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Privacy of Genetic Information: A Review of the Laws in the United States

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Abstract

This paper examines the privacy of genetic information and the laws in the United States designed to protect genetic privacy. While all 50 states have laws protecting the privacy of health information, there are many states that have additional laws that carve out additional protections specifically for genetic information. The majority of the individual states have enacted legislation to protect individuals from discrimination on the basis of genetic information, and most of this legislation also has provisions to protect the privacy of genetic information. On the Federal level, there has been no antidiscrimination or genetic privacy legislation. Secretary Donna Shalala of the Department of Health and Human Services has issued proposed regulations to protect the privacy of individually identifiable health information. These regulations encompass individually identifiable health information and do not make specific provisions for genetic information. The variety of laws regarding genetic privacy, some found in statutes to protect health information and some found in statutes to prevent genetic discrimination, presents challenges to those charged with administering and executing these laws.

Keywords:

Genetic; Privacy; States; Legislation

Introduction

On June 26, 2000, leaders of the public Human Genome Project and Celera Genomics Corporation announced that both had successfully completed the production of a working draft of the human genome. This historic milestone was announced with President Clinton at a White House event that included a satellite link to Prime Minster Tony Blair and genome leaders in the U.K. who contributed significantly to the public effort. While these advances and their application to medical practice have heightened public awareness of the positive impact of genetics research on human health, they have also raised concerns about who will have access to personal genetic information and how it will be used.

A wide variety of individuals and organizations may desire genetic information for use as a predictor of future illness, health care costs, or ability to perform a job. Family members, educational institutions, the courts, and others may also want access to genetic information.

To address these concerns, many states in the United States have enacted legislation to protect the privacy and confidentiality of genetic information and to protect individuals from discrimination on the basis of genetic information. To date, thirty-seven states have enacted legislation to prevent genetic discrimination by health insurers and twenty-four states have enacted legislation to prevent genetic discrimination by employers. While a few states limit their legislation to provisions prohibiting the use of genetic information, most legislation combines the prohibition of the use of genetic information with a privacy component that prohibits access to the information.

In addition to the states with statutes that specifically address genetic information privacy, each of the fifty states has a medical record confidentiality statute designed to offer privacy and confidentiality protection for medical information obtained in the course of health care delivery [1]. The level of protection afforded to medical information varies widely from state to state, but all state statutes are designed to provide access to medical records if authorized by the individual or as otherwise provided by law.

Discussion

State Legislative Activity

Legislative activity in the United States concerning genetic privacy has primarily revolved around the protection of individual genetic information relating to medical conditions that could negatively affect and encourage discrimination in health insurance and employment. There are specific histories behind each state's legislative activity, and states vary in the degree and manner in which genetic information is protected and defined. The following are a few examples of interesting components of state laws regarding genetic information[1].

Colorado, Oregon, Louisiana, and Florida define genetic information as personal property, although this is worded differently by each state [2]. Colorado provides that genetic information is the unique property of the individual. In Florida, the results of DNA analysis are the exclusive property of the individual. Louisiana provides that an insured's or enrollee's genetic information is the property of the individual. Oregon provides that an individual's genetic information and DNA sample are the property of the individual "except when the information or sample is used in anonymous research."

Nevada and New Mexico require the destruction of genetic information if requested by the person to whom the genetic information pertains unless retention is necessary for criminal investigation or authorized by court order [3]. New Mexico furthermore allows the retention of genetic information if authorized under a research protocol approved by an institutional review board. Nevada law does not specifically allow this, although it does permit the individual to whom the genetic information pertains to authorize the researchers to retain the genetic information after the study is completed or after the individual has withdrawn from the study. Nevada also explicitly requires the destruction of genetic information upon completion of the study or if the individual withdraws from the study.

Sixteen states issue either civil or criminal penalties for violating genetic privacy laws. California, for example, assesses a civil penalty or misdemeanor, depending on whether emotional, physical or bodily harm was done to the test subject by any person who willfully or negligently discloses genetic test results to any third party that reveals the identity of the test subject [4]. Illinois provides for right of action and damages for violations of the law [5]. Nevada permits any person who suffers an injury as a result of unlawful disclosure of information to bring civil action for the recovery of damages [6]. New Mexico provides for a civil action against violations of the law [7], and New York provides civil penalties for violations [8]. South Carolina provides that a violation of genetic privacy law is considered an unfair trade practice [9].

Four states—Delaware, Nevada, New Mexico and Oregon—have laws requiring individual access to personal genetic information [10].

Massachusetts recently signed into law a comprehensive act to maintain the privacy of genetic test results by: prohibiting the requirement or performance of a genetic test without informed consent of the individual to whom the test pertains; prohibiting disclosure of genetic information without the specific consent of the individual to whom the information pertains; and providing specific civil penalties for violations [11]. Massachusetts also has statutes prohibiting the requirement of genetic information results as a condition of employment or insurance and prohibiting insurers from discriminating on the basis of genetic test results [12].

Oregon has very comprehensive genetic privacy protections, requiring personal access to genetic information, informed consent for obtaining, retaining or disclosing genetic information, and defines both genetic information and DNA samples as personal property [13]. Oregon laws also provide specific penalties for violations.

Michigan recently enacted privacy laws that require physicians or others who wish to perform a genetic test on an individual to have the informed consent of that individual [14]. The individual or individual's legally authorized representative must have full understanding of the nature and purpose of the genetic test; the effectiveness and limitations of the test; the implications, including medical risks and benefits; the future uses of the samples taken; the meaning of the results; and who else will have access to the sample and information.

Missouri's privacy laws require that any genetic information held by any person "in the ordinary course of business, practice of a profession or rendering of a service" be considered part of an individual's confidential medical records [15]. The law furthermore prohibits the disclosure of genetic information unless written the individual to whom such information pertains grants authorization. However, these requirements do not apply to statistical health data that does not reveal the identity of individuals; health research conducted according to the Federal Common Rule[2]; information released for legal or regulatory processes; or information that is released for body identification purposes. While the law recognizes genetic information as a part of an individual's confidential medical records, it does not clarify whether or not the rules mandating the privacy of confidential medical records applies to genetic information as well.

Oklahoma, in addition to prohibiting disclosure of genetic information except under certain requirements, requires that all research records of individual subjects in genetics research studies be kept confidential and prohibits disclosure of such records to employers or health insurers without consent of the subject [16]. This, however, does not apply to insurers or third parties dealing with insurers in connection with the obtaining, maintaining, use, disclosure or redisclosure of genetic information. This law applies only to the genetic information maintained in a subject's research records and does not address genetic information that is used for direct medical or therapeutic uses.

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[1] For a comprehensive table listing all state genetic privacy laws, visit the National Conference of State Legislatures' Genetic Technologies Project, State Genetics Privacy Laws: http://www.ncsl.org/programs/employ/genetics/prt.htm

[2] 45 Code of Federal Regulations (CFR) 46 and 21 CFR 50 and 56.

Texas insurance code and civil statutes prohibit disclosure of genetic test results unless specifically authorized by the individual or individual's representative, and also require that a "sample of genetic material taken for a genetic test" be destroyed promptly after the purpose for which the sample was taken. However, certain restrictions apply, such as when the sample is retained by court order or when the sample was obtained for research that has been cleared by an institutional review board and needs to be retained [17].

Vermont law prohibits persons from being required to undergo genetic testing except in certain specific cases [18]. It furthermore requires individuals being tested to be informed that the results of the genetic test may become part of their individual permanent medical record. Vermont also prohibits the use of genetic information or the fact that genetic counseling or testing services were requested to affect the terms and conditions of employment.

Federal Legislative Activity

At the Federal level, Secretary Donna Shalala of the Department of Health and Human Services has proposed privacy regulations applicable to individually identifiable health information [19]. These proposed regulations are designed to encompass individually identifiable health information. These regulations will apply to health information regardless of the type of information and will include genetic information.

In February 2000, President Clinton signed an executive order that prohibits federal employers from requiring or requesting genetic tests as a condition of being hired or receiving benefits and it provides strong privacy protections for any genetic information used for medical treatment and research [20]. The Executive Order prohibits any federal employment department from requesting, requiring, collecting, or purchasing protected genetic information with respect to any employee, or information about a request for or the receipt of genetic services by such employee. The implications of the Executive Order are that genetic information will not be collected or used by Federal agencies.

Conclusion

The wide variety of laws, and sources of laws, presents a challenge to administer and to follow the pertinent law or laws. However, protection of genetic information is a major for the public. Rapid advances in genetics research and the emerging applications to medical practice have heightened public awareness and public concerns about who will have access to this information and how it will be used. Even with medical record privacy and confidentiality laws in place in each state, the possible loss of his or her genetic privacy can play a role in an individual's decision whether to undergo genetic testing. A Harris poll found that 86% of those surveyed were concerned that insurers and employers might use genetic information against them [21].

Those involved with maintaining and protection health information, i.e., health information management (HIM) professionals, face a daunting task of making sure they provide the protections afforded by their state laws and by the Federal government regulations. However, it is the responsibility of the HIM professional to not only be aware of state and federal laws and regulations to protect genetic information, but to insure that the release of information practices adhere to the letter and the spirit of the law. This is where HIM professionals interconnect expertise and ethical decision making to protect the privacy and confidentiality of patients. These ethical principles are true regardless of the type of medical information, but are particularly important when the medical information is potentially predictive, has implications for family members and may result in stigmatization and discrimination.

References

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[2] Colo. Rev. Stat. Ann. § 10-3-1104.7 (West 2000); Ore. Rev. Stat. § 659.715 (State of Oregon Legislative Counsel Committee 1999); Lsa. Rev. Stat. Ann. § 22:213.7 (West 2000); Fla. Stat. Ann. § 760.40 (West 2000).

[3] Nev. Rev. Stat. § 629.141 (Nevada Legislative Counsel Bureau 1999); New Mex. Stat. 1978, Ann. § 24-21-3 (Matthew Bender, Inc. 2000); Ore. Rev. Stat. § 659.705 (State of Oregon Legislative Counsel Committee 1999).

[4] Ann. Cal. Ins. Code § 10149.1 (West 1999).

[5] Ill. Comp. Stat. Ann. § 410:513/45 (West 2000).

[6] Nev. Rev. Stat. § 629.201 (Nevada Legislative Counsel Bureau 1999).

[7] New Mex. Stat. 1978, Ann. § 24-21-7 (Matthew Bender, Inc. 2000).

[8] New York Ann. Civ. Rts. Law § 79-l (McKinney 1997).

[9] Code of Law of South Carolina, 1976 Ann. § 38-93-50 (State of South Carolina 1999).

[10] Del. Code Ann. § 16:1223 (State of Delaware 1999); Nev. Rev. Stat. § 629.161 (Nevada Legislative

[11] Counsel Bureau 1999); New Mex. Stat. 1978, Ann. § 24-21-5 (Matthew Bender, Inc. 2000).

[12] Chapter 254 of the Acts of 2000, An Act Relative to Insurance and Genetic Testing and Privacy Protection (visited October 20, 2000 http://www.state.ma/us/legis/laws/seslaw00/s1000254.htm).

[13] Mass. Gen. Laws Ann.§ 151B (West 2000).

[14] Ore. Rev. Stat. § 659.700 to § 659.715 (State of Oregon Legislative Counsel Committee 1999).

[15] Mich. Comp. Law Ann. § 333.17020 & § 333.17520 (West 2000).

[16] Ann. Missouri Stat. § 375.1309 (Vernon 1999).

[17] Okl. Stat. Ann. § 36:3614.3 & § 36:3614.4 (West 2000).

[18] Ann. Texas Stat. Insurance Code § 21.73 (Vernon 1999); Ann. Texas Civ. Stat. § 9031 (Vernon 1999).

[19] Stat. Ann. § 18:9931 to § 18:9335 (Secretary of Statutory Revision Commission for the State of Vermont 1999).

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