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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 creates 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 up to \$250,000 for knowing violations committed with the intent to sell or use a person's DNA for commercial purposes (ORS 192.541).

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

- Identification of deceased individuals;
- Paternity;
- Newborn screening;
- Genetic information from a decedent for medical diagnoses of blood relatives; and
- 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 Department of Human Services (**DHS**) Public Health Division to adopt rules establishing minimum research standards for the collecting and testing of genetic information.

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.

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 lead to 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 obtaining genetic information from an individual. This particular provision caused problems for both the law enforcement and medical research communities.

The 1999 Legislative Assembly modified Oregon's then-existing genetic privacy laws with the goal of balancing the protection of patient confidentiality with the continuation of vital medical research in Oregon. Also, at the urging of Oregon Health & 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 the 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 of the subjects. 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 legislative change that better aligns Oregon genetic privacy statutes with federal medical information privacy statutes (HIPAA). Senate Bill 244 amended existing law to allow disclosure of genetic information for purposes of treatment, payment and healthcare operations without specific authorization. All HIPAA restrictions remain, and Oregon law prohibiting discriminatory use of genetic information remains in effect.

In 2009, ACGPR's biennial report to the Legislative Assembly did not make any legislative recommendations. Because the May 2008 federal Genetic Information Nondiscrimination Act (GINA) had recently

been enacted, the Committee instead decided to use the next biennium to review the current national discussion of genetic privacy and discuss a strategy to perform a thorough review of GINA's impact on Oregon's genetic privacy statutes and resolve any potential conflict or overlap.

Federal Law

The federal government regulates research involving human subjects conducted, supported, or otherwise regulated by any federal department or agency (56 FR 28003, revised November 13, 2001). These regulations, known as the Common Rule because 15 federal agencies adopted them simultaneously, apply to genetic research with human subjects. These regulations do not preempt state laws or regulations that provide additional protections for human subjects. In fact, as part of Senate Bill 114 (2001), the Legislative Assembly made the Common Rule applicable to non-federally funded research conducted in Oregon.

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 the Genetic Information Nondiscrimination Act (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.

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