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Background Brief on ...

Genetic Privacy

Oregon, like many other states, has adopted genetic privacy laws to protect the public from unknowing disclosure of genetic information (ORS 192.531 to 192.549). Oregon's genetic privacy statute was created prior to the federal Health Insurance Portability and Accountability Act (**HIPAA**) that provides basic disclosure protections for a patient's health information, including genetic information.

In Oregon, it is a Class A misdemeanor to unlawfully obtain, retain, or disclose genetic information (ORS 192.543). Oregon law also provides a civil cause of action against anyone who unlawfully obtains or discloses genetic information, with the right to obtain the greater of actual damages or set statutory damages that range from \$100 (for negligent violations) to \$250,000 (for knowing violations with intent to sell or use a person's genetic information for commercial purposes) (ORS 192.541).

Oregon law allows the use of genetic information without an individual's consent for:

- Identification of deceased persons;
- Establishment of paternity;
- Newborn screening;
- Medical diagnoses of blood relatives of a deceased person; and,
- Pursuant to a court order.

The law also requires that individuals be given the option to request their biological sample or health information not be used for anonymous or coded genetic research. Otherwise, these samples are available for genetic research under existing law. Additionally, Oregon law required the Oregon Health Authority (**OHA**) Public Health Division to adopt rules establishing minimum research standards for the collecting and testing of genetic information (ORS 192.547).

All genetic research using information and samples collected in Oregon, whether anonymous, coded, or identified, must be reviewed by an institutional review board that follows strict federal rules for human subject research (ORS 192.547).

Oregon law prohibits an employer from obtaining or using genetic information to discriminate against an employee or prospective employee. The law also prohibits insurance companies from using genetic information to price or decline individual policies (ORS 746.135).

History

The 1995 Legislative Assembly enacted Oregon's first genetic privacy law over concerns that the improper collection, retention, or disclosure of genetic information could cause significant harm to the individual, including stigmatization and discrimination in employment, education, health care and insurance. The 1995 law established genetic information as the property of the individual and, as such, required law enforcement, district attorneys, and researchers to obtain informed consent before collecting or using a person's genetic information. This particular provision caused problems for both law enforcement and medical research communities.

The 1999 Legislative Assembly modified Oregon's then-existing genetic privacy laws with the goal of balancing protections of patient confidentiality with the continuation of vital medical research in Oregon. Also, at the urging of Oregon Health and Science University (**OHSU**), the pharmaceutical research industry, and the Oregon Medical Association, the Legislative Assembly created the Genetic Research Advisory Committee (**GRAC**) to study the use and disclosure of genetic information and to report back to the 2001 Legislative Assembly.

Following GRAC review, the 2001 Legislative Assembly enacted Senate Bill 114. The most significant change deleted the provision that declared DNA to be the property of the individual and instead deemed that genetic

information is private and an individual has a right to protection of that privacy. In addition, Senate Bill 114 continued GRAC, renaming it the Advisory Committee on Genetic Privacy and Research (**ACGPR**), and charging it to study the use and disclosure of genetic information and to develop and refine a legal framework that defines the rights of individuals whose DNA samples are collected, stored, analyzed, and disclosed. Senate Bill 114 also imposed upon ACGPR the duty to report biennially to the Legislature.

Changes affecting the definitions and standards for coded and anonymous genetic research were made to the Oregon genetic privacy law during the 2003 Legislative Session through Senate Bill 618.

In 2005, ACGPR once again reported back to the Legislative Assembly and, at the urging of ACGPR, the Legislative Assembly enacted Senate Bill 1025 that established a set of limited conditions under which researchers could conduct anonymous or coded genetic research studies without seeking the prior written consent from contributors. A key component of this legislation was the need for a one-time notification of patients by health care providers. Patients must be informed of their right to decline the use of their health information or specimens in these types of genetic research studies.

In 2007, ACGPR's biennial report to the Legislative Assembly recommended one change to better align Oregon's genetic privacy statutes with HIPAA. Senate Bill 244 amended existing law to allow disclosure of genetic information for purposes of treatment, payment and health care operations without specific authorization. All HIPAA restrictions remain, and Oregon law prohibiting discriminatory use of genetic information remains in effect.

In 2009, no recommendations were included in ACGPR's biennial report to the Legislative Assembly. A new federal law had recently been enacted (the Genetic Information Nondiscrimination Act (**GINA**) discussed below) and ACGPR decided to review current

discussions at the national level to try and determine how to evaluate GINA's impact, if any, on Oregon's genetic privacy statutes.

In 2011, ACGPR's biennial report to the Legislative Assembly did not recommend any changes to Oregon's genetic privacy statutes, but emphasized the importance of identifying and reconciling any redundancies or inconsistencies between federal and state privacy laws.

HIPAA, GINA, and potential changes to other federal laws

HIPAA establishes a basic threshold for the protection of health care data. Health care data includes the genetic information of individual patients. These regulations set limitations on the release of health records and provide individuals with more control over their personal health information.

In May 2008, Congress passed GINA. The goal of the legislation is to establish a national and uniform basic standard to protect the public from genetic discrimination in health insurance and employment. The health insurance provision of the law took effect May 2009 and the employment provision in November 2009.

The federal government also regulates research involving human subjects conducted, supported, or otherwise regulated by any federal department or agency (pursuant to 56 FR 28003) (revised November 13, 2001). These regulations are known as the Common Rule due to their simultaneous adoption by a number of federal agencies. State laws may supplement or provide for greater protections. Senate Bill 114 (2001), discussed previously, made the Common Rule applicable to nonfederally funded research conducted in Oregon.

On July 26, 2011, the federal Department of Health and Human Services opened a comment period for an advance notice of proposed rulemaking with regard to the Common Rule, with significant changes designed to strengthen protections for human research subjects, including an opt-out for anonymous/coded research involving biological samples that is

very similar to Oregon's. If enacted, the proposed changes may make some or all of Oregon's genetic privacy protections with regard to research redundant.

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