain genetic information or genetic samples for purposes of delivering or documenting clinical health care;
- allow disclosure of genetic information for the purpose of treatment, payment, or health care operations as allowable under federal rules for other protected health information.

Outcome 1: Laura Zukowski will redistribute the DHS legislative concept by e-mail.

Outcome 2: The committee will not decide at this point whether it wishes to endorse the DHS legislative concept. Discussions will continue as to whether genetic information should be treated differently from other medical information in the clinical setting and whether the prohibition should be maintained against disclosure of genetic information without authorization for purposes of treatment, payment, and routine healthcare operations.

Other Business

Trish Backlar announced that Portland State University is sponsoring a 2005 Spring Symposium, “Genetic Testing, Privacy, and Race.” It will be a free evening event and open to the general public. Troy Duster and others have committed to joining the event.

Outcome 1: Trish will e-mail more information.

Outcome 2: Planning is still underway. Suggestions are welcome. Please e-mail Trish directly, backlarp@pdx.edu.

Adjourn

2004 Meeting Schedule

May 5	September 1
June 2	October 6
July 7	November 3
August 4	December 1

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