

Advisory Committee on Genetic Privacy and Research

Work Session Minutes — June 4, 2003

Attendees

(Co-Chairpersons) Astrid Newell and Ted Falk, Bob Koler, Kara Manning, Marc Marengo, Trish Backlar, Kerry Silvey, Emily Harris, Gwen Dayton, Laura Zukowski

(Guests) Lauren Rhoades and Rita Aikins,

Welcome/Introductions

Two guests joined the meeting today: Lauren Rhoades, intern with the Oregon Association of Hospitals and Health Systems; Rita Aikins, Compliance Officer with Providence Health System.

Clarification of Terms

Consent — refers to giving permission for a procedure or for “invasion” or “use” of the body.

Authorization — applies to release of information and/or samples.

HIPAA — applies to the release of information within the health care industry only. Enrolled HB 2305 amends various Oregon statutes covering “health care providers” to be in compliance with new HIPAA regulations that took effect in April.

Oregon Revised Statute 192.531 to 192.549 (“Oregon’s genetic privacy law”) — applies to the release of information and/or samples; applies to everyone in the State of Oregon with certain defined exceptions; applies to the activities of obtaining, retaining, and disclosing genetic information and/or samples.

Forms Review/Revision/Development

- Consent for Obtaining/Retaining Genetic Materials
- Authorization to Disclose Genetic Materials
- Sample Statement Relating to Anonymous Genetic Research Opt-Out Provision

There was a lengthy discussion about procedures and forms for informed consent and authorization concerning genetic information. The discussion touched on many issues related to various laws (HIPAA, Oregon’s genetic privacy law, the newly enrolled HB 2305, multiple statutes covering medical providers, HIV privacy protections) and how these laws end up being implemented on an everyday basis in medical settings and in non-medical settings.

Some health care entities have contacted DHS staff and requested clarification around ongoing disclosures of genetic information, especially as they relate to payment, retention

of samples, and laboratory testing. There is concern that once a genetic diagnosis is in someone's medical record, it is nearly impossible and not always practical to remove that information when releasing medical records or during routine payment procedures by third party payers. In some situations, insurance companies are given on-line access to provider records, including genetic tests that have been done and results. Further complications to protecting genetic privacy include: the large and ever increasing number of genetic tests (and other tests that reveal underlying genetic conditions); the legal requirement that providers document all care; various quality improvement requirements to retain samples, such as accreditation reviews under JCAHO.

The discussion actually began with concerns that the forms referenced in OAR 333-025-0140 are neither compliant with the law or educational. These sample consent forms were compared to the authorization forms from enrolled HB 2305, which covers health care providers only. Customizing different forms to address the needs of various covered entities seems the most practical approach.

Writing the administrative rules for the newly enrolled SB 618 could provide an opportunity to clarify some of these issues.

Outcome: Astrid Newell will contact the Attorney General's office for written clarification on these two issues:

1) Does current law require medical providers who record genetic information in a patient's confidential medical record to have express written authorization of the patient or patient's representative? Does DHS have authority to make rules exempting medical providers from any requirement of such authorization? (retaining genetic information in medical records);

2) Does current law require medical providers who use or disclose genetic information for treatment, payment, and health care operations to have express written authorization of the patient or patient's representative? Does DHS have authority to make rules exempting medical providers from any requirement of such authorization? (disclosing genetic information for treatment, payment, and health care operations).

Educational Materials Development

- Genetic Privacy Fact Sheet
- Module for Clinicians
- Module for Researchers/IRBs
- Module for Social Service Agencies/Providers
- Web Page

The group agreed generally to customize various fact sheets about genetic privacy requirements and rights for different audiences.

Outcome 1: In the hope of influencing standards of care, rather than attempting to dictate rigid requirements for providers, the group will write into the administrative

rules that DHS develops educational materials from time to time and how to obtain them. These documents could be posted on the state website and/or published.

Outcome 2: The committee will consider redefining “genetic information” to be more inclusive of presymptomatic and asymptomatic condition.

Next Meeting — Full Committee

Wednesday, July 2

1:00 to 4:00 p.m.

Oregon Medical Association

5210 S.W. Corbett Avenue

Agenda:

- policy and forms
- development of educational materials and fact sheets

Future Full Committee Meetings

Wednesday, July 2

Wednesday, September 3

Wednesday, October 1

Wednesday, November 5

Wednesday, December 3

1:00 to 4:00 p.m.

Oregon Medical Association

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