

D R A F T

FOR DISCUSSION ONLY

MISUSE OF GENETIC INFORMATION IN EMPLOYMENT AND INSURANCE ACT

NATIONAL CONFERENCE OF COMMISSIONERS

ON UNIFORM LAWS

For Drafting Committee Meeting February 28 - March 1, 2008

WITH PREFATORY AND REPORTER'S NOTES

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ON UNIFORM LAWS

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February 12, 2008

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MISUSE OF GENETIC INFORMATION IN EMPLOYMENT AND INSURANCE ACT

Prefatory Note

The scientific developments in the field of genetics are often characterized as a “revolution.” This revolution is ushering in a new era of greater understanding of human biological processes and the promise of new approaches to medicine that can tailor medical treatments to individuals’ genetic traits. Genetic tests also offer the possibility of identifying individuals who are at risk of developing certain diseases in the future. Unfortunately, while risk information has the potential to improve preventative medicine, it is also subject to misunderstanding and misuse.

There are important policy issues concerning the appropriate form and scope of regulation of genetic information. Appropriate goals for regulation include that (1) individuals should not be coerced into having genetic tests; (2) individuals who want to be tested should not be discouraged through fear of how the results will be used; (3) genetic information should not be used for irrational discrimination, that is, where there is no scientific basis for discrimination; and (4) even “rational” discrimination should be prohibited when it violates public policy, including the policy of preventing discrimination on the basis of disability. Cynthia Nance, Paul Miller, & Mark Rothstein, *Discrimination in Employment on the Basis of Genetics*, 6 Employee Rights & Employment Policy Journal 57, 79 (2002). See also Henry T. Greely, *Genotype Discrimination: The Complex Case for Some Legislative Protection*, 149 U. Pa. L. Rev. 1483, 1500 (2001).

To encourage individuals to undergo testing that can lead to advances in genetics and improved medical care, it is important to prevent fears that their privacy may be invaded or that testing may lead to detrimental treatment. In a 1997 national survey, 63% of the respondents reported that they would not take genetic tests if employers or insurers could obtain access to the results. Department of Labor, Department of Health & Human Services, Equal Employment Opportunity Commission, & Department of Justice, *Genetic Information and the Workplace* (Jan. 20, 1998) (available at <http://www.genome.gov/10001732>). In an actual genetic study of individuals at risk for hereditary colon cancer, only 43% of those eligible participated. Of those who declined, 39% said the primary reason was fear that the test results would affect their medical insurance coverage. D. Hadley, et al, *Genetic Counseling and testing in families with hereditary nonpolyposis colorectal cancer*, *Archives of Internal Medicine* 163: 573-582 (2003). These examples illustrate that individuals must have control not only over whether or not to undergo a test, but also over the information that results from genetic testing.

The Drafting Committee has articulated four concepts that support the goals of protecting privacy and encouraging testing: control, confidentiality, consent, and counseling. The principle of knowing and voluntary consent can allow an individual to control genetic testing by vesting the decision in the individual to be tested. A baseline rule of confidentiality, coupled with the individual’s capability to consent to exceptions, can allow an individual to control how others access, use, retain, or disclose the individual’s genetic information. Finally, given the complexities and uncertainties of genetic science, genetic counseling is necessary if these

decisions about consent are to be knowing and informed.

The point about preventing irrational discrimination needs elaboration. Because the human genome has been portrayed with images such as “blueprint,” “code,” and “future diary,” public misunderstandings of the role of genetics are common. Employers and insurers cannot be expected to be exempt from such misunderstandings, which may cause them to exaggerate the predictive potential of genetic information.

There are some rare genetic diseases, such as Huntington’s disease, that are caused by a single gene and that can be predicted with certainty from an individual’s genetic sequence. These diseases may arguably justify “rational” discrimination. But such monogenetic diseases are the exception. They have received much attention as the first diseases for which researchers established a genetic link, but they afflict relatively few individuals. And even with such diseases, there is usually variation in the age that symptoms appear and in their severity.

The genetic causation of most diseases is far more complex. It is more common for medical conditions to result from interactions among multiple genes and with the environment. Most of the diseases that are linked to a genetic variation do not appear in all of the individuals with that genotype. This is termed “incomplete penetrance.” For example, certain forms of the BRCA 1 gene are strongly associated with susceptibility to breast cancer. But only 50 to 85 percent of women who have this form of the gene will ever develop the disease. Moreover, the frequency of particular gene variants and their degree of penetrance often differ among ethnic groups, which also complicates the clinical sensitivity of genetic tests and their predictive capabilities.

Another complicating factor for accurate prediction is that often a large number of genetic variations can cause the same disease. More than 180 different sequences of beta-globin genes are associated with the blood disease beta-thalassemia. And the severity of the symptoms of patients with this disease vary dramatically. Similarly, there are more than 300 forms of the gene responsible for cystic fibrosis. Unfortunately, identifying the variant of the gene does not explain the variation in symptoms.

Low penetrance, multiple genetic variations that may cause a single disease, and other sources of complications diminish the predictive value of genetic testing. In addition to the over-inclusiveness of many medical predictions based on genetic tests (in that a person with a predisposing genotype may never have symptoms of the disease), genetic predictions are also often extremely under-inclusive. For example, the predisposing variants of the BRCA 1 and BRCA 2 genes are present in only 5 to 10 percent of breast cancer patients. Thus, genetic data often do not provide an accurate individualized prediction. This is a major justification for the regulation of genetic information.

Proposals to regulate genetic information, however, have provoked a major policy debate over the wisdom of “genetic exceptionalism,” that is, the regulation of genetic testing and information as a special category rather than as part of more comprehensive regulation of medical testing and information. *See generally* T.H. Murray, *Genetic Exceptionalism and Future Diaries: Is Genetic Information Different from other Information*, in *Genetic Secrets: Protecting*

Privacy and Confidentiality in the Genetic Era (Mark A. Rothstein ed. 1977); Sonia M. Sutter, *The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation?*, 79 Wash U. L.Q. 669 (2001).

In the course of this debate, many arguments for singling out genetics for special attention have been raised and rejected. In the early 1990s, the Task Force on Genetic Information and Insurance, a joint working group of the National Institutes of Health and the United States Department of Energy, considered and rejected three justifications for such a policy: (1) They decided that genetic information is not sufficiently distinct from other health information on the basis of its prophetic potential. Genetic predispositions can be affected by many factors and information on non-genetic characteristics, such as lifestyle, may be better health predictors; (2) Genetic information is also not unique in its implications for family members; and (3) Genetic information is not the only type of health information with the ability to stigmatize.

Other arguments for exceptionalism include that genetic information is particularly sensitive in that it identifies normal variations that fuel discrimination despite their lack of clinical significance. Genetic codes are also viewed as immutable, so that one test can follow a person forever, and genetic information is more probabilistic than other types of medical information. These arguments can also be refuted as a basis for exceptionalism on the ground that they apply as well to other types of health information. Laine Friedman Ross, *Genetic Exceptionalism vs. Paradigm Shift: Lessons from HIV*, 29 J. L. Med. & Ethics 141 (2001).

There are also objections to treating genetic information separately on practical grounds. The distinction between genetic and non-genetic disorders is increasingly difficult to draw; most conditions have both a genetic and non-genetic component. Opponents of exceptionalism also contend that it is unrealistic to separate genetic information in medical records, so that it would be impossible to comply with restrictions on disclosing genetic information to employers or insurers. L.O. Gostin & J.G. Hodge, *Genetic Privacy and the Law: An End to Genetics Exceptionalism*, 40 *Jurimetrics* 21 (1999). Also, there is a social argument that it is unwise to enact laws that treat genetic conditions as if there is a stigma attached to them because that reinforces such attitudes and becomes a self-fulfilling prophecy. Moreover, treating genetics as unique only encourages the public view that genetics exert a special control over our lives, a view termed “genetic essentialism.” See, e.g., Rochelle Cooper Dreyfus & Dorothy Nelkin, *The Jurisprudence of Genetics*, 45 *Vand. L. Rev.* 313 (1992).

Most of the opponents of genetic exceptionalism do not oppose privacy protections, rather they advocate more holistic approaches to health information and its use in employment and insurance. The larger debate is about how to protect medical data from harmful uses while providing access for uses that individuals, clinicians, and society regard as beneficial. Genetic information is one part of the problem posed by the ease of collecting, storing, and disseminating personal information. Thus it is possible to argue that the exceptionalism debate is a distraction from more important questions about how regulations should be adapted to new scientific developments. Zita Lazzarini, *What Lessons Can We Learn from the Exceptionalism Debate (Finally)?*, 29 *J. L. Med. & Policy* 149 (2001). In the context of health insurance, one commentator maintains that “[g]enetic equity should be regarded not as an exceptional goal, but as an aim consistent with a broader movement toward equitable access to health care in a time of

scarcity.” John V. Jacobi, *Genetic Discrimination in a Time of False Hopes*, 30 Fla. St. U. L. Rev. 363, 364 (2003).

Scientific advances in genetics mean that a very large amount of information can be obtained from one small sample that is easily obtained and analyzed, yielding data that is easily stored and disseminated. This is not unique, but the concentration of information makes genetic information, which combines the power of many other types of medical information, seem particularly threatening. The drafting committee’s charge, which covers the misuse of genetic information in employment and insurance, responds to the large number of states that have enacted legislation. That legislation is highly inconsistent and often deals only partially with the issues associated with genetic information. The charge does contemplate genetic exceptionalism by focusing on use of genetic information rather than on health information or privacy more generally. Broader measures for all medical information may not be practical at this time. Nonetheless, it is still important to respond to problems with the use of genetic information. Perhaps regulation of the use of genetic information can serve as an example for policies that need to be developed for the treatment of medical information more generally.

Privacy Protections in General

General Policy Issues

The genetic revolution has raised challenges for several different aspects of privacy: informational privacy, physical privacy, decisional privacy, and proprietary privacy. See Anita L. Allen, *Genetic Privacy: Emerging Concepts and Values*, in *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* 31 (Mark A. Rothstein, ed. 1997).

Informational privacy can be thought of as an individual’s ability to determine what information about that individual should be available to others. “By controlling personal information, individuals can control the extent to which other people can participate in their lives.” David Orentlicher, *Genetic Privacy in the Patient-Physician Relationship*, in *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* 77 (Mark A. Rothstein, ed. 1997). Informational privacy of any type is challenging given advances in information technology that greatly increase the potential for others to access or disclose one’s personal information.

In the genetic context, an individual’s primary informational concern is the confidentiality or anonymity of the results of genetic testing. This privacy interest extends beyond the results of one’s personal genetic testing to genetic testing of blood relatives, which can also provide information about the individual. The desire to maintain the privacy of this genetic information often has a consequential motivation: people are concerned about others using their genetic information to their detriment. It also springs from a sense of the intrinsic value of keeping such personal information private whether or not the release of genetic information could lead to adverse consequences. The understanding that one’s characteristics, and even one’s personality, are strongly linked to one’s genetic composition heightens the sense that this information is a reflection of personal identity, and thus has inherent personal value.

The other forms of privacy are also important in the context of genetics. Physical privacy, the protection of bodily and personal space, is implicated by genetic testing or treatment. The importance of this form of privacy is recognized in concern for informed, voluntary consent for genetic testing. Decisional privacy, the freedom to make choices without interference by others, is implicated by the need to make decisions about using genetic services. Decisional privacy is an important tenet of genetic counseling, which supports autonomous decisionmaking about having genetic testing and learning the results of the testing. Proprietary privacy, control over possessions and economic interests, is implicated by the value of some individuals' samples or genetic information and by a sense of ownership of one's own identity. *See Anita L. Allen, Genetic Privacy: Emerging Concepts and Values, in Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era 31 (Mark A. Rothstein, ed. 1997).*

Privacy is valued in society and law, but not absolutely. The important interest in genetic privacy and confidentiality must be balanced against competing values, including facilitating medical research, improving medical care, protecting public health, enforcing the law, and controlling costs.

The Federal Regulatory Context

State legislation on privacy of medical information is set against the background of the 1996 Health Insurance Portability and Accountability Act (HIPAA). Title II of HIPAA required the Department of Health and Human Services to promulgate rules that created standards for the use and dissemination of health care information, including what is now called "The Privacy Rule."

The Privacy Rule, which took effect in 2003, regulates those who create and disclose health information – individual practitioners, multi-national health plans, pharmacies, and information clearinghouses – but not many of the key recipients of this information. "Covered entities," which include most health insurers, may disclose "protected health information," i.e., "individually identifiable health information" to facilitate treatment, payment, or health care operations. For other disclosures, with some exceptions, they must first obtain "consent," "authorization," or "agreement" from the individual, depending on the circumstances of the disclosure. Covered entities must follow these rules when they disclose health information to employers or life, disability-income, or long-term-care insurers, but employers and these insurers are not directly subject to the HIPAA regulations and so do not need to follow these rules in their own treatment of the information.

The Privacy Rule also allows individuals access to their own health information and gives them the right to request a correction of any inaccurate data. Covered entities must notify individuals of uses of their protected health information and keep records of disclosures.

Currently federal legislation is pending that would establish specific privacy requirements for genetic information. The Genetic Information Nondiscrimination Act of 2007, S. 358 and H.R. 493, governs entities already covered by the HIPAA privacy regulations. It would prohibit these health insurers from requesting, requiring or purchasing genetic information prior to an individual's enrollment and from using genetic information in underwriting or determining

eligibility. The legislation would also limit access, use, and disclosure of genetic information by employers, labor organizations, employment agencies, and joint labor-management committees. Its provisions do not apply to life or disability-income insurers.

Current State Statutes

Approximately 15 states have statutes that protect the privacy of genetic information in general, without regard to employment or insurance or any other specific context. Most of these statutes are tailored to cover information derived from genetic testing, although some establish a principle of confidentiality for medical information more generally. (Cal, Maine, ND) Many of these statutes declare that genetic testing and test results are confidential. *See, e.g.*, Ariz. (confidential and privileged), Cal, Maine, New York, Oregon. A few states have established a property right in genetic test results. Alaska Stat. § 18.13.010 (exclusive property right in DNA sample and results of analysis performed on sample); Fla. Stat. § 760.40 (results of DNA analysis are the exclusive property of the person tested); OR (repealed)).

Most of these generally-applicable statutes prohibit obtaining, analyzing, retaining, or disclosing genetic test results without the informed consent or specific authorization of the tested individual. All these statutes also define exceptions where genetic information may be obtained or disclosures may be made without authorization. Typical exceptions include law enforcement purposes and paternity determinations. Some states also exempt certain forms of insurance. *See, e.g.*, Mass. (disability-income and long-term-care insurance); NH (life, disability-income, and long-term-care insurance); NMex (life, disability-income, and long-term-care insurance if underwriting based on sound actuarial principles); OK (life, disability-income, and long-term-care insurance). Others make special provisions for research. *See, e.g.*, NY; OR (repealed).

The NCCUSL Draft

This draft protects privacy through limitations on the ability of employers and insurers to require genetic tests and to access, use, retain, and disclose genetic information in combination with requirements that employees and insureds authorize testing and access, use, retention, and disclosure of their genetic information. The Drafting Committee considered adopting a property right as a means to protect privacy of genetic information, but decided against this approach. While it might make sense to recognize a property right in genetic information in general, it is difficult to do only in the context of employment and insurance. Moreover, a majority of the committee felt that a system of limitations on testing, access, use, retention, and disclosure would be as effective as a property right in providing control over genetic information.

Although HIPAA does include general preemption provisions, they do not apply to state laws that relate to the privacy of individually identifiable health information that are contrary to and more stringent than the federal requirements. Thus HIPAA provides a floor, not a ceiling, for privacy protections and would not preempt the privacy provisions of the Act.

Employment

General Policy Issues

Currently, there is no comprehensive statute or regulation that declares genetic information confidential, restricts employer access, or requires employers to protect the privacy of their employees' genetic information. Many contend that employers' ability to obtain genetic information should be limited because it has few appropriate uses in the workplace. The concern is that if employers are permitted to consider genetic information in making personnel decisions, individuals may be unfairly barred or dismissed from employment for reasons that are not related to their ability to do the job. This is an especially high risk with predictive genetic information because so many persons tend to exaggerate the role of genes in disease and mistakenly regard an increased risk of an illness as a certainty that it will occur.

Employers arguably have an economic incentive to use genetic information to avoid hiring employees with higher medical insurance claims, higher absenteeism, or lower productivity. They may also wish to avoid the effect of high health care costs incurred by employees' dependents. Somewhat perversely, because the federal Health Insurance Portability and Accountability Act (HIPAA) protects employees against discrimination in health insurance based on medical conditions, including genetic characteristics, the most effective way for employers to avoid high insurance costs is to screen applicants and avoid hiring high-risk individuals. Nonetheless, there are few well-documented cases of genetic discrimination in employment.

In 1996, the NIH-DOE Joint Working Group on Ethical, Legal, and Social Implications of Human Genome Research (ELSI Working Group) and the National Action Plan of Breast Cancer developed and issued the following recommendations for state and federal policy makers to protect against genetic discrimination in employment. To a large extent, these recommendations mirror the approach of the Americans With Disabilities Act, described below.

- Employment organizations should be prohibited from using genetic information to affect the hiring of an individual or to affect the terms, conditions, privileges, benefits or termination of employment unless the employment organization can prove this information is job related and consistent with business activity.
- Employment organizations should be prohibited from requesting or requiring collection or disclosure of genetic information prior to a conditional offer of employment, and under all circumstances, employment organizations should be prohibited from requesting or requiring collection or disclosure of genetic information unless the employment organization can prove this information is job related and consistent with business necessity, or otherwise mandated by law. Written and informed consent should be required for each request, collection or disclosure.
- Employment organizations should be restricted from access to genetic information contained in medical records released by individuals as a condition of employment, in claims filed for reimbursement of health care costs and other sources.

- Employment organizations should be prohibited from releasing genetic information without prior written authorization of the individual. Written authorization should be required for each disclosure and include to whom the disclosure will be made.
- Violators of these provisions should be subject to strong enforcement mechanisms, including private right of action.

Karen Rothenberg et al., *Genetic Information and the Workplace: Legislative Approaches and Policy Challenges*, 275 Science 1755 (1996).

The Federal Regulatory Context

The states are legislating in a regulatory environment in which two federal statutes provide modest legal protections against discrimination in employment on a genetic basis: Title VII of the Civil Rights Act of 1964 (Title VII) and the Americans with Disabilities Act (ADA). These statutes are also important because many states have their own version of these statutes which they have modified to incorporate genetic protections.

Title VII prohibits employer discrimination on the basis of race, sex, color, national origin, and religion. It is applicable to genetic discrimination if an employer tests a group of employees in one of the protected classes. For example, the court in *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*, 135 F.3d 1260 (9th Cir. 1998), held that testing only black employees for the sickle cell trait violated Title VII by imposing a condition of employment on the basis of race. It is also possible that testing all employees could violate the Act if the test were for a trait closely associated with a protected group, such as sickle cell trait (which is more prevalent among African-Americans) or Tay-Sachs disease (associated with Ashkenazi Jewish ancestry). However, in these circumstances the statute would require the difficult showing that the testing was a pretext for intentional discrimination against the group or that it had a statistically significant disparate impact on employment opportunities of members of the group. Most importantly, the narrow focus on employers' actions with respect to certain groups means that Title VII would certainly not apply if an employer instituted a screening program for traits that are not strongly associated with a protected group. See Pauline T. Kim, *Genetic Discrimination, Genetic Privacy: Rethinking Employee Protections for a Brave New Workplace*, 96 NW U. L. Rev. 1497 (2002).

The ADA could provide some protections against genetic discrimination through its regulation of disability discrimination, although this potential is limited by the United States Supreme Court's narrow interpretation of the statute. See, e.g., *Sutton v. United Air Lines, Inc.*, 527 U.S. 471, 484-85 (1999) (stating ADA is intended to have limited coverage). "Disability" is defined under the ADA as (1) a physical or mental impairment that substantially limits one or more of the major life activities of an individual; (2) a record of such impairment; or (3) being regarded as having such an impairment. 42 U.S.C. § 12112(d)(2). If a genetically-caused disease results in a disability under the first prong of the definition, the ADA's protections will apply. The genetic connection is irrelevant; the statute protects the person because of the person's

disability, not its cause. Similarly, under the second prong the ADA covers individuals with a prior history of a genetically-related disability, such as a person recovering from a cancer. Of course, if these genetic conditions do not qualify under the definition of “disability” by substantially limiting a major life activity, the individual is not covered by the ADA.

The application of the ADA to discrimination based on a genetic trait that is not manifested in symptomatic disease is a more difficult question. In 1995 the EEOC issued a policy statement that an individual should be “regarded as” having a disability under the statute’s third prong if the employer discriminates on the basis of “genetic information relating to illness, disease, or other disorders.” EEOC Order No. 915.002 § 902 (1995). This interpretation of the statute has not been considered by the courts, although several United States Supreme Court justices have expressed their disapproval in dicta. *See, e.g., Bragdon v. Abbott*, 524 U.S. 624, 661 (1998) (Rehnquist, J., joined by Scalia, J. & Thomas, J., concurring in part & dissenting in part). Moreover, the EEOC’s position has been criticized in both conceptual and practical terms. *See, e.g., Pauline T. Kim, Genetic Discrimination, Genetic Privacy: Rethinking Employee Protections for a Brave New Workplace*, 96 NW U. L. Rev. 1497 (2002).

The ADA protects a disabled job applicant or employee from discrimination in the workplace. This includes a duty to provide reasonable accommodations to a qualified individual with a disability unless the accommodation would impose an undue hardship on the operation of the business. The ADA also regulates testing and access to information by prohibiting medical examinations or testing before a job offer. However, after making a “conditional offer,” an employer may require an applicant to take a medical exam. After making a conditional offer employers also have the right to require that individuals sign a blanket release disclosing all their medical records to the employer. Furthermore, once an individual is hired, an employer may test the employee if it can justify the testing as job-related. Thus, despite the ADA’s protections against discrimination through its requirements for reasonable accommodations, the ease of employer access to medical information may deter individuals from obtaining testing.

Currently, federal legislation is pending that would increase the role of the federal government in regulating genetic testing and genetic information in employment. HR 493, the Genetic Nondiscrimination Act of 2007, was passed by the House of Representatives on April 26, 2007. A similar bill, S.358, has been reported out of committee and is pending in the Senate. The legislation contains parallel provisions that apply to employers, employment agencies, labor organizations, and training programs. These entities are prohibited from discriminating on the basis of genetic information. They are also prohibited from acquiring genetic information, with exceptions that include offering genetic services as part of an employer wellness program and genetic monitoring that is required by federal or state law. Employees may bring claims for disparate treatment based on genetic information, but not for disparate impact. Remedies are limited to those available under Title VII of the Civil Rights Act of 1964, the Government Employee Rights Act of 1991, the Congressional Accountability Act of 1995, Chapter 5 of Title 3 of the United States Code, or Section 717 of the Civil Rights Act of 1964. In six years, a study group will make recommendations regarding whether or not to add a cause of action for disparate treatment.

Current State Statutes

Concern about economic incentives for employers has led 34 states, as of January 2006, to enact statutes that regulate the use of genetic information or genetic testing by employers. One group of states has used an existing state statute as a platform, amending it to apply to genetic testing or information. A second, larger, group has enacted statutes that are specifically tailored for genetic issues. This diversity of approaches has led to much inconsistency in state law.

In the first group, some states have extended their disability statutes to prohibit discrimination by employers based on genetic information under the rubric of disability. *See, e.g.*, Hawaii RS §§ 378-1 to 378-6; Illinois, 410 ILCS 513/5 to 513/30 (tied to federal Americans with Disability Act); Mich Comp Laws Ann §§ 37.1201-37.1202; NY Exec Law §§ 292, 296 (adds genetic conditions to the definition of protected disability).

Other states in the group that has adapted existing statutes have built on their statutes that prohibit discrimination in employment, expanding them from race, sex, national origin, and other protected classes, to include discrimination based on genetic information. *See, e.g.*, Ariz Rev Stat Ann § 41-1463; Cal Govt Code §§ 12926, 12940; Conn Gen Stat Ann § 46a-60; Mass Gen L ch 151B; Nev Stat § 613.345; NJ Stat Ann §§ 10:5-5, 10:5-12.

Wisconsin has used its Fair Employment Act as its vehicle, amending it to restrict the ability of employers to conduct genetic testing and use genetic information. Wis Stat § 111.372.

States in the second group have enacted special statutes that regulate genetic testing or the use of genetic information. This is the largest group of states, but the extent to which they concentrate on the context of employment varies to some extent. Most commonly, the provisions are tailored specifically for employment. *See, e.g.*, Ark Code Ann §§ 11-5-401 to 11-5-405; Del Code Ann § 710; Kan Stat Ann §§ 44-1002(m), 44-1009(a)(9); La Rev Stat Ann §§ 23.302, 23.368-369; Iowa Code § 729.6; Me Rev Stat Ann tit 5, § 19301; Md Code Ann art. 49B §§ 15,16; Minn Stat § 181.974; Neb Rev Stat § 48-236; NH Rev Stat Ann §§ 141-H:1 to 141-H:5; NC Gen Stat § 95-28.1A; Okla Stat tit 36, § 3614.2; Or Rev Stat § 659A.300; RI Gen Laws §§ 28-6.7-1 to 28-6.7-4; S.D. codified laws §§ 60-2-20 to 60-2-21; Tex Lab Code Ann § 21.401; Utah Code Ann §§ 26-45-101 to 26-45-106; Vt Stat Ann tit 18, §§ 9331-9335; Va Code Ann § 40.1-28.7:1(A); Wash Rev Code Ann § 49.44.180. Some statutes cover genetic information more broadly, regulating its use in employment along with insurance and other activities. *See, e.g.*, N Mex Stat Ann § 24-21-2. For other statutes, the focus is on broad regulation of genetic testing and information, with coverage that applies to employers along with others who might use the information. *See, e.g.*, Fla Stat § 760.4; NJ Stat Ann § 10:5-44, Or Rev Stat § 192.537.

The states that have special statutes limiting genetic testing or the use of genetic information in the employment setting have obviously embraced exceptionalism. But so, for the most part, have the states that have added discrimination based on genetic information to their employment discrimination statutes. This is the case because genetic characteristics are singled out and treated differently from other medical conditions under these statutes. An exception is California, whose statute prohibits employment discrimination on the basis of medical conditions in addition to the more traditional categories of race, sex, and national origin. Under this statutory scheme, a genetic characteristic is treated as a medical condition and receives the same protection as other health problems. Finally, disability statutes by definition single out certain

types of medical conditions for special protection: those that are disabling because they limit a major life activity. When genetic predispositions or conditions are defined as disabilities, they are treated similarly to this class of medical conditions. However, to the extent that a genetic condition does not fit within the rubric of “limiting a major life activity,” it is being treated differently from other non-disabling medical conditions under these statutes.

The NCCUSL Draft

The draft prohibits imposes strict limitations on genetic testing and access to genetic information by employers. Exceptions include genetic screening for susceptibility to harm from a workplace condition and genetic monitoring of the effects of exposure, which are permitted with the employee’s authorization. Employers’ use of genetic information is also limited and an employer may not take an adverse employment action against an employee unless it is necessary to protect the health or safety of others from a direct threat of harm due to an employee’s genetic characteristic. An employer must treat an employee’s genetic information as confidential and may not retain it or disclose it to others without employee authorization.

Health Insurance

General Policy Issues

As in the employment arena, the treatment of genetic information by health insurers raises concerns for individuals’ privacy and for how genetic information may be used by the industry. Privacy is a great concern because the health care system is where much genetic information is generated and stored.

Discrimination in health insurance is a uniquely American problem because the United States does not guarantee coverage of health care expenses for its citizens as other wealthy nations do. Legislation in this area responds to public perceptions that health insurers will deny coverage or increase premiums based on predictive genetic information. This may be irrational discrimination. In addition, individuals who fear reduced or more expensive health care coverage may avoid genetic tests that could provide useful information for improving their health. The legislative restrictions are designed to avoid these outcomes.

The main argument against regulation in this market is that genetic information would allow insurers to decrease adverse selection. Adverse selection is the disproportionate purchase of insurance by individuals who have medical reasons to believe they will need to make claims. It leads to insurer losses when applicants fail to disclose the relevant health information and it is a particular concern with individual health insurance policies. The industry and a number of scholars contend that avoiding losses due to adverse selection based on genetic information will lead to more affordable insurance.

In 1995, the NIH-DOE Joint Working Group on Ethical, Legal, and Social Implications of Human Genome Research (ELSI Working Group) and the National Action Plan of Breast Cancer developed and issued the following recommendations for state and federal policy makers to protect against genetic discrimination in health insurance. The recommendations apply to both

group and individual health plans.

- Insurance providers should be prohibited from using genetic information, or an individual's request for genetic services, to deny or limit any coverage or establish eligibility, continuation, enrollment or contribution requirements.
- Insurance providers should be prohibited from establishing differential rates or premium payments based on genetic information or an individual's request for genetic services.
- Insurance providers should be prohibited from requesting or requiring collection or disclosure of genetic information.
- Insurance providers and other holders of genetic information should be prohibited from releasing genetic information without prior written authorization of the individual. Written authorization should be required for each disclosure and include to whom the disclosure would be made.

Kathy Hudson et al., *Genetic Discrimination and Health Insurance: An Urgent Need for Reform*, 270 *Science* 392 (1995).

One study of state restrictions on the use of genetic information in health insurance concluded that there are almost no well-documented cases of insurers asking for genetic test results for pre-symptomatic conditions in either states with regulation or states without such regulation. The author argued that use of genetic information is not cost effective and is not seen by insurers as increasing the accuracy of their underwriting. Nonetheless, he believes that state laws will have an effect by making it less likely that insurers will use genetic information in the future, because the laws have helped convince insurers that use of this information is not socially acceptable. Mark A. Hall, *Legal Rules and Industry Norms: The Impact of Laws Restricting Health Insurers' Use of Genetic Information*, 40 *Jurimetrics J.* 93 (1999).

The Federal Regulatory Context

As with employment, the states legislate against the background of federal statutes governing health insurance. The 1996 Health Insurance Portability and Accountability Act (HIPAA) partially addresses the treatment and use of genetic information in health insurance. Title I amends the Employee Retirement Income Security Act (ERISA) and the Public Health Service Act with regard to availability of health insurance.

Under HIPAA's Title I provisions on availability of health insurance, an employee-sponsored group health insurance plan may not deny an applicant coverage as a result of a health-status related factor, including genetic information. Plans are specifically prohibited from using "genetic information" in establishing eligibility or benefit levels. The law also prohibits exclusions for pre-existing conditions on the basis of a genetic predisposition to a particular condition. Moreover, a plan may not restrict coverage, restrict benefits, or charge higher

premiums based on the health status of an enrolled employee. Title I covers employer-sponsored group health insurance plans for 50 or more individuals, including self-insured plans. As a result, this part of HIPAA regulates only a portion of the health insurance market. It does not apply to employees in small group health insurance plans or to individual health insurance coverage.

Title II of HIPAA mandated security and privacy provisions for health care information. The Department of Health and Human Services issued regulations called the Privacy Rule, which took effect in 2003. The regulations cover “health plans,” a category that includes both individual and group health insurers. It allows health insurers to disclose “protected health information,” i.e., “individually identifiable health information” to facilitate treatment, payment, or health care operations. Otherwise, health insurers must first obtain authorization from the individual. The privacy rule also allows individuals access to their own health information and gives them the right to request a correction of any inaccurate data. Insurers must notify individuals of uses of their protected health information and keep records of disclosures of that information. The Privacy Rule applies more widely than Title I because it includes individual health insurance, but there are some exceptions to its coverage that would be closed by this Act.

Pending federal legislation would specifically regulate genetic tests and the use of genetic information in the health insurance industry. As of early October 2007, S. 358 was pending in the Senate and H.R. 493 had been passed in the House of Representatives. These bills extend the protections against use of genetic information in determining eligibility or rates to the individual health insurance market and limit genetic testing by health insurers. Entities that are already covered by the HIPAA privacy regulations would be subject to specific prohibitions on the collection and use of genetic information.

Current State Statutes

The law in 47 states restricts the use of genetic information by health insurers in some way. Some states impose restrictions only on group health insurance (Ak, Iowa, SD, Wy), and some only on individual policies (Hawaii, Nebraska, WV), but most cover both group and individual health insurance and hence have a broader reach than HIPAA’s coverage provisions.

There are five main types of state regulation of genetics in health insurance. First, many states prohibit insurers from requiring individuals to have genetic tests or to disclose genetic information to the insurer. (Ark, Cal, Col, Fla, Ga, Haw, Ill, Ind, Kan, Md, Mich, Minn, Mo, Montana, Neb, NH, NMex, NY, OH, OK, Or, RI, SD, Tenn, UT, Wis). In a few states (Mich, Neb) this restriction on access to information stands alone, but most states have additional measures.

Second, a number of states prohibit health insurers from disclosing genetic information without informed consent or authorization. (Ariz, Cal, Col, Del, Ga, Haw, Ill, Ky, La, Me, Md, Mass, Mich, Mo, Nev, NH, NJ, NMex, NY, Or, RI, SC, Tenn, Tex, Vt, Va, Wash).

In addition to these privacy-based protections, there are also restrictions on health insurers’ use of genetic information. In a third category, a large number of statutes provide that insurers may not establish rules for eligibility, that is, deny coverage, based on genetic

information. (Alaska, Ariz, Ark, Cal, Col, Conn, Del, Fla, Ga, Haw, Ill, Ind, Iowa, Kan, Ky, La, Me, Mass, Minn, Mo, Mont, Nev, NH, NJ, NMex, NY, NC, OH, OK, Or, RI, SC, SD, Tenn, Tex, UT, Ve, Va, WVa, Wis, Wy).

Fourth, most of these same states impose some type of limit on the use of genetic information for risk selection or classification in health insurance, such as higher premiums, reduced coverage or reduced benefits. Many states simply prohibit insurers from considering genetic information for these purposes.

Fifth, some states do not permit health insurers to impose pre-existing condition exclusions based on predictive genetic information in the absence of a diagnosis based on symptoms of the disease or condition. (Alaska, Conn, Idaho, Iowa, Ky, others).

The NCCUSL Draft

The draft prohibits genetic information from being considered in determining eligibility for health insurance coverage or in setting rates, terms, and conditions for health insurance policies. Health insurers are permitted to consult genetic information for their billing functions. And the draft does not restrict testing and access to genetic information for therapeutic purposes by insurers who provide health care services.

The draft does not consider the emerging health issue of access to genetic services and insurance coverage for their costs. Currently the states with laws in this area cover newborn screening and genetic childhood diseases. According to the National Conference of State Legislatures, no state currently requires coverage of testing for adult onset genetic disorders such as breast cancer, but bills are being introduced frequently.

Life Insurance, Disability-income Insurance, and Long-term-care Insurance

General Policy Issues

Life, disability-income, and long-term-care insurance can be distinguished from health insurance in that individual underwriting of policies is more common. This is because a larger proportion of the market for these insurance products consists of individual coverage than group coverage. According to the National Conference of State Legislatures, approximately 60 percent of life insurance, 40 percent of disability-income insurance, and almost all of long-term-care insurance is underwritten individually, compared to only about 10 percent of health insurance. Individual underwriting decisions take individual characteristics into account in determining risk and use this risk calculation in determining an individual's premium rates and the terms and conditions for coverage and benefits. Individual underwriting could be done more accurately with access to genetic information if that genetic information provides an accurate prediction of the likelihood of claims.

The argument for restricting access to genetic information by the insurance industry is that its predictive power is easily exaggerated and insurers may force applicants to take genetic tests and then deny insurance or charge more based on genetic characteristics. This raises the

possibility that a large class of people will lack coverage even though they are not sick and never will become sick. There are also privacy concerns with commercial access to sensitive genetic information and predictions that individuals will avoid genetic testing for fear of adverse effects on their insurability. From the industry perspective, as with health insurance, insurers worry about adverse selection. If applicants seek coverage because a genetic characteristic exposes them to risk, but the insurer does not have this information, this puts the insurer at a financial disadvantage. *See generally* Mark A. Rothstein, ed., *Genetics and Life Insurance: Medical Underwriting and Social Policy* (2004).

The Federal Regulatory Context

Obtaining, retaining, and disclosing information. The insurance industry is primarily regulated by the states, but there are federal laws that affect privacy procedures for some aspects of obtaining, retaining, or disclosing medical information. First, HIPAA is the primary source of privacy rules in the medical context. Long-term-care insurers, like health-care insurers, are directly subject to the privacy rules in HIPAA.

Life and disability-income insurers are not directly subject to HIPAA, but their methods of obtaining medical information are affected indirectly because HIPAA controls the way in which health care providers can furnish them with medical information. Under HIPAA, the consumer must first provide an authorization for disclosure by the health care provider. Therefore, in order to obtain medical information from a health care provider to underwrite new coverage or evaluate a claim, an insurer's forms must meet HIPAA requirements for consumer authorization. HIPAA does not apply, however, to other forms of access, (such as genetic testing by a life or disability-income insurance company) or to the use, retention, or disclosure of genetic information by life or disability-income insurers.

Second, the Fair Credit Reporting Act affects insurers' ability to disclose as well as obtain medical information (including genetic information). It imposes requirements on obtaining, using and disclosing "consumer reports." The term consumer report may include medical information, including genetic information, that is used as a factor in establishing eligibility for insurance. It does not, however, include medical information disclosed to an affiliate in connection with the business of insurance or annuities and hence such disclosures are not regulated by the act.

The Fair Credit Reporting Act was amended in 2003 by the Fair and Accurate Credit Transactions Act (FACT Act) in response to concerns about the use of medical information in determinations of eligibility for credit. Under the FACT Act, consumer reporting agencies may furnish a consumer report containing medical information in connection with an insurance transaction only with consumer consent. In addition, an insurer or other third party who receives medical information from an insurer in connection with the business of insurance may not re-disclose that information except as necessary to carry out the purpose for which the information was initially disclosed or as otherwise permitted by law.

Third, the Gramm-Leach-Bliley Act (GLBA) protects consumers from certain disclosures of their "nonpublic personal information." In general, this information may not be shared by a

financial institution (including insurers) with an unaffiliated third party unless the consumer has been given notice and an opportunity to opt-out of such sharing. However, sharing without an opt-out opportunity is permitted if it is in connection with the performance of business activities or a joint marketing agreement between financial institutions. The GLBA requires state insurance regulators to adopt rules to implement and enforce its provisions. In doing so, many states have gone further in protecting medical information by requiring an authorization from the consumer (opt-in) before medical information may be shared, as described below.

The State Regulatory Context

Obtaining, retaining, and disclosing information. Disclosure of genetic information by insurers is covered under state provisions on general information practices in the insurance industry. First, about 18 states have adopted provisions based on the National Association of Insurance Commissioners' Insurance Information and Privacy Protection Model Act. These provisions require written authorization from a consumer before an insurer may share personal consumer information, except as needed to perform basic insurance functions. *See, e.g.,* Ariz. Rev. Stat. §§ 20-2101 to 20-2102; Cal. Ins. Code §§ 791.01 to 791.23; Conn. Gen. Stat. §§ 38a-975 to 38a-999a; Ga. Code Ann. §§ 33-39-1 to 33-39-23; 215 Ill. Comp. Stat. Ann. 5/1001 to 5/1024; Me. Rev. Stat. Ann. tit. 24-A §§ 2201 to 2220; Mass. Gen. Laws ch 175I §§ 1 to 22; Minn. Stat. Ann. §§ 72A.49 to 72A.505; Mont. Code Ann. §§ 33-19-101 to 33-19-409; Nev. Admin Code §§ 679B.560 to 679B.750; N.J. Stat. Ann. §§ 17:23A-1 to 17:23A-22; N.C. Gen. Stat. §§ 58-39-1 to 58-39-125; Ohio Rev. Code Ann. §§ 3904.1 to 3904.22; Or. Rev. Stat. §§ 746.600 to 740.690; Va. Code Ann. §§ 38.2-600 to 38.2-620.

Second, in implementing the GLBA, 27 states have adopted provisions specifically protecting medical information from disclosure by insurance companies. These provisions are based on the National Association of Insurance Commissioners' Privacy of Consumer Financial and Health Information Model Regulation. It provides that an insurer may not disclose nonpublic personal health information unless the consumer has provided authorization or unless the disclosure is made in connection with insurance business functions. *See* Alaska Admin. Code tit. 3 §§ 26.605 to 26.749; Ark. Ins. Rule & Reg. 74; Cal. Fin. Code §§ 4050 to 4060; Colo. Admin. Ins. Reg 6-4-1; Conn. Admin. Code tit. 38a §§ 8-105 to 8-123; Fla. Admin. Code §§ 690-128.001 to 690-128.025; Iowa Admin. Code §§ 191-90.1 to 191-90.26; Kan. Admin. Regs. § 40-1-46; 806 Ky Admin. Regs. 3:210-3:220; Md. Admin. Code §§ 31.16.08.01 to 31.16.08.24; Neb. Rev. Stat. § 44-901 to 44-925; N.H. Admin. Code Ins. §§ 3001.01 to 3006.05; N.Y. Comp. Code R. & Regs. tit 11, §§ 420.0 to 420.24 (Reg. 169); N.D. Admin. Code §§ 45-14-01-01 to 45-14-01-25; Okla. Admin. Code §§ 365:35-1-1 to 365:35-1-54; Or. Admin. R. 836-080-0501 to 836-080-0551 & 836-080-0600 to 836-080-0700; 31 Pa.Code §§ 146a.1 to 146a.44 & 146b.1 to 146b.24; R.I. Code Regulation 100; S.C. Code Ann. Regs. 69-58; S.D. Admin R. 20:06:45:01 to 20:06:45:31; Tex. Admin Code §§ 22.1 to 22.67; Utah Admin Code 590-206; Vt. Code R. IH-2001-1; Wash. Admin Code §§ 284-04-120 to 284-04-260; W. Va. Code St. R. §§ 114-57-1 to 114-57-22; Wis. Admin. Code § § 25.01 to 25.95; Wyo Ins. Regs. ch. 54 §§ 1 to 26.

Use of Information. General limitations on the use of information in insurance underwriting are included in the Unfair Trade Practices Acts in effect in almost every state. These limitations apply to genetic information as well as to other information. Typically, these

provisions prohibit “making or permitting any unfair discrimination between individuals of the same class and equal expectation of life in the rates charged for any life insurance policy or annuity . . . or in any other terms and conditions of such policy.” National Association of Insurance Commissioners Model Unfair Trade Practices Act § 4(G)(1). In many states, disability-income and long-term-care insurance are regulated as health insurance. For health insurance, a typical provision prohibits “unfair discrimination between individuals of the same class and of essentially the same hazard in the amount of premium, policy fees or rates charged for any accident or health insurance policy or in the benefits payable thereunder, or in any of the terms and conditions of such policy, or in any other manner.” § 4(G)(2).

In both life and health insurance, practices that constitute “unfair discrimination” between individuals of the same class are identified as “refusing to insure, refusing to continue to insure, or limiting the amount, extent, or kind of coverage available to an individual or charging a different rate for the same coverage solely because of a physical or mental impairment, except where the refusal, limitation or rate differential is based on sound actuarial principles or is related to actual or reasonably anticipated experience.” National Association of Insurance Commissioners Model Regulation on Unfair Discrimination in Life and Health Insurance on the Basis of Physical or Mental Impairment § 3.

Some states also specifically regulate the use of genetic information in life, disability-income or long-term-care insurance. Many of them reiterate their Unfair Trade Practices Act by requiring an actuarial justification for the use of genetic information in determining eligibility and in underwriting. This does not address, however, the important question of whether there is a sufficient scientific basis for assessing risk and how the sufficiency of that scientific basis should be determined. Moreover, an additional question in the genetic context is whether or not there are conditions that should be excluded from consideration even if there is an actuarial justification for different treatment.

A 1997 study by the Human Genetics Advisory Commission in the United Kingdom concluded that it is unlikely that actuarially-sound genetic predictions of adult death will be validated and available anytime in the near future. Genetic tests need to be connected to medical and epidemiological research to establish what consequences for health and life-span can be inferred from a given genetic test. The Commission concluded that a requirement to disclose genetic tests as a condition of obtaining insurance would be acceptable only after research has established an association between a given pattern of test results and life events that are relevant for the insurance product. They recommended continuing a moratorium on requiring test results. They also predicted that the life insurance industry could withstand the limited adverse selection that might result from non-disclosure. Human Genetics Advisory Commission, *The Implications of Genetic Testing for Insurance* (1997).

Current State Genetic Statutes

At least twenty-three states have legislation that regulates genetic testing or the use of genetic information in life, disability, or long-term-care insurance. Twenty-two states have statutes that pertain to life insurance, nineteen apply to disability insurance, and fifteen cover long-term-care insurance.

Obtaining and disclosing genetic information. The most common privacy protection in state law is a requirement for informed consent or authorization for genetic testing by the individual to be tested. Several states have general provisions requiring informed consent to obtain genetic information that are applicable to insurers. *See, e.g.*, Alaska Stat. §§ 18.13.010 (informed and written consent needed for DNA collection, analysis, retention, & disclosure); Del. Code Ann. § 1221(a) (same); Fla. Stat. Ann. § 760.40(2)(a) (informed consent necessary to perform DNA analysis). A larger number of states specifically require an individual's informed consent or authorization for genetic testing for life, disability-income, or long-term-care insurance. *See* Ariz. Rev. Stat. Ann. § 20-448.02(A) (life, disability-income, long-term-care); Cal. Ins. Code § 10148 (life, disability-income); Colo. Rev. State § 10-3-1104.7(10)(a) (life, individual disability-income); Minn. Stat. Ann. § 72A.139 (life); Nev. Rev. Stat. Ann. § 629.151 (life); N.J. Stat. Ann. § 17B:30-12(f) (life, disability-income); N.Y. Ins. Law § 2615(a) (life, disability-income, long-term-care); Or. Rev. Stat. § 192.535 (life, disability-income, long-term-care); Vt. Stat. Ann. tit. 18, § 9332(d) (life, disability-income, long-term-care). In a couple of states, insurers that require genetic tests must pay the cost of the test. Cal. Ins. Code § 10148 (life and disability-income); Minn. Stat. Ann. § 72A.139 (life).

Other states prohibit insurance companies from requiring genetic testing as a condition of obtaining insurance. For all three types of insurance, insurers may not require applicants in Massachusetts or Vermont to undergo a genetic test as a condition of issuing or renewing a policy. Mass. Gen. Laws Ann. Ch. 175, § 120E (life); Mass. Gen. Laws Ann. Ch. 175, § 108I (disability-income, long-term-care); Vt. Stat. Ann. tit. 18, § 9334(a). In California, there is a special provision for long-term-care insurance that prohibits insurers from requiring genetic testing to determine insurability or for underwriting. Cal. Ins. Code § 10233.1.

A couple of states impose restrictions on asking applicants for genetic information. In Kentucky, disability-income insurers may not request or require an applicant to disclose a genetic test. Ky. Rev. Stat. Ann. § 304.12-085(3). In contrast, in Massachusetts, all three types of insurers may ask if an applicant has taken a genetic test. The application form must indicate, however, that the applicant is not required to answer questions about genetic testing or genetic information, but that failure to answer may result in denial of coverage or an increased rate. Mass. Gen. Laws Ann. Ch. 175, § 120E (life insurance); Mass. Gen. Laws Ann. Ch. 175, § 108I (disability-income and long-term-care insurance).

Finally, some states also regulate disclosure of genetic information, requiring either informed consent or authorization of the individual tested. *See, e.g.*, Alaska Stat. §§ 18.13.010; Cal. Ins. Code § 10149.1. Another approach classifies genetic information with mental health information and HIV status as “sensitive health information” that requires protections against disclosure beyond that required for medical information. *See, e.g.*, Conn. Gen. Stat. § 38a-999. In terms of access to test results by the individual tested, some states require insurers to provide test results to the individual or the individual's designated physician. *See, e.g.*, Fla. Stat. § 760.40(3) (general); Minn. Stat. Ann. § 72A.139 (life insurance); N.J. Stat. Ann. § 17B:30-12(f) (life & disability-income insurance, with option for genetic counseling); N.Y. Ins. Law § 2615(e) (if adverse decision for life, disability-income, or long-term-care insurance).

Use of genetic information. The broadest restrictions on use of genetic information

prohibit insurers from using genetic testing results or genetic information to determine eligibility or for underwriting. *See* Colo. Rev. Stat. § 10-3-1104.7(3)(b) (group disability-income & long-term-care insurance); Kan. Stat. Ann. § 40-2259(d) (disability-income & long-term-care insurance). Arizona prevents disability-income and long-term-care insurers from using information about a genetic predisposition in underwriting by permitting those insurers to use genetic test results only if there is an actual diagnosis of a genetic condition. Ariz. Rev. Stat. Ann. § 20-448(F). Both Oregon and Vermont prevent all three types of insurers from using any genetic information about a blood relative for either eligibility or underwriting. Or. Rev. Stat. § 746.135; Vt. Stat. Ann. tit. 18, § 9334(a).

Other states restrict use of genetic information by prohibiting insurers from denying coverage or underwriting based on the applicant's status as a carrier of a genetic disease. California specifies that life and disability-income insurers may not rely on information about an applicant's genetic characteristic that causes no adverse effects on the carrier, even though it might be associated with disability in the applicant's offspring. Cal. Ins. Code § 10143. These traits include, but are not limited to, Tay Sachs trait, sickle cell trait, thalassemia trait and X-linked hemophilia A. Other states similarly prohibit insurance decisions based on specific genetic traits. *See* Fla. Stat. Ann. § 626.9706 (sickle-cell trait) (life); La. Rev. Stat. Ann. § 22:652.1(A), (D) (sickle-cell trait & severe disability) (life and disability-income); N.C. Gen. Stat. § 58-58-25 (sickle-cell trait & hemoglobin C trait) (life); Tenn. Code Ann. § 56-7-207 (sickle-cell trait & hemoglobin C trait) (life).

Finally, a number of state genetic statutes reiterate standards for underwriting that duplicate provisions of most state Unfair Practices Act, stating that the use of genetic information in underwriting must be based on an actuarial justification, may not be used for unfair discrimination, or must be reasonably related to risk. *See* Ariz. Rev. Stat. Ann. § 20-448(E) (life, disability-income & long-term-care insurance); Kan. Stat. Ann. § 40-2259(d) (life insurance); 24A Me. Rev. Stat. Ann. § 2159-C(3) (life, disability-income & long-term-care); Md. Code Ann., Ins. § 27-208(a)(3) (life, disability-income & long-term-care insurance); Mass. Gen. Laws Ann. Ch. 175, § 120E (life, disability-income & long-term-care insurance); Mont. Code Ann. § 33-18-206 (life, disability-income & long-term-care insurance); N.J. Stat. Ann. § 17B:30-12(f) (life & disability-income insurance); N.M. Stat. Ann. § 24-21-4 (C) (life, disability-income & long-term-care insurance); Vt. Stat. Ann. tit. 18, § 4724(3) (life, disability-income & long-term-care insurance); Wis. Stat. Ann. § 631.89 (life & disability-income insurance).

The NCCUSL Draft

The draft allows life insurers, disability-income insurers, and long-term-care insurers to require genetic tests and use genetic information for coverage and underwriting decisions only as scientific developments justify that use. The draft places a burden on insurers to show that a positive genetic test is reliably associated with increased medical risk of mortality or morbidity. If an insurer can demonstrate that to a reasonable degree of scientific certainty, it can use the information. If the available scientific evidence does not meet this standard, use of the genetic information would be a violation of state unfair practices insurance law.

1 (5) “Family medical history” means information about the occurrence of a medical
2 condition in a family member of an individual.

3 (6) “Family member” means an individual’s spouse or domestic partner, child whether
4 related to the individual by whole or half blood, affinity, or adoption, and the parent, grandparent,
5 great grandparent, sibling, first cousin, aunt, uncle, great-aunt, great-uncle, niece, or nephew of
6 the individual, the individual’s spouse or domestic partner, or the individual’s child, whether
7 related to the individual, the individual’s spouse or domestic partner, or child by the whole or
8 half blood.

9 (7) “Genetic counseling” means the process of:

10 (A) assessing an individual’s genetic risk for an inherited condition by interpreting
11 family medical histories;

12 (B) providing unbiased education about the inheritance, testing, management, and
13 prevention of a genetic condition;

14 (C) helping an individual understand the risks and benefits of testing for a genetic
15 trait to promote informed decision making about whether or not to undergo genetic testing; and

16 (D) providing support and resources as appropriate to help an individual adapt to
17 the medical, psychological, and familial implications of having or being at risk of having a
18 genetic condition.

19 (8) “Genetic information” means information:

20 (A) based on an individual’s genetic tests or the genetic tests of an individual’s
21 family member; or

22 (B) about an individual’s or an individual’s family member’s request for or receipt
23 of genetic services.

1 (9) “Genetic monitoring” means a periodic examination to identify or evaluate a
2 modification to genetic material, such as chromosomal damage or evidence of increased
3 occurrence of mutation, owing to toxic or hazardous exposure.

4 (10) “Genetic service” means a genetic test, genetic counseling, or genetic education.

5 (11) “Genetic test” means an analysis of human genetic material, including
6 deoxyribonucleic acid, ribonucleic acid, chromosomes, proteins, and metabolites, that is intended
7 to detect a genotype, genetic marker, mutation, or chromosomal change.

8 (12) “Health insurance” means a health-care arrangement assuming financial risk to pay
9 for, purchase, or furnish health-care services to patients, insureds, or beneficiaries, including:

10 (A) insurance that covers hospital, medical, or health expenses;

11 (B) an employee welfare-benefit plan;

12 (C) a health maintenance organization;

13 (D) a preferred-provider organization;

14 (E) a medical service organization;

15 (F) a physician-hospital organization;

16 (G) a self-insured health plan;

17 (H) a prepaid health-care service plan; or

18 (I) another health-care arrangement in which risk is assumed.

19 (13) “Insured” means an individual who is covered by or applying for coverage under a
20 policy of health, life, disability-income, or long-term-care insurance.

21 (14) “Insurer” means a person engaged in the business of health, life, disability-income,
22 or long-term-care insurance in this state, regardless of where a contract of insurance is written or
23 the plan is administered. The term includes an insurance agent, broker, underwriter, and third-

1 party administrator.

2 (15) “Licensing authority” means a regulatory authority that provides a credential or
3 certifies competence that is necessary for an employee to qualify for employment or to participate
4 in a profession.

5 (16) “Life insurance” means insurance against the financial risk of death.

6 (17) “Long-term-care insurance” means insurance that provides coverage for not less than
7 12 consecutive months for one or more necessary diagnostic, preventive, therapeutic,
8 rehabilitative, maintenance, or personal-care services provided in a setting other than an acute
9 care unit of a hospital. The term includes a policy or rider that provides for payment of benefits
10 based upon cognitive impairment or inability to perform the activities of daily living.

11 (18) “Person” means an individual, corporation, business trust, estate, trust, partnership,
12 limited liability company, association, joint venture, public corporation, government or
13 governmental subdivision, agency or instrumentality, or any other legal or commercial entity.

14 (19) “Predisposing genetic characteristic” means a gene variant or genetic marker that is
15 determined from genetic information and is associated with an individual’s increased risk of
16 developing a disease or medical condition for which the individual is presently asymptomatic.

17 (20) “Record” means information that is inscribed on a tangible medium or that is stored
18 in an electronic or other medium and is retrievable in perceivable form.

19 (21) “Sign” means, with present intent to authenticate or adopt a record:

20 (A) to execute or adopt a tangible symbol; or

21 (B) to attach to or logically associate with the record an electronic symbol, sound,
22 or process.

23 **Reporter’s Notes**
24

1 *Paragraph (1). (Adverse insurance determination)* The use of genetic information makes
2 an insurance determination adverse if it leads to denial of coverage or coverage on less favorable
3 terms than would have been available absent the insurer’s consideration of the information. This
4 definition is relevant to an individual’s ability to correct a faulty genetic test that has
5 consequences for insurance eligibility or terms.
6

7 *Paragraph (2). (Disability-income insurance)* This definition of disability-income
8 insurance is used in several state statutes on genetic testing. *See, e.g.*, Cal. Ins. Code § 10147;
9 N.H. Rev. Stat. Ann. § 141-H:1. The committee discussed substituting the term “income” for
10 “earning capacity,” but did not take any action.
11

12 *Paragraph (3). (Employee)* The definition of employee is adapted from the National
13 Conference of Commissioners on Uniform State Law’s Model Employment Termination Act.
14 The definition in that Act is modified by including applicants for employment within the
15 definition of employee. The definition’s requirement for compensation is intended to exclude
16 volunteers from the definition of employee.
17

18 An alternative approach suggested by the Style Committee liaison would be a separate
19 definition of “applicant” as an individual who is applying to work for compensation. This
20 suggestion was not adopted at this time because the substantive provisions of the draft do not
21 differentiate between protections for applicants and those for employees. In addition, the
22 definition of “insured” includes applicants for insurance as well individuals who receive
23 coverage. Thus there is a potential for confusion in the substantive sections if the definition of
24 “insured” includes applicants but the definition of “employee” does not.
25

26 A second suggestion from our Style Committee liaison is to add an additional section to
27 Article I that links the treatment of applicants to that of employees. Possibilities include: “For
28 purposes of this Act, an applicant for employment is treated the same as an employee”; or “An
29 applicant for employment subject to the Act has the same rights and responsibilities as an
30 employee under the Act.”
31

32 The drafting committee considered including independent contractors in the definition of
33 employees, but decided to leave their categorization to be determined by general employment
34 law. This approach is not intended, however, to provide employers with an avenue to evade their
35 obligations by classifying employees as independent contractors.
36

37 *Paragraph (4). (Employer)* The definition of employer is linked to the definition of
38 “person” in paragraph 16 and therefore encompasses all types of entities, including governmental
39 and non-profit employers. “Employer” takes its meaning from the broad definition of
40 “employee” in paragraph 3.
41

42 As the definition of employer is currently drafted, the act would cover all employers
43 regardless of size. One consideration is whether the requirements of the act would prove too
44 burdensome for small employers. Many statutes specify a minimum size using the number of
45 employees as a proxy for size. For example, Title VII of the Civil Rights Act of 1964 covers
46 employers who had 15 or more employees for each working day in 20 or more weeks over the

1 course of a year. The definition in the Uniform Law Commissioner’s Model Employment
2 Termination Act requires five employees and extends the measurement period to two years.

3
4 Another way to limit the types of employers that are covered would be to exclude
5 immediate family members from the count of employees, as is done in the Fair Labor Standards
6 Act and the National Conference of Commissioners on Uniform State Law’s Model Employment
7 Termination Act. In addition, some state statutes exclude particular employee groups, such as
8 household workers or farm workers, in determining employer status.

9
10 *Paragraph (5). (Family medical history)* Family medical history is often a source of
11 genetic information in that it is used to evaluate the likelihood that an individual carries an
12 inherited trait. The act’s definition of “genetic information” does not encompass medical history,
13 so a separate definition is needed when the act’s provisions apply more broadly.

14
15 *Paragraph (6). (Family member)* A family member is defined broadly to encompass all
16 individuals whose own genotype could influence an employment or insurance decision. The
17 term includes (1) biological relations whose genetic information might provide information about
18 the genetic make-up of an individual employee or insured, (2) dependants whose risk of future
19 genetically-linked medical conditions could affect employer health care costs or family insurance
20 coverage and hence affect employment or insurance decisions, and (3) dependants’ biological
21 relations whose genetic information might provide information about the genetic make-up of a
22 dependant. The term “child” includes both adopted and biologically-related children because
23 either can affect health-care costs or family insurance coverage.

24
25 The family members are listed in the definition, replacing a reference to “the fourth
26 degree of consanguinity” at the request of the Style Committee. This approach is consistent with
27 that of other uniform acts, including the Uniform Adoption Act.

28
29 Many employers provide health insurance for employees’ unmarried partners. Therefore,
30 an unmarried partner can be a dependent whose risk of a genetically-linked medical condition
31 could affect employment or insurance decisions. As a result, “domestic partner” is included in
32 the definition of family member for purposes of obtaining, retaining, using, and disclosing
33 genetic information.

34
35 This definition is not meant to affect other state law definitions of marriage or family.

36
37 *Paragraph (7). (Genetic counseling)* Genetic counseling is a key to an individual’s
38 informed decision making about getting a genetic test, understanding the result, and authorizing
39 its use, retention, or disclosure. Most states that license genetic counselors have a definition of
40 genetic counseling, but the majority of states do not license genetic counselors or regulate genetic
41 counseling. Note that the definition does not require that genetic counseling be performed by a
42 genetic counselor. Physicians and geneticists are also qualified to provide genetic counseling.

43
44 The definition uses the term genetic “condition,” which is intended to have a broad
45 interpretation. Genetic condition includes the concepts of genetic disease and disorder, but in
46 some circumstances it may also refer to a positive or benign trait or characteristic that is linked to

1 a particular genotype.

2
3 Genetic counseling is usually a two-step process consisting of 1) counseling before a test
4 about the decision whether or not to have the test and 2) counseling after the test if the test
5 indicates the individual is at risk, although for some conditions counseling may also be
6 appropriate if the test indicates the individual is not at risk. The functions listed in (A)-(C) of the
7 definition of genetic counseling take place before an individual decides whether or not to have
8 the test. The functions in (D) take place after the test, if necessary.

9
10 *Paragraph (8). (Genetic information)* This definition of “genetic information” is
11 modeled on state provisions that do not include family history in the definition. (Ark, Del, LA,
12 Minn, Neb, NH, NY, OK, OR, UT, VT) This narrow definition of genetic information is
13 important for Article 4 on life, disability-income, and long-term-care insurance, in which the
14 draft allows these insurers to continue to collect information on family history, even though
15 family history is a major source of information for evaluation an individual’s genetic risks.

16
17 Many states use a more comprehensive definition of “genetic information” that includes
18 information on genetic characteristics broadly, whether obtained from genetic tests or family
19 medical history. (Cal, Conn, Hawaii, LA, Maine, MD, Mass, Mich, NJ, NMex, NC, RI, SD, TX,
20 WA). In addition, H.R. 493 and S. 358, the federal bills to prohibit discrimination on the basis of
21 genetic information with respect to health insurance and employment introduced in January
22 2007, also use a broad definition. The federal definition provides that the term means
23 “information about (i) an individual’s genetic tests; (ii) the genetic tests of family members of the
24 individual; or (iii) the occurrence of a disease of disorder in family members of the individual.”
25 Information about the sex or age of an individual is excluded from this definition.

26
27 The drafting committee has endorsed using the broader meaning, including family
28 history, for Articles 2 and 3 on employment and health insurance. This meaning is conveyed in
29 these articles by combining the narrowly defined term “genetic information” with the term
30 “family medical history.”

31
32 Information about an individual’s request for or receipt of genetic services is included in
33 the category of genetic information for ease of drafting.

34
35 *Paragraph (9). (Genetic monitoring)* The definition of “genetic monitoring” is drawn
36 from the description in Office of Technology Assessment, *Genetic Monitoring and Screening in*
37 *the Workplace* 4 (1990). The focus in monitoring is not on inherited characteristics, but on
38 genetic alterations in a group of exposed individuals over time. Genetic monitoring is typically
39 undertaken by employers to identify risks for groups of employees who have been exposed to
40 hazardous substances or to target work sites for safety and health measures. Testing for this
41 purpose is permitted in Section 201.

42
43 *Paragraph (10). (Genetic service)* “Genetic service” is a broader category than genetic
44 testing. The term includes activities associated with obtaining genetic information that could
45 create assumptions about an individual’s genetic status even in the absence of information about
46 genetic test results or medical history. “Counseling” implies a one-on-one consultation, so the

1 definition also includes “genetic education” in order to capture group information sessions on
2 genetic conditions. Members of the drafting committee have expressed concern, however, that
3 “education” may make the definition too broad. While the definition of a “genetic service” does
4 not separately define the term “genetic,” the term should be interpreted to be consistent with the
5 definitions of “genetic test” and “genetic information.”
6

7 *Paragraph (11). (Genetic test)* “Genetic test” is defined in terms of (1) the material that
8 the test analyzes and (2) the purpose of the test. This structure and the lists in the definition are
9 derived from the definition of “genetic test” in the medical insurance provisions of H.R. 493 and
10 S. 358, federal bills to prohibit discrimination on the basis of genetic information with respect to
11 health insurance and employment introduced in January 2007.
12

13 The first clause makes specific reference to the types of biological material that are
14 currently analyzed in genetic tests. Note that genetic tests can be conducted not only on gene
15 sequences, but also on biological products such as proteins or metabolites that can indicate
16 genetic make-up. The second clause specifies that the test must be for the purpose of
17 determining an individual’s genetic make-up through the identification of a genotype, genetic
18 marker, mutation, or chromosomal change.
19

20 Both clauses are equally important to the definition. First, some of the materials listed in
21 the first clause, especially proteins and metabolites, are tested for many medical purposes. A test
22 of a protein or metabolite does not constitute a genetic test unless it is administered for the
23 purpose of determining individual’s genetic make-up as specified in the second clause.
24 Therefore, a test such as a cholesterol measurement, which does not identify a specific genotype,
25 would not be considered a genetic test under the draft. Second, some genetic diagnoses are made
26 without laboratory tests of the type listed in the first clause. For example, a doctor may identify a
27 genetic condition based on specific physical features occurring in combination, or
28 “dismorphology.” This physical diagnosis of an individual’s genetic-make-up does not constitute
29 a genetic test under the draft because it is not a test of “genetic material.”
30

31 Insurance industry representatives have expressed the fear that this definition is so broad
32 that it will sweep in routine medical tests such as cholesterol measurements. It is true that a
33 cholesterol test analyzes proteins. A cholesterol test is not, however, given specifically to detect
34 a genotype, genetic marker, mutation, or chromosomal change. Instead, a high cholesterol
35 reading may indicate an inappropriate diet, lack of exercise, and/or a condition called inherited
36 familial high cholesterol. If the measurement of cholesterol leads a doctor or insurance company
37 to do further testing to see if an individual has a specific genotype, then that would be a genetic
38 test under the draft’s definition.
39

40 The draft follows the example of states with definitions of genetic testing that are not
41 limited to identifying genotypes associated with diseases or impairments. (Fla, Haw, Mass, NH,
42 Ore, UT). In contrast, many other states statutes limit their definition of “genetic test” to testing
43 for disease-related genes. (Ariz, Ark, Del, Ill, Iowa, Kan, LA, Maine, MD, Mich, Minn, Nev,
44 MO, Neb, NJ, NM, NY, NC, OK, OR, RI, TX, VT, VA, WI). While most of the reasons that an
45 employer or insurer might currently seek or use genetic information probably involve a disease,
46 disorder, or impairment, this may not always be the case. One can imagine, for example, that the

1 presence or absence of behavioral traits might also be a criterion for selecting an employee.
2 While the current evidence linking behavior to genes is tenuous, this area continues to be the
3 subject of investigation. Moreover, a broad definition of “genetic test” will facilitate the
4 application of the statute to topics outside employment and insurance, if that is the direction the
5 National Conference of Commissioners on Uniform State Laws takes. For example, provisions
6 governing the retention of samples used for research or identification would cover testing that is
7 not necessarily linked to disease.
8

9 *Paragraph (12). (Health insurance)* The definition of “health insurance” is meant to be
10 broad. Definitions and terms of art vary greatly among the states. For example, a number of
11 states use the term “disability insurance” for what is commonly thought of as “health insurance.”
12 The definition is written in terms of functions and organizational structures and is intended to
13 capture the full range of health insurance without regard to specific state designations. It adopts
14 the broad framework used in Ala. Code § 27-53-1(3), supplemented with terms for health care
15 arrangements used in other states. In addition, the definition includes a “health care arrangement
16 in which risk is assumed,” which serves as a catch-all category. This concept is drawn from Fla.
17 Stat. § 627.4301.
18

19 *Paragraph (13). (Insured)* The definition of “insured” is intended to cover applicants for
20 insurance as well as those covered by insurance policies.
21

22 *Paragraph (14). (Insurer)* The definition of “insurer” is intended to cover broadly
23 insurance companies and other persons and individuals that issue health, life, disability-income,
24 or long-term-care insurance and all persons who might obtain, use, or disclose genetic
25 information associated with that process. Nothing in this definition is intended to subject
26 insurance agents, brokers, underwriters, or third-party administrators to insurance regulations to
27 which they are not already subject.
28

29 *Paragraph (15). (Licensing authority)* Licensing authorities serve as gatekeepers to
30 certain types of employment by providing credentials that are required either under state law or
31 by an employer. Examples include state bar and medical examination boards, which control
32 entry to the practice of law and medicine, and state departments of motor vehicles, which issue
33 commercial drivers licenses necessary for some employment.
34

35 *Paragraph (16). (Life insurance)* “Life insurance” is intended to be defined broadly.
36 This definition is drawn from N.H. Rev. Stat. § 401:1(III).
37

38 *Paragraph (17). (Long-term-care insurance)* The starting point for the definition of
39 “long-term-care insurance” is N.H. Rev. Stat. § 415-D:3(V). The definition is intended to
40 include all coverage of this nature whether it is provided on an expense-incurred, indemnity,
41 prepaid, or other basis.
42

43 *Paragraph (18). (Person)* This draft uses the broad version of the standard National
44 Conference of Commissioners on Uniform State Laws definition of “person.”
45

46 *Paragraph (19). (Predisposing genetic characteristic)* A “predisposing genetic

1 characteristic” refers to a genotype that signals an increased risk of a certain disease or condition.
2 The term does not include symptomatic diseases or conditions or genetic characteristics that are
3 manifest in a disease, medical condition, or disability. The broader terms “genetic test” and
4 “genetic information” may include both predisposing and manifest genetic characteristics as well
5 as genetic information that does not necessarily pertain to health.
6

7 While the terms “propensity” or “susceptibility” are often used, the actual manifestation
8 of a disease or condition may depend on a complex chain of events and the degree to which risk
9 is elevated may be quite small. “Predisposing genetic characteristic” is meant to signal the
10 tenuous connection between a genotype or marker and a physical manifestation.
11

12 *Paragraph (20). (Record)* The definition of “record” is the standard National Conference
13 of Commissioners on Uniform State Laws definition.
14

15 *Paragraph (21). (Sign)* The definition of “sign” is the standard National Conference of
16 Commissioners on Uniform State Laws definition.

1 [ARTICLE] 2

2 EMPLOYMENT

3 SECTION 201. GENETIC TESTING.

4 (a) Except as otherwise provided in this section or by law other than this [act], an
5 employer, employment agency, labor organization, or licensing authority may not require, offer,
6 or provide a genetic test to an employee.

7 (b) An employer, employment agency, labor organization, or licensing authority may
8 offer a genetic test and, with prior authorization for the test by an employee that meets the
9 requirements of Section 202, may provide the genetic test:

10 (1) to determine the employee's predisposing genetic characteristics that may
11 create susceptibility to harm to the employee from a workplace condition;

12 (2) to monitor the effects of the employee's exposure to a workplace condition as
13 part of a genetic monitoring program; or

14 (3) as part of a confidential, preventative health program for employees.

15 (c) An employer, employment agency, labor organization, or licensing authority that
16 offers a genetic test to an employee shall provide and pay for genetic counseling for the employee
17 about the risks and benefits of the genetic test before the employee considers authorizing the test
18 unless the employee knowingly and voluntarily waives counseling in a signed record that informs
19 the employee of the benefits of genetic counseling;

20 (d) An employer, employment agency, labor organization, or licensing authority that
21 provides a genetic test to an employee shall:

22 (1) pay for the genetic test;

23 (2) require the testing organization to report the test result to the employee and a

1 health-care professional designated by the employee unless the employee directs otherwise;

2 (3) provide and pay for genetic counseling for the employee about a positive test
3 result; and

4 (4) require the destruction of the employee’s biological sample obtained for a
5 genetic test as soon as permitted by law after the test is completed unless retention of the sample
6 is authorized by the employee, permitted by law other than this [act], or ordered by a court,
7 arbitral tribunal, or administrative agency.

8 (e) If a court, arbitral tribunal, or administrative agency orders an employee to undergo a
9 genetic test under Section 202(d), the employer, employment agency, labor organization, or
10 licensing authority shall provide and pay for the genetic test for the employee.

11 **Reporter’s Notes**

12
13 *Applicability of Article 2.* This article is intended to apply broadly in the employment
14 setting to an employer, employment agency, labor organization, or licensing authority.
15 Employment agencies, labor organizations, and licensing authorities are included because they
16 control access to employment through referrals or licensing.

17
18 *Relationship between genetic testing and access to genetic information.* Genetic testing
19 is a means by which an employer can obtain genetic information, but it is also possible for
20 employers to supply testing without gaining access to individualized test results. Therefore the
21 draft separates provisions on employer access to genetic information, treated in Section 203,
22 from the provisions in this section on genetic testing. An employer should supply testing through
23 an outside medical organization. *See* Mark A. Rothstein, *Genetics and the Workforce of the Next*
24 *Hundred Years*, 2000 Colum. Bus. L. Rev. 371 (2000).

25
26 *Genetic testing.* Many states broadly prohibit employers from subjecting employees to
27 genetic testing. *See, e.g.*, Iowa Code Ann. § 729.6 (employer may not “solicit, require, or
28 administer” a genetic test as a condition of employment); Kan. Stat. Ann. § 44-1009(a)(9)
29 (employer may not subject, directly or indirectly, any employee to any genetic screening or test);
30 Md. Code Art. 49B § 16(a) (employer may not “request or require” genetic tests as a condition
31 for hiring or determining benefits); Mass. Gen. L. Art. 151B § 4(19) (unlawful to “solicit
32 submission to, require, or administer a genetic test” as a condition of employment); Mich. Comp.
33 Laws § 37.1202 (no employer may require a genetic test as a condition of employment); Minn.
34 Stat. Ann. § 181.974(subd. 2) (employer may not “administer a genetic test” as a condition of
35 employment); Neb. Rev. Stat. § 48-236 (employer may not require a genetic test as a condition or
36 employment or promotion); Nev. Rev. Stat. § 613.345 (unlawful employment practice to “require

1 or administer” a genetic test as a condition of employment); N.H. Rev. Stat. § 141-H (may not
2 “solicit, require, or administer” genetic testing as a condition of employment); RI Stat. § 28-6.7-1
3 (employer may not “request, require, or administer” a genetic test); Utah Code Ann. § 26-45-103
4 (employer may not “request or require” an individual or blood relative to submit to a genetic test
5 in connection with an employment decision); Vt. Stat. Ann. § 9333 (may not require genetic
6 testing as a condition of employment); Va. Code Ann. § 40.1-28.7-1 (employer may not “request,
7 require, solicit, or administer” a genetic test as a condition of employment); Wash. Rev. Code
8 Ann. § 49.44.180 (unlawful to require employee to submit to genetic screening as condition of
9 employment); Wis. Stat. Ann. § 111.372 (employer may not “solicit, require, or administer” a
10 genetic test as a condition of employment unless employee requests test).

11
12 In contrast, this section does not prohibit testing entirely, but instead strictly limits the
13 purposes for which an employer may provide a genetic test.

14
15 *Subsection (a) General prohibition on genetic testing.* The general rule is that an
16 employer, employment agency, labor organization, or licensing authority may not offer or
17 provide genetic tests to employees. The other subsections establish limited exceptions and set
18 requirements for counseling and reporting that must be met if a genetic test is provided.

19
20 *Subsection (b) Acceptable purposes for an employer to supply genetic tests.* The draft
21 permits employers to offer genetic testing for three purposes: to determine predisposing
22 characteristics that may create susceptibility for harm to the employee due to workplace
23 conditions, to monitor exposure to workplace conditions as part of an ongoing program, and as
24 part of a confidential preventative health program for employees.

25
26 The drafting committee considered, but did not adopt, a provision that would permit
27 employers to supply genetic testing in order to protect the safety of other employees in the
28 workplace. It would be very rare for a genetic marker to indicate a safety threat to other
29 employees with sufficient certainty to justify a genetic test. The draft does not limit an
30 employer’s ability to take an employee’s manifested medical condition into account for safety
31 purposes, subject to the provisions of the Americans With Disabilities Act. In addition, Section
32 205 permits an employer to use an employee’s genetic information to protect health and safety if
33 the employee provides the genetic information to the employer in accordance with Section 203.

34
35 *Subsection (b)(1) Employee susceptibility.* Determining employee susceptibility to harm
36 from exposure to workplace substances, called “genetic screening,” is one situation in which
37 some states have permitted employers to test with the consent of the employee. Iowa, Louisiana,
38 New Hampshire, New York, and Wisconsin all have nearly identical provisions that permit
39 genetic testing of an employee to determine an employee’s susceptibility to toxic substances if
40 the employee requests testing, provides informed consent or authorization, and the employer does
41 not terminate the employee or take other adverse action as a result of testing. Iowa Code Ann. §
42 729.6(7); N.H. Rev. Stat. § 141-H:3; N.Y. Exec. Law § 296; Wis. Stat. Ann. § 111.372.

43
44 The utility of testing for susceptibility to workplace exposures is illustrated by chronic
45 beryllium disease. Beryllium is a lightweight metal used in many industries that poses the threat
46 of this disease when dust or fumes are inhaled. Industry protections have greatly reduced

1 exposure, but a small portion of the population can contract the disease even after a very brief
2 exposure. A genetic marker has reportedly been identified for this extreme sensitivity that
3 purports to show with certainty which individuals will contract beryllium disease and die from
4 short exposure. Cynthia Nance, Paul Miller, & Mark Rothstein, *Discrimination in Employment*
5 *on the Basis of Genetics*, 6 Employee Rights & Employment Policy Journal 57, 63-64 (2002). If
6 so, testing could provide information that could define an individual's risk from workplace
7 exposure to beryllium.

8
9 The draft allows an employer to supply testing for such susceptibilities, but unless the
10 employee volunteers the test results under Section 203(b), the employer is not authorized to
11 obtain them.

12
13 *Subsection (b)(2) Genetic monitoring program.* Monitoring for damage to employees'
14 genes from workplace exposure to harmful substances is another possible justification for testing.
15 The states that permit an employer to screen for genetic susceptibility to harmful workplace
16 substances also permit monitoring for exposure provided the employee requests testing, provides
17 informed consent or authorization, and the employer does not terminate the employee or take
18 other adverse action as a result of testing. Iowa Code Ann. § 729.6(7); N.H. Rev. Stat. § 141-
19 H:3; N.Y. Exec. Law § 296; Wis. Stat. Ann. § 111.372. In addition, Louisiana authorizes
20 monitoring of biological effects of toxic substances in the workplace if the employee has
21 provided authorization and is notified of the results. La. Rev. Stat. § 23:368. More generally, the
22 definitions and prohibitions in many state's statutes do not appear to restrict monitoring for
23 genetic damage, or are ambiguous on this issue.

24
25 Genetic damage is caused by mutagens, that is, substances that are capable of triggering
26 change in the genetic material of a cell. Genetic damage appears in the form of recessive and
27 dominant mutations, large rearrangements of DNA, point mutations, or loss of genetic material.
28 Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace* 71
29 (1990).

30
31 There are multiple genetic tests for exposure to mutagens at both the chromosomal and
32 molecular level. The most common indicators of chromosomal (cytogenic) damage are
33 chromosomal aberrations (CAs) and sister chromatid exchanges (SCEs). CAs are chromosomes
34 with breakage or rearrangements. *Id.* at 62. CAs are more likely to be induced by ionizing
35 radiation than chemical agents, but there are notable exceptions. For example, vinyl chloride
36 exposure results in increased CAs and places workers at risk of developing a form of liver
37 cancer. Workers exposed to benzene show elevated CAs and are at increased risk of leukemia.
38 *Id.* at 65. Sister chromatids are the two daughter strands of a duplicated chromosome. An
39 exchange results when apparently equivalent sections of the sister chromatids of the same
40 chromosome are switched during cell division. SCE is a sensitive marker for DNA damage and
41 repair that results only from chemical mutagens, not from radiation. *Id.* at 63.

42
43 As of 1990, no occupational studies had directly connected chromosomal abnormalities to
44 increased individual risk for disease. Thus, while CA and SCE monitoring may have predictive
45 value for a group, it is not a reliable way to predict health risks for an individual. *Id.* at 66.
46 Monitoring can, however, be used by employers to reduce exposures to known mutagens to a

1 level that does not affect individuals' chromosome morphology or DNA. Data on CAs are
2 routinely used by regulatory agencies in the process of setting exposure standards for industry.
3 *Id.*
4

5 There are also new techniques that measure exposure to mutagens at the molecular level.
6 They include measuring the frequency of lymphocytes (T-cells) in which the HPRT gene has
7 been inactivated by mutation; detecting DNA "adducts" (an alteration in which exogenous
8 material is bound to DNA); determining DNA repair (which indicates excision damage);
9 measuring the DNA content of cells as a means to detect tumors (which contain cells with
10 elevated levels of chromosomes); and detecting oncogenes (cancer-causing genes), which can be
11 activated by damage such as translocations, breaks, and deletions of DNA. *Id.* at 66-69. There
12 is a potential that detecting activated oncogenes and DNA adducts may eventually provide a
13 method for predicting disease in asymptomatic individuals. *Id.* at 71.
14

15 This draft recognizes the utility of monitoring in the workplace using such tests, and
16 permits employers to supply genetic testing as part of a genetic monitoring program. Employers
17 may not, however, have access to test results except in the aggregate, non-individually
18 identifiable form prescribed in Section 203(c).
19

20 *Subsection (b)(3) Employee health plan.* An employer that provides preventative health
21 services to encourage a healthy workplace may include genetic testing as part of those services.
22 The test results would not be available to the employer unless the employee volunteers them
23 under section 203(b).
24

25 *Subsection (c) Genetic counseling when an employer offers a test.* The draft requires
26 employers to provide genetic counseling about the risks and benefits of the test before signing the
27 authorization for testing, so that the employee can make an informed decision about whether or
28 not to have the test. The committee decided that an employee may, however, decline the
29 counseling.
30

31 Employer-provided genetic counseling should normally be conducted by professionals –
32 typically genetic counselors, geneticists, or physicians – from outside the employer organization.
33

34 *Subsection (d) Requirements when an employer provides a genetic test.*
35

36 *Subsection (d) (1) Payment.* This subsection imposes a payment obligation on the
37 employer who provides a genetic test.
38

39 *Subsection (d) (2) Reporting test results.* This subsection provides for reporting genetic
40 test results to the employee when an employer supplies testing. The reporting obligation is
41 incurred whether or not the employer may obtain the test results under Section 203. An employer
42 must be sensitive, however, to the fact that not all individuals wish to know their genetic
43 information. The draft recognizes an employee's right to decline to know the results of a genetic
44 test. An employee may not wish to be informed of the result because of the psychological
45 burdens that may accompany such knowledge.
46

1 *Subsection (d) (3) Genetic counseling.* Along with reporting test results to a health care
2 professional, the draft mandates the availability of genetic counseling so that the results can be
3 interpreted for the employee if the result is positive.
4

5 *Subsection (d)(4) Destruction of the sample obtained for testing.* The provision for
6 prompt destruction of a sample obtained for genetic testing supplied by an employer protects the
7 employee’s privacy by preventing subsequent testing of the sample. It also recognizes, however,
8 that a testing laboratory is required to retain samples for certain time periods for certification
9 testing and other purposes. The provision follows statutes adopted in New Jersey and Oregon.
10

11 Possible alternative approaches (1) put the burden on the employee by requiring that the
12 sample be destroyed promptly on the request of the individual tested or (2) specify that a sample
13 may be retained for a period of time. Some provisions combine elements of more than one
14 approach. In New York, for example, a sample may be retained for ten years if authorized by the
15 individual from whom the sample was obtained.
16

17 *Subsection (e) Legal proceedings.* This subsection requires an employer to supply the
18 genetic testing when a court, arbitral tribunal, or administrative agency has ordered that an
19 employer may obtain genetic information relevant to a claim or defense in a legal proceeding
20 under subsection 203(d).
21

22 **SECTION 202. EMPLOYEE AUTHORIZATION FOR A GENETIC TEST.**

23 (a) Except as otherwise provided by law other than this [act], an employee’s authorization
24 for a genetic test must be knowing and voluntary and indicated by a record signed by the
25 employee. The employer must provide and pay for genetic counseling for the employee prior to
26 the authorization unless the employee knowingly and voluntarily waives genetic counseling in a
27 signed record after receiving information about that genetic counseling;

28 (b) An authorization form for a genetic test for employment must:

29 (1) describe the genetic test to be performed, its purpose, and its permitted uses;

30 (2) inform the employee that only the authorized genetic test will be performed on
31 the employee’s biological sample;

32 (3) inform the employee that the employer, employment agency, labor
33 organization, or licensing authority is obligated to provide and pay for genetic counseling about

1 the risks and benefits of the test before the employee considers the authorization;

2 (4) inform the employee that the employer, employment agency, labor
3 organization, or licensing authority is obligated to provide and pay for genetic counseling about
4 the test result unless the employee waives genetic counseling.

5 (5) inform the employee that the test result will be reported to the employee and a
6 health-care professional designated by the employee unless the employee directs otherwise;

7 (6) include an opportunity for the employee to provide directions about reporting
8 test results and genetic counseling;

9 (7) inform the employee that the employee’s biological sample will be destroyed
10 as soon as permitted by law after the test is completed unless the employee authorizes retention
11 of the sample or unless otherwise ordered by a court, arbitral tribunal, or administrative agency;

12 and

13 (8) state that the employee is entitled to a copy of the authorization form.

14 **Reporter’s Notes**

15
16 The Drafting Committee has chosen to maintain privacy for genetic testing and genetic
17 information by establishing an authorization requirement that is coupled with statutory limits and
18 duties imposed on employers, employment agencies, labor organizations, and licensing
19 authorities. Under this approach, an employee must affirmatively authorize any genetic testing or
20 access, use, retention, or disclosure of genetic information. The authorization requirement is not
21 simply an extra procedural step because Article 2 establishes limitations on the situations in
22 which employers may request authorization from employees.

23
24 The drafting committee considered, but did not adopt alternatives that would (1) establish
25 a general property right in a biological sample an individual provides for genetic testing and in
26 the resulting genetic information or (2) establish a limited property applicable only to the context
27 of employment.

28
29 This section deals with genetic testing. It sets forth an authorization requirement and the
30 elements that must be contained in an authorization form. The term “authorization” is used
31 instead of “informed consent” to avoid confusion with the use of that term in medical practice.

32
33 *Subsection (a) Requirement for authorization for genetic testing.* Under Section 201, an

1 employer, employment agency, labor organization, or licensing authority may supply genetic
2 tests under certain circumstances but only with prior authorization from the employee.

3
4 In order to meet the requirement of this subsection that an authorization be knowing and
5 voluntary, an employee or insured should have genetic counseling before signing the
6 authorization. Genetic counseling provides employees or insureds with adequate information to
7 make an informed decision about genetic testing. It also makes them aware of their options
8 regarding reporting of test results and help in interpreting them through genetic counseling. An
9 employer, employment agency, labor organization, or licensing authority that offers a genetic test
10 has an obligation to provide genetic counseling at the employer's cost under Section 201(c).
11 Genetic counseling may be provided by a genetic counselor, but may also be provided by a
12 qualified physician or geneticist. An employee may waive genetic counseling, but must first be
13 made aware of the benefits of genetic counseling.

14
15 The Drafting Committee anticipated that there might be circumstances in which an
16 individual is incapacitated or incapable of authorizing a genetic test. This situation is left to
17 existing law of the state that provides for power of attorney, guardianship, or other substitute
18 decision makers.

19
20 An open question for Drafting Committee consideration is whether circumstances of
21 incapacity should be treated in the reporter's notes or a provision should be added to the text.

22
23 *Subsection (b) Content of authorization for testing.* The section draws on N.Y. Civ.
24 Rights Law § 79-1 (McKinney), which establishes requirements for consent for a genetic test.

25
26 The limitation in (b)(2) to the authorized test is consistent with the requirements for prior
27 authorization in Section 201.

28
29 The requirements in subsection (b)(3)-(6) reflect the obligation of the employer,
30 employment agency, labor organization, or licensing authority to provide genetic counseling
31 under Section 201(c).

32
33 The notification provision for retention of the sample in (b)(7) is consistent with the
34 employer's obligation to ensure the sample is destroyed under Section 201(c)(3), which
35 recognize that the testing laboratory may be required to retain the sample for certification
36 purposes.

37
38 The following is a sample form that could be used to authorize genetic testing by an employer.

39
40 Authorization for Genetic Testing

41
42 Limited Authorization

43 Only the genetic tests that you authorize on this form will be performed on your biological
44 sample. These tests are voluntary.

45
46 Availability of Genetic Counseling

1 Before you complete this authorization form, it is highly recommended that you meet with a
2 genetic counselor who will help you understand and evaluate the risks and benefits of having the
3 tests listed below. [Name of employer, employment agency, labor organization, or licensing
4 authority] will provide and pay for this genetic counseling.
5

6 Proposed Genetic Tests

7 [Name of employer, employment agency, labor organization, or licensing authority] proposes to
8 provide the following genetic tests:
9

- 10 _____ [Name of test]
11 The purpose of this test is to determine if you have a genetic characteristic that
12 predisposes you to harm from _____ [workplace condition]. [Name of
13 employer, employment agency, labor organization, or licensing authority] may not request
14 or require you to disclose this test result and it will not have access to the test result
15 unless you authorize it. If you authorize [employer, employment agency, labor
16 organization, or licensing authority] to have access to the test result, it will be used only
17 for the following purposes: _____.
18
- 19 _____ [Name of test]
20 This test is provided as part of a genetic monitoring program. The purpose of this test is
21 to monitor the effect of your exposure to _____ [workplace condition]. The
22 result of the test will be used only for the following purposes: _____.
23 [Name of employer, employment agency, labor organization, or licensing authority] will
24 have access to the test results of all employees who authorize this test only in an
25 aggregate form that does not include individually identifiable information.
26
- 27 _____ [Name of test]
28 This test is provided as part of a confidential preventative health plan. The purpose of the
29 test is _____. [Name of employer, employment agency, labor
30 organization, or licensing authority] may not request or require you to disclose this test
31 result and it will not have access to the test result unless you authorize it. If you authorize
32 access to the test result, it will be used only for the following purposes: _____.
33

34 Reporting Test Results and Genetic Counseling

35 The test results will be reported to you and to a health-care professional who you designate
36 unless you direct otherwise. It is recommended that you receive genetic counseling about the test
37 results. _____ [Name of employer, employment agency, labor
38 organization, or licensing authority] will provide and pay for genetic counseling about the test
39 results unless you decline genetic counseling.
40

- 41 I wish to receive test results.
42 I do not wish to receive test results.
43
- 44 Report test results to the following health care professional:
45 Name: _____
46 Address: _____

1 Do not report test results to a health care professional.

2
3 I wish to receive genetic counseling about the test results.

4 I decline genetic counseling about the test results.

5
6 Destruction of your Biological Sample

7 After the genetic test, your biological sample will be destroyed as soon as permitted by law
8 unless you choose to authorize otherwise in writing or a court, arbitral tribunal, or administrative
9 agency requires retention of the sample.

10
11 Copy of this form

12 You are entitled to a copy of this authorization form.

13
14 I _____ [print name] authorize the genetic test(s) I have checked above.

15
16
17 _____
18 Signature

Date

19 **SECTION 203. ACCESS TO GENETIC INFORMATION.**

20 (a) Except as otherwise provided in this section, an employer, employment agency, labor
21 organization, or licensing authority may not knowingly obtain or directly or indirectly inquire
22 about, request, or require an employee to provide an employee's genetic information or family
23 medical history.

24 (b) An employer, employment agency, labor organization, or licensing authority may
25 access an employee's genetic information or family medical history if the employee voluntarily
26 submits the employee's genetic information or family medical history to the employer,
27 employment agency, labor organization, or licensing authority. If an employee voluntarily
28 submits genetic information or family medical history retained by a source other than the
29 employee, the employee must authorize the employer's access in accordance with Section 208.

30 (c) If an employer, employment agency, labor organization, or licensing authority offers a
31 genetic test as part of a genetic monitoring program under Section 201, the employer,
32 employment agency, labor organization, or licensing authority must receive the genetic test

1 results in an aggregate form that does not disclose individually identifiable information.

2 (d) An employer, employment agency, labor organization, or licensing authority may
3 obtain genetic information or family medical history about an employee without the employee's
4 authorization if:

5 (1) the employee has placed the employee's health at issue in a judicial, arbitral,
6 or administrative agency proceeding in which the employer, employment agency, labor
7 organization, or licensing authority is a defendant;

8 (2) the genetic information or family medical history is relevant to a claim or
9 defense in the proceeding; and

10 (3) on a motion by the employer, employment agency, labor organization, or
11 licensing authority a court, arbitral tribunal, or administrative agency orders the employee to
12 undergo a genetic test or provide genetic information or family medical history after finding that
13 the employer, employment agency, labor organization, or licensing authority has demonstrated
14 compelling need and that the information is otherwise unavailable.

15 **Reporter's Notes**

16
17 *Existing state law.* An employer, employment agency, labor organization, or licensing
18 authority gets health information in a variety of ways including applications, interviews,
19 references, post-offer medical exams, post-offer releases of medical records, Family and Medical
20 Leave Act requests, workers' compensation claims, health insurance claims to self-insured
21 employers, and voluntary disclosures by employees. Many states have tried to limit employer
22 access to genetic information. There are statutes that prohibit an employer from requiring,
23 requesting, or administering genetic testing, obtaining genetic information, making inquiries
24 about genetic information, or some combination of these methods of accessing genetic
25 information. (Conn, Del, Iowa, Kan, MD, Mass, Mich, Minn, Neb, Nev, NH, NY, OR, RI, Tex,
26 UT, VT, VA, WA, WI).

27
28 *Privacy rationale.* One rationale for limiting employer access to genetic information is
29 the view that an employee should be able to keep genetic information private. At least one state
30 has a constitutional right of privacy that appears to be relevant to genetic information. (Alaska)
31 Another rationale is to make genetic discrimination less likely. Unlike discrimination based on
32 sex or race, an employer cannot discriminate on the basis of genetic characteristics unless it has

1 access to genetic information.
2

3 Scholars have argued that a privacy rationale makes more sense for protecting genetic
4 information in the employment context than an anti-discrimination rationale. Statutory
5 protections based on anti-discrimination rationales are designed for socially-recognized groups
6 that have been historically disadvantaged. Genetic variations do not fit especially well within
7 this paradigm. *See, e.g.,* Pauline T. Kim, *Genetic Discrimination, Genetic Privacy: Rethinking*
8 *Employee Protections for a Brave New Workplace*, 96 NW U. L. Rev. 1497 (2002).
9

10 *Subsection (a) Access to genetic information.* The draft permits an employer,
11 employment agency, labor organization, or licensing authority to access genetic information
12 about an employee at the employee’s instigation only. This follows the approach of a number of
13 states that restrict an employer’s ability to require or obtain genetic information. *See, e.g.,* Conn.
14 Stat. Ann. § 46a-60(11) (employer may not “request or require” genetic information from
15 employee); Kan. Stat. Ann. § 44-1009(a)(9) (employer may not seek to obtain, obtain, or use
16 testing information to distinguish employees or restrict a right or benefit); La. Rev. Stat. § 23:368
17 (employer may not “require, collect, or purchase” protected genetic information with respect to
18 an employee); Md. Code Art. 49B § 16(a) (employer may not “request or require” genetic
19 information as a condition for hiring or determining benefits); Mass. Gen. L. Art. 151B § 4(19)
20 (unlawful to “collect, solicit or require disclosure of genetic information” as a condition of
21 employment); Mich. Comp. Laws § 37.1202 (no employer may “directly or indirectly acquire or
22 have access to” an employee’s or family member’s genetic information unless an individual
23 provides it voluntarily); Minn. Stat. Ann. § 181.974(subd. 2) (employer may not “request,
24 require, or collect” protected genetic information as a condition of employment); Neb. Rev. Stat.
25 § 48-236 (employer may not require genetic information as a condition or employment or
26 promotion); Utah Code Ann. § 26-45-103 (employer may not “access or otherwise take into
27 consideration” private genetic information in connection with an employment decision); Wash.
28 Rev. Code Ann. § 49.44.180 (unlawful to require employee to submit genetic information as
29 condition of employment).
30

31 The draft also allows employees to keep private information that could lead to
32 discrimination based on assumptions about genetics, even in the absence of genetic information.
33 It does this by including information about requests for or receipt of genetic services in the
34 definition of genetic information. If an individual is unable to keep private his use of genetic
35 services such as counseling, the individual may be deterred from obtaining this service for fear
36 that an employer will assume the employee has reason to think he has a genetic disorder.
37

38 The draft follows a number of state statutes that prohibit employers from accessing or
39 using information about an employee’s request for or use of genetic services. *See, e.g.,* La. Rev.
40 Stat. § 23:368 (employer may not “require, collect, or purchase” information about an
41 employee’s request for or use of genetic services); Maine Rev. Stat. Ann. § 19302 (employer may
42 not discriminate on basis that an individual received a genetic test or genetic counseling except
43 when based on a bona fide occupational qualification); N.C. Gen. Stat. Ann. § 95-28.1A
44 (unlawful to deny employment of account of request for genetic testing or counseling services);
45 Utah Code Ann. § 26-45-103 (employer may not inquire into whether an individual or blood
46 relative has taken or refused to take a genetic test); Vt. Stat. Ann. § 9333 (employer may not use

1 the fact that genetic counseling or tested services have been requested or performed).

2
3 The draft's approach to employer access is in contrast to that of anti-discrimination
4 statutes, which typically allow employers to compel testing or to require employees to provide
5 genetic information under certain circumstances. Most of the states that rely on disability
6 statutes to regulate genetic information follow the Americans with Disabilities Act (ADA),
7 which permits an employer to test an applicant and access an applicant's medical records after a
8 conditional offer of employment. 29 C.F.R. § 1630.14(b). This approach opens the door broadly
9 to genetic information once an employer has made a conditional offer of employment. In
10 addition, under the ADA and most state statutes modeled on it, after an employee is hired, an
11 employer can obtain medical information if it has a reasonable belief that the employee is unable
12 to perform the essential functions of his or her job due to a medical condition. 29 C.F.R. §
13 1630.14(c). States that have amended their employment discrimination statutes to include
14 genetics usually follow the rubric of these statutes and permit genetic testing or collection of
15 genetic information when it is relevant to "job-related qualifications" or justified by "business
16 necessity." However, members of the drafting committee were concerned that tying the Act's
17 protections to the concept of "job-related" medical information would not provide adequate
18 protection for genetic information. In interpreting the ADA, some courts have interpreted that
19 category broadly to permit employers to access medical information, thus narrowing the scope of
20 protection.

21
22 The draft's approach also contrasts with California's and Minnesota's more
23 comprehensive limitations on employer access, which prohibit employers from accessing non-job
24 related medical information at any time. An advantage of California's and Minnesota's approach
25 is that it does not depend on how "genetic information" is defined. In addition, it does not rely
26 on custodians of medical files to make a distinction between genetic information and medical
27 information more generally, which are usually mixed in medical files. Practically speaking,
28 when an employee signs a release permitting employer access to medical records, everything in
29 the records is included. There are those who maintain that legislation is needed to limit an
30 employer's ability to obtain any non-job-related health information during the hiring process or
31 employment. See Mark A. Rothstien, *Genetic Exceptionalism and Legislative Pragmatism*, 35
32 Hastings Center Report No. 4 (2005), at 35. The drafting committee discussed this approach, but
33 declined to adopt it because it extends beyond the scope granted to the committee.

34
35 The prohibition on seeking or inquiring about genetic information is not intended to
36 prevent an employer from informing an employee about the availability of a genetic test that is
37 relevant to conditions in the workplace or from informing an employee about a genetic
38 monitoring program.

39
40 If an employee authorizes employer access to genetic information, the conditions under
41 which an employee grants that authorization are important. Some states permit employers to
42 request genetic information under the apparent assumption that an employee's consent to an
43 employer's request is voluntary. It is possible, however, to argue that in the context of at-will
44 employment, the need to retain one's job may turn an employer's request for genetic information
45 into a demand that an employee dare not refuse. Thus some statutes prohibit even requests or
46 inquiries. See, e.g., Mass. Gen. L. Art. 151B § 4(19) (unlawful to "question a person about their

1 genetic information or genetic information concerning their family members”); Nev. Rev. Stat. §
2 613.345 (unlawful employment practice to “ask or encourage” an employee to submit to a
3 genetic test). This draft follows that approach.
4

5 A more stringent level of protection could protect workers from ever providing genetic
6 information or authorizing access, even on their own initiative. But a blanket prohibition on any
7 disclosure arguably goes too far. It would prevent an employee from sharing information that
8 could be used to protect the person from situations in which the employee is genetically
9 susceptible to harm. In addition, it would make it easy to violate the act inadvertently by
10 disclosing information an employee does not realize is genetic information. Instead, this draft
11 follows a middle approach that permits employees to volunteer genetic information, but does not
12 generally permit employers to require it.
13

14 *Subsection (b) Voluntary provision.* Employees who provide genetic information
15 voluntarily may do so directly, through oral statements or by turning over reports of test results.
16 They may also do so by permitting an employer to see medical records held by a third party. In
17 the case of disclosures made by a third party to an employer, the draft requires prior authorization
18 by the employee. The prohibition on employer inquiries is intended to apply to inquiries directed
19 to other entities as well as to inquiries directed to the employee.
20

21 A complication is that employers who have access to medical records (which is permitted
22 under the ADA after a conditional offer of employment or during employment for job-related
23 purposes) will in practical terms also have access to genetic information because it is interspersed
24 throughout medical records. An employer that requests any medical information is likely to
25 receive the entire file, including genetic information. The committee considered the fact that
26 mental health records are kept separate from medical records and HIPAA requires a separate
27 authorization before they can be disclosed. However, mental health records are not determined
28 by the content of the record, but as those kept by a psychologist or psychiatrist. The committee
29 considered, but rejected, requiring genetic tests to be kept in a separate record. An alternative
30 solution would be to develop technologies that can limit the scope of information disclosed by
31 health care providers. Mark A. Rothstein & Meghan Talbott, *Compelled Disclosure of Health*
32 *Information: Protecting Against the Greatest Potential Threat to Privacy*, 295 JAMA 2882
33 (2006).
34

35 *Subsection (c) Genetic monitoring programs.* Genetic monitoring programs are typically
36 undertaken by employers to identify risks for groups of employees who have been exposed to
37 hazardous substances or to target work sites for safety and health measures. Monitoring is testing
38 designed to detect whether the genetic material of a group of individuals has changed over time.
39 The premise is that such changes could indicate increased risk of future illness. Aggregated data
40 from tests for genetic damage is sufficient to allow an employer to reduce exposures to levels that
41 do not affect individuals’ chromosome morphology or DNA. Office of Technology Assessment,
42 *Genetic Monitoring and Screening in the Workplace* 66 (1990). However, while monitoring may
43 have predictive value for a group, the techniques that are used do not currently measure increased
44 individual health risks.
45

46 This subsection permits employers to access genetic information as part of a genetic

1 monitoring program. Section 201 permits an employer to offer employees genetic tests as part of
2 a monitoring program and section 205 permits employers to use genetic information for
3 monitoring purposes. The rationale for genetic monitoring programs is discussed in more depth
4 in the Reporter’s notes to section 201.
5

6 *Subsection (d) Legal proceedings.* This draft provides for an employer to obtain an
7 employee’s genetic information if the employee places his health at issue in a legal proceeding.
8 This right is limited in that it applies only if the employer has satisfied the burden of proof to
9 show compelling need and that the information is otherwise unavailable. Only that portion of an
10 employee’s genetic information that is relevant to a claim or defense may be provided. This
11 subsection is meant to operate in conjunction with subsection 205(a)(3), which permits an
12 employer to use genetic information in a legal proceeding. Subsection 201(c) requires the
13 employer to pay for this test. These procedures provide more protection than Rule 35 of the
14 Federal Rules of Civil Procedure or state equivalents, which provide that a court may order a
15 physical examination on motion for good cause shown. The drafting committee considered a
16 requirement that the genetic test results be sealed or placed under a protective order, but decided
17 to leave this to existing law.
18

19 The substance of the subsection follows Utah’s statute, which authorizes genetic testing
20 when an employee has placed his or her health at issue in a proceeding, but only by order of a
21 court or administrative agency after finding compelling need and that the information is
22 otherwise unavailable. Utah Code Ann. § 26-45-103(2). Other states have more narrowly
23 authorized employer testing to investigate a workers’ compensation claim. (NH, NY).
24

25 **SECTION 204. PROHIBITION ON USE OF GENETIC INFORMATION.** Except
26 as otherwise provided in Section 205(a)(1), an employer, employment agency, labor
27 organization, or licensing authority may not take an adverse employment action against an
28 employee based on the employee’s genetic information or family medical history.

29 **Reporter’s Notes**
30

31 Many state statutes limit use of genetic information by prohibiting discrimination among
32 employees or applicants for employment on the basis of genetic information. (Ark, Ill, Kan, LA,
33 Maine, MD, Mass, Mich, MO, Neb, Nev, NJ, NY, NC, OK, OR, RI, SD, Tex). Others more
34 generally ban any use of genetic information in employment. For example, New Mexico’s 2005
35 statute provides simply that “[i]t is unlawful for a person to use genetic information in
36 employment, . . .” In Utah, employers may not take into account genetic information about an
37 individual in connection with an employment decision. Similarly, in Iowa, an employer may not
38 use genetic information to “affect the terms, conditions, or privileges of employment” of a person
39 who gets a genetic test. Iowa Code Ann. § 729.6(2).
40

41 This draft follows the example of Minnesota and Wisconsin, which prohibit adverse

1 employment actions based on genetic information. Minn. Stat. § 181.974 subd. 2(a)(2) (may not
2 “affect the terms or conditions of employment or terminate the employment of any person based
3 on protected genetic information”); Wis. Stat. § 111.375 (may not “affect terms, conditions or
4 privileges of employment, labor organization membership or licensure or terminate the
5 employment labor organization membership or licensure”). The term used in the draft, “adverse
6 employment decision” is a term of art in employment law that does not need to be defined in this
7 act.
8

9 This restriction on employment actions is particularly important because of uncertainty
10 about how courts will apply federal statutes to decisions based on genetic information that
11 predicts employee susceptibility to harm from workplace exposures. On one hand, in 1991 the
12 United States Supreme Court held that a chemical company’s policy barring women of child-
13 bearing age from employment opportunities that involved exposure to lead violated Title VII
14 prohibitions on gender discrimination. *International Union v. Johnson Controls*, 499 U.S. 187
15 (1991). On the other hand, the ADA allows employers to act on health information, even in the
16 case of disability, when there is a direct threat to the health or safety of others in the workplace.
17 The Equal Employment Opportunity Commission (EEOC) has interpreted this ADA provision to
18 apply when there is no risk to others but when an employer can show that an individual’s
19 disability poses a significant risk of harm to the individual. The United States Supreme Court
20 upheld this interpretation. *Chevron v. Echazabal*, 122 S. Ct. 2045 (2002). Although the
21 *Echazabal* case did not involve a genetic characteristic, but rather a worker’s liver damage due to
22 exposure to workplace solvents, the implication of the case is that in the absence of a prohibition
23 in a state statute, an employer may make adverse employment decisions based on genetic
24 screening or monitoring requested by an employee even if there is no threat to others. This
25 section, in conjunction with section 204(a), would not permit an employer to take an adverse
26 employment action unless an employee has a genetic characteristic that creates a direct threat of
27 harm to others. Harm to the employee is not a justification. As a result, employers would not be
28 able to use an employee’s genetic information in the way the employee’s health information was
29 used in the *Echazabal* case.
30

31 Note that because the section uses the term “genetic information,” which is defined with
32 reference to a “genetic test,” it does not necessarily prevent an employer from making decisions
33 based on the effects of an employee’s manifest genetic condition or disease in the workplace.
34 Some employees with genetic conditions would be covered under the ADA if the condition limits
35 a major life activity, but there is no comprehensive protection for individuals with medical
36 conditions that result from genetic traits. While some maintain that attempts to prevent genetic
37 discrimination are mostly meaningless without protection for people who have genetic diseases,
38 see Mark A. Rothstein, *Genetic Privacy and Confidentiality: Why They are so Hard to Protect*,
39 26 J. L. Med. & Ethics 181 (1998), others emphasize the difficulties with either policy choice,
40 see Henry T. Greely, *Genotype Discrimination: The Complex Case for Some Legislative*
41 *Protection*, 149 U. Pa. L. Rev. 1483, 1503 (2001).
42

1 create this type of threat and the drafting committee has been unable to identify any known
2 genetic trait that would qualify.

3
4 *Subsections (a)(2) and (a)(3). Monitoring programs or legal proceedings.* This
5 subsection permits an employer to use genetic information for a monitoring program or
6 defending a legal proceeding, which is consistent with the purposes for which an employer may
7 access an employee’s genetic information under Section 203.

8
9 *Subsection (b). Employee susceptibility to harm in the workplace.* This subsection, in
10 combination with section 204, follows the lead of the states that permit genetic testing to
11 determine susceptibility to harm from a workplace substance only when an employer does not
12 use the information to terminate or take other adverse action against the employee. *See* Iowa
13 Code Ann. § 729.6(7); N.H. Rev. Stat. § 141-H:3; N.Y. Exec. Law § 296; Wis. Stat. Ann. §
14 111.372. An employer may offer genetic testing to screen for susceptibility to harm under
15 section 201, but may not access the results of the testing without authorization from the
16 employee. If an employee volunteers genetic information about susceptibility to harm from
17 workplace exposures under section 203, the draft permits the employer to reduce the potentially
18 harmful exposure, but not to make an employment decision that would adversely affect the
19 employee.

20
21 The Brush-Wellman company in Cleveland, Ohio, developed a program (since
22 discontinued) that provides a model for permissible use of screening or monitoring information.
23 Brush-Wellman conducted genetic tests for its employees who work with beryllium, but the
24 testing was voluntary and confidential. Moreover, the test results were provided to the employee,
25 who made the decision on what action to take. The company took no action against the
26 employee as a result of the genetic testing. Cynthia Nance, Paul Miller, & Mark Rothstein,
27 *Discrimination in Employment on the Basis of Genetics*, 6 Employee Rights & Employment
28 Policy Journal 57, 64-65 (2002).

29
30 **SECTION 206. ACCESS TO GENETIC INFORMATION BY EMPLOYEE.**

31 (a) Except as provided in subsection (b), an employee may inspect, request correction of,
32 or obtain a copy of the employee’s genetic information or family medical history from any record
33 of an employer, employment agency, labor organization, or licensing authority which contains
34 the information. If an employee requests correction of genetic information or family medical
35 history, the employer, employment agency, labor organization, or licensing authority shall
36 include the request for correction and supporting data in the employee’s record.

37 (b) Except as otherwise provided by law other than this [act], an employee may not access

1 genetic information or family medical history compiled in reasonable anticipation of, or for use
2 in, a civil, criminal, arbitral, or administrative proceeding.

3 **Reporter's Notes**

4
5 This section is based on the conclusion that an employee ought to be able to find out what
6 genetic information an employer knows about an employee and to have the same information. It
7 is based on 16 Del. Code § 1223. It also provides a mechanism for an employee to correct
8 genetic information contained in employer records.
9

10 If the employer supplied the genetic testing, information may also be kept in files at the
11 laboratory that performed the testing. The employer's responsibility to correct errors does not
12 extend to the testing laboratory, which is regulated under the Clinical Laboratory Improvement
13 Amendments, (CLIA), 42 U.S.C. § 263a.
14

15 The section makes an exception for information compiled for litigation, except to the
16 extent the employee has a right of access under the discovery rules. This exception is drawn
17 from the HIPAA Privacy Rule. 45 C.F.R. § 164.524.
18

19 **SECTION 207. CONFIDENTIALITY; RETENTION AND DISCLOSURE OF** 20 **GENETIC INFORMATION.**

21 (a) Except as otherwise provided in subsection (e), an employer, employment agency,
22 labor organization, or licensing authority shall treat an employee's genetic information, family
23 medical history, or authorization for an employer, employment agency, labor organization, or
24 licensing authority to supply genetic testing or to obtain, retain, or disclose genetic information as
25 a confidential record.

26 (b) Except as provided in subsection (e), if an employee authorizes an employer,
27 employment agency, labor organization, or licensing authority to retain a record of an employee's
28 genetic information or family medical history, the employer, employment agency, labor
29 organization, or licensing authority shall retain the record or require the record to be retained
30 separately from the employee's personnel files.

31 (c) An employer, employment agency, labor organization, or licensing authority that is

1 authorized under this [article] to supply genetic testing or to access, retain, or disclose genetic
2 information or family medical history shall retain the authorization or require the authorization to
3 be retained separately from the employee’s personnel files. The employer, employment agency,
4 labor organization, or licensing authority shall retain a record of the authorization for six years
5 from the date the authorization was created or the date the authorization expired, whichever is
6 later.

7 (d) Except as otherwise provided in subsection (e) or as necessary to defend a claim in a
8 judicial, arbitral, or administrative proceeding, an employer, employment agency, labor
9 organization, or licensing authority may not disclose an employee’s individually identifiable
10 genetic information to a person other than the employee unless the employee authorizes the
11 disclosure or unless otherwise ordered by a court, arbitral tribunal, or administrative agency.

12 (e) This section does not apply to an employee’s genetic information obtained in
13 aggregate form pursuant to Section 203(c) for use in a genetic monitoring program.

14 **Reporter’s Notes**

15
16 *Subsection (a) Confidentiality.* This subsection declares that genetic information, family
17 medical history, and authorizations concerning genetic tests or information is confidential in the
18 employment context. “Genetic information” is a category that includes information about use of
19 or request for genetic services.
20

21 *Subsection (b) Retention of genetic information or family medical history.* If an
22 employer obtains any genetic information or family medical history under Section 203, it needs
23 the employee’s authorization under Section 208 to retain the information. The separate storage
24 requirement serves to protect the employee’s privacy and is modeled on La. Rev. Stat. §
25 23:368(B).
26

27 Under Section 209, an employee may revoke this authorization under certain
28 circumstances.
29

30 *Subsection (c) Retention of employee authorizations.* An employee’s authorizations for
31 genetic testing or employer access, retention, or disclosure of genetic information under Sections
32 202 or 208 are also confidential records that must be kept separate from the employee’s
33 personnel files. The provision that the authorization must be retained for six years is adapted

1 from the HIPAA regulations that govern documentation and retention of a signed authorization.
2 45 C.F.R. §§ 164.508 (b) (6), § 164.530(j).

3
4 *Subsection (d) Disclosure of genetic information or family medical history.* The draft is
5 consistent with disclosure provisions in a number of states that have enacted (1) general privacy
6 protections for genetic information that prohibit disclosure without informed consent or
7 authorization (Alaska, Cal, Del, Fla, Maine, Mass, Nev, NH, NJ, NMex, NY, OR) or (2) specific
8 protections against the disclosure of genetic information by employers (Ariz, Fla, LA, Mass,
9 NH, NJ, Or, RI).

10
11 *Subsection (e) Genetic monitoring program.* An employer may retain and disclose
12 genetic information without an employee’s specific authorization for a genetic monitoring
13 program. An employer is allowed access to this information only in an aggregate form that does
14 not identify individual employees, which should minimize the effects of retaining monitoring
15 information for an employee’s privacy. An employer may need to disclose aggregate monitoring
16 information in order to analyze trends or take action to reduce risk in the workplace.
17

18 **SECTION 208. AUTHORIZATION FOR ACCESS, USE, RETENTION, OR**
19 **DISCLOSURE OF GENETIC INFORMATION OR FAMILY MEDICAL HISTORY.**

20 (a) Except as otherwise provided by this [act] or by law other than this [act], an
21 employer, employment agency, labor organization, or licensing authority may not access, use,
22 retain, or disclose an employee’s genetic information or family medical history without the
23 employee’s knowing and voluntary authorization indicated by a record signed and dated by the
24 employee. An employer, employment agency, labor organization, or licensing authority that
25 receives a valid authorization to access, use, retain, or disclose genetic information or family
26 medical history may do so only in accordance with the authorization.

27 (b) An authorization form to access, use, retain, or disclose an employee’s genetic
28 information or family medical history must:

29 (1) describe the genetic information or family medical history to be accessed,
30 used, retained, or disclosed in a specific and meaningful fashion;

31 (2) identify or describe the person that is authorized to access, use, retain, or

1 disclose the genetic information or family medical history;

2 (3) if the authorization is for access to genetic information or family medical
3 history through disclosure by another person to an employer, employment agency, labor
4 organization, or licensing authority insurer, identify or describe the person authorized to make
5 the disclosure;

6 (4) if the authorization is for use of genetic information or family medical history,
7 describe the permitted uses;

8 (5) if the authorization is for retention of genetic information or family medical
9 history, describe where the information will be retained and identify or describe the custodian of
10 the information;

11 (6) if the authorization is for disclosure to a third person, identify or describe the
12 third person to which the authorized person may disclose the genetic information or family
13 medical history;

14 (7) if the authorization is for disclosure to a third person, state that the genetic
15 information or family medical history disclosed by the authorized person may be subject to
16 redisclosure by the recipient and no longer be protected;

17 (8) indicate the duration of the authorization with an expiration date or expiration
18 event that relates to the employee or to the purpose of the access, use, retention, or disclosure;

19 (9) state that the employee may revoke the authorization at any time in a signed
20 record, subject to the right of a person that acted in reliance on the authorization before receiving
21 notice of revocation, and provide instructions on how to revoke an authorization; and

22 (10) state that the employee is entitled to a copy of the authorization form.

23 (c) An employee may amend the employee's authorization for an employer, employment

1 agency, labor organization, or licensing authority to access, use, retain, or disclose the
2 employee’s genetic information or family medical history.

3 **Reporter’s Notes**

4
5 This section requires an employee to provide an authorization before an employer,
6 employment agency, labor organization, or licensing authority may access, use, retain or disclose
7 genetic information or family medical history.

8
9 The draft does not disturb existing law that allows a minor to seek repudiation of consent
10 and expunge records when the minor reaches the age of majority.

11
12 *Subsection (a) General requirement for authorization.* This subsection would establish a
13 requirement that an employer, employment agency, labor organization, or licensing authority
14 must be authorized by the employee before it may access, retain, or disclose genetic information,
15 except as provided elsewhere in the act. In order to give a valid authorization, the employee
16 must be informed as provided in the following subsections and must act voluntarily. This
17 subsection also includes a requirement that an authorization must be indicated by a signed and
18 dated record. This authorization requirement is coupled with limitations on access, use,
19 retention, and disclosure in Sections 203, 204, 205, and 207.

20
21 Other law of the state may provide for a substitute decisionmaker or signer if the
22 employee is incapacitated or incompetent. This situation is left to existing law of the state that
23 governs power of attorney, guardianship, or other substitute decision makers. The drafting
24 committee indicated that it would give further consideration to the question whether this issue
25 should be treated in the text.

26
27 *Subsection (b) Content of authorization.* The provision on authorization for access, use,
28 retention, or disclosure of genetic information or family medical history is adapted from the
29 HIPAA Privacy Rule regulations for “uses and disclosures for which an authorization is
30 required.” 45 C.F.R. §§ 164.508 (a) and (c), 164.512(a). The subsection adapts these regulations
31 to apply to genetic information and family medical history, and expands them to include
32 authorization for access and retention as well as for use and disclosure.

33
34 An advantage of using the HIPAA regulations as the foundation for the authorization
35 requirements is that the requirements to authorize a disclosure by a health care provider to an
36 employer, employment agency, labor organization, licensing authority, or insurer would be
37 similar to the requirements that health care provider must follow as a covered entity under
38 HIPAA. The context of the HIPAA regulations is different enough, however, that they cannot be
39 transported directly into the Act without modification. Moreover, states are permitted to impose
40 their own, more stringent, privacy requirements. 45 C.F.R. § 160.203(b). Some have enacted
41 statutes with different requirements for disclosing health care information, which reduces the
42 uniformity that would theoretically be achieved by using the HIPAA format. Therefore, while
43 the structure of this subsection is modeled on the HIPAA regulations, it includes some additional
44 provisions from various state statutes. *See, e.g., Me. Rev. Stat. Ann. tit. 22 § 1711-C.*

1 The following are sample forms that could be used for an employee to authorize an employer to
2 access and use genetic information, to retain genetic information, or to disclose genetic
3 information.

4
5 Authorization for Access and Use

6
7 I _____ [print name] authorize _____ [name of employer, employment
8 agency, labor organization, or licensing authority] to access the following genetic test results or
9 family medical history and use it for the purposes identified:

10
11 _____ [Name of test and condition tested for] .

12 The purpose of this test is to determine if you have a genetic characteristic that predisposes you
13 to harm from _____ [workplace condition]. _____ [name of employer,
14 employment agency, labor organization, or licensing authority] will use this information only for
15 the following purposes: _____.

16
17 Family medical history information about _____ [name of medical condition].
18 _____ [name of employer, employment agency, labor organization, or licensing
19 authority] will use this information only for the following purposes: _____.

20
21 Disclosure by _____ [name of person to disclose] of genetic information
22 about _____ [name of test and condition]. _____ [name of employer,
23 employment agency, labor organization, or licensing authority] will use this information only for
24 the following purposes: _____.

25
26
27 You may revoke this authorization for access and use at any time by sending a letter to
28 _____ [name and address] unless _____ [name of employer,
29 employment agency, labor organization, or licensing authority] has
30 _____ [description of action that would be taken based on the information].

31
32 You are entitled to a copy of this authorization form.

33
34 This authorization is valid until _____ [date or event].

35
36 _____
37 Signature

_____ Date

38
39
40 Authorization for Retention of Genetic Information

41
42 I authorize _____ [name of employer, employment agency, labor organization, or
43 licensing authority] to retain the following genetic information:

44
45 _____ [Name of test and condition tested for] .

1 Family medical history information about _____ [name of medical condition].

2
3 You may revoke this authorization for access and use at any time by sending a letter to
4 _____ [name and address] unless _____ [name of employer,
5 employment agency, labor organization, or licensing authority] has
6 _____ [description of action that would be taken based on the information].

7
8 You are entitled to a copy of this authorization form.

9
10 This authorization is valid until _____ [date or event].

11
12 _____
13 Signature

Date

14
15
16 Authorization for Disclosure of Genetic Information

17
18 I authorize _____ [name of person authorized to make disclosure] to disclose the
19 following genetic information or family medical history to _____ [name of
20 recipient of the information]. This authorization does not control the genetic information or
21 family medical history following the disclosure and there is a possibility that the information will
22 be redisclosed by the recipient.

23
24 _____ [Name of test and condition tested for] .

25
26 Family medical history information about _____ [name of medical condition].

27
28 You may revoke this authorization for disclosure at any time by sending a letter to
29 _____ [name and address] unless _____ [name of employer,
30 employment agency, labor organization, or licensing authority] has already disclosed the
31 information.

32
33 You are entitled to a copy of this authorization form.

34
35 This authorization is valid until _____ [date or event].

36
37 _____
38 Signature

Date

39
40 *Subsection (c) Amendment.* An employee is permitted to change the terms of the
41 employee's authorization in a new authorization that complies with the requirements of this
42 section.

1 punitive damages, or other legal or equitable relief. The court shall award a prevailing plaintiff
2 reasonable attorney's fees and costs unless justice requires otherwise.

3 **Reporter's Notes**

4
5 The draft is intended to provide remedies for privacy violations, employment
6 determinations based on misuse of genetic information, or other harms. Privacy violations
7 involve access, retention, or disclosure of genetic information that does not comply with the Act.
8 Employment determinations could include failure to license, hire, refer for employment,
9 promote, or termination, demotion, reduction in pay, reassignment, or any other adverse action.
10 Other harms could include torts such as intentional infliction of emotional distress. The
11 appropriate remedy will vary with the type of violation.
12

13 A privacy rights perspective assumes an intrinsic harm from the invasion of privacy,
14 whether or not consequential damages are incurred. Because of difficulties in measuring damage
15 to privacy interests, several states that provide a private right of action for privacy violations
16 involving genetic information also specify statutory damages, with higher amounts when the
17 violation is willful or leads to monetary gain for the violator. Alaska Stat. § 18.13.020 (actual
18 damages plus \$5,000, or plus \$1,000 if there is monetary gain); N.H. Rev. Stat. § 141-H:6 (not
19 less than \$1,000 per violation); NM Stat. Ann. § 24-21-6 (economic loss plus damages of up to
20 \$5,000 if the violation results from willful or grossly negligent conduct).
21

22 States with genetic statutes tend to provide relief for violations using a mixture of
23 administrative and civil processes, although a few have enacted criminal penalties. Many state
24 statutes that emphasize discrimination require employees to submit claims of unlawful
25 employment discrimination based on use of genetic information to a state agency or the federal
26 Equal Opportunity Employment Commission. Using a state employment discrimination agency
27 may make sense for enforcement of provisions related to employment decisions because such
28 agencies already have the apparatus in place to enforce state civil rights and disability statutes.
29 For privacy violations, however, such agencies do not have expertise in controlling the flow of
30 information and the typical remedies for employment discrimination are not necessarily
31 appropriate for a privacy violation. Enforcement could be turned over to an agency with that
32 expertise, but the drafters wish to avoid the cost of creating and funding a new agency.
33

34 The section does not increase the enforcement burden on state agencies. The remedy for
35 a violation of the article is limited to a private civil action. Fee and cost shifting are included to
36 compensate prevailing employees for their costs to enforce the statute.

1 [ARTICLE] 3

2 HEALTH INSURANCE

3 SECTION 301. GENETIC TESTING; ACCESS TO GENETIC INFORMATION.

4 (a) In determining eligibility for health-insurance coverage and in setting rates, terms,
5 and conditions for a health-insurance policy, an insurer may not:

6 (1) require or request an insured or an insured’s family member to take a genetic
7 test;

8 (2) require or request an insured’s genetic information or family medical history;
9 or

10 (3) inquire whether an insured or an insured’s family member has taken or
11 refused to take a genetic test or accessed genetic services.

12 (b) Except as otherwise provided by law other than this [act], an insurer that receives a
13 claim for payment under a health-insurance policy may access, without specific authorization by
14 the insured, genetic information and family medical history that the insurer may use under
15 Section 303 to determine a payment obligation.

16 (c) This [article] does not limit an insurer that directly provides health-care services in
17 providing a genetic test to an insured or accessing an insured’s genetic information or family
18 medical history for the purpose of providing health-care services for the insured.

19 Reporter’s Notes

20
21 *Applicability of Article 3.* The draft is meant to apply broadly to health insurance,
22 whether issued on an individual, group, or other basis. This article closes the gaps left by Title I
23 of HIPAA, which prohibits discrimination in enrollment and premiums based on health status
24 related factors, including genetic information. Title I, however, does not apply to small group
25 and individual coverage, which is covered by this article. In addition to individual and group
26 health insurance policies, some state statutes reference health insurance issued on a franchise or
27 blanket basis. These forms of health insurance are also subject to this article.
28

1 The drafting committee intends that this article also applies to employee welfare plans
2 unless there is a controlling judicial decision that the article is preempted by the Employee
3 Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. § 1001 et seq. Federal preemption
4 is relevant because the United States Supreme Court has held that ERISA applies to employee
5 benefit plans such as health insurance as well as to employee pension plans. *Inter-Modal Rail*
6 *Employees Ass'n v. Atchison, Topeka and Santa Fe Ry. Co.*, 520 U.S. 510 (1997). The United
7 States Supreme Court has recognized three types of preemption under ERISA that are relevant to
8 this draft act: express, complete, and conflict preemption. Complete preemption and conflict
9 preemption are relevant to enforcement and civil remedies and are discussed in the notes to
10 Section 307.

11
12 In order to simplify the administration of plans by ensuring that they are subject to only
13 one set of regulations, ERISA expressly preempts state regulation of the administration of
14 employee benefit plans to the extent those regulations “relate to” employee benefit plans. 29
15 U.S.C. § 1144(a). The statute contains a savings clause, however, that saves laws that regulate
16 insurance from ERISA preemption. 29 U.S.C. § 1144(b)(2)(A). The issue of whether state
17 regulations are preempted by ERISA has led to extensive litigation.

18
19 Recently, the United States Supreme Court clarified the application of the savings clause.
20 In order to fall under ERISA’s savings clause, a state law must first be “specifically directed
21 toward” the insurance industry. *Kentucky Ass'n of Health Plans, Inc. v. Miller*, 123 S. Ct. 1471,
22 1475 (2003). Laws of general application that merely have “some bearing on insurers” do not
23 fall under the clause. *Id.* Second, the ERISA provision saves state laws that regulate
24 “insurance,” not “insurers,” so a law must regulate insurers “with respect to their insurance
25 practices.” *Id.* A state law regulates an insurer with respect to insurance practices if it controls
26 the terms of insurance policies, *id.* at 1476, or if it “substantially affect[s] the risk pooling
27 arrangement between the insurer and the insured,” *id.* at 1477. This act regulates insurance
28 practices and thus falls under ERISA’s savings clause.

29
30 The preemption question is further complicated by that fact that ERISA also contains
31 what is referred to as the “deemer clause,” which creates an exception to the savings clause. It
32 provides that “neither an employee benefit plan . . . nor any trust established under such plan,
33 shall be deemed to be an insurance company or other insurer . . . for purposes of any law of any
34 State purporting to regulate insurance companies . . .” 29 U.S.C. § 1144(b)(2)(B). The United
35 States Supreme Court has interpreted the deemer clause to exempt self-funded (i.e. uninsured)
36 health plans from the savings clause. Thus the Court concluded that “self-funded ERISA plans
37 are exempt from state regulation insofar as that regulation ‘relate[s] to’ the plans.” *FMC Corp. v.*
38 *Holliday*, 498 U.S. 52, 61 (1990). Under this decision, this act is preempted as applied to self-
39 funded employee benefit plans.

40
41 The distinction in *FCM Corp.* between insured and self-insured health plans has not been
42 overruled and continues to be applied by lower courts. *See, e.g., Daly v. Marriott International,*
43 *Inc.*, 415 F.3d 889 (8th Cir. 2005) (“deemer clause” of ERISA preemption provision exempted
44 employer funded health plan from application of state mental-health parity law); *Blue Cross Blue*
45 *Shield of Alabama v. Sanders*, 138 F.3d 1347 (11th Cir. 1998).

1 predisposing genetic characteristic as a preexisting condition for purposes of limiting or
2 excluding benefits or coverage. This is consistent with statutes in several states that do not
3 permit health insurers to impose preexisting condition exclusions based on predictive genetic
4 information in the absence of a diagnosis based on symptoms of the disease or condition.
5 (Alaska, Conn, Idaho, Iowa, Ky, OR).
6

7 There are many alternative approaches to regulating the use of genetic information in
8 health insurance. Some other states take an approach like that of HIPAA and use a non-
9 discrimination provision that prohibits higher premiums than those charged to similarly situated
10 individuals. (Alaska, Ark, Ill, Iowa). Yet other states prohibit the use of genetic information for
11 underwriting health insurance without actuarial justification. (Ariz, WV). In some states, use
12 of genetic information for risk selection is permitted if an individual submits the information
13 voluntarily or if the information is favorable to the individual. (Ill, Ind, Mass, Mo, NY). Yet
14 other states regulate this use by prohibiting insurers from increasing policy rates based on genetic
15 information. (Md, Mont, Or, Tex).
16

17 This section illustrates some of the problems with treating genetic information as a
18 distinct category of medical information. First, the section offers less protection than HIPAA in
19 terms of eligibility decisions for individual and small group coverage because it regulates use of
20 genetic information only, not information on all medical conditions. Second, it is often
21 permissible for insurers to consider existing medical conditions in determining coverage and
22 premiums under other law so long as they treat like situations alike. This section would impose a
23 different standard by prohibiting consideration of conditions revealed by a genetic test, thus
24 raising the practical question of which conditions are “genetic.” Even conditions with a genetic
25 component are rarely entirely “genetic.”
26

27 A major policy question for the drafting committee is whether health care insurers should
28 be prohibited from denying coverage or offering less favorable terms based on an applicant’s
29 manifest genetic disease or only on an applicant’s predisposing genetic characteristics. An
30 argument can be made that protection for genetic information as defined in this draft is too wide.
31 As discussed above, the prohibition would create a different standard for genetic illnesses than
32 for other medical conditions. Some analysts maintain that attempts to prevent genetic
33 discrimination are mostly meaningless without protection for people who have genetic diseases.
34 See Mark A. Rothstein, *Genetic Privacy and Confidentiality: Why They are so Hard to Protect*,
35 26 J. L. Med. & Ethics 181 (1998). Others think that this would place too great a burden on
36 insurers. See, e.g., Henry T. Greely, *Genotype Discrimination: The Complex Case for Some*
37 *Legislative Protection*, 149 U. Pa. L. Rev. 1483, 1503 (2001). An alternative consistent with the
38 latter position would be to limit the restrictions to predictive information by substituting
39 “predisposing genetic characteristic” for “genetic information” in subsection (a).
40

41 SECTION 303. AUTHORIZED USE OF GENETIC INFORMATION.

42 (a) An insurer that receives a claim for payment under a health-insurance policy for a
43 genetic test or genetic counseling may use genetic information and family medical history

1 regarding the need for a genetic test, but not the results of the test, to determine the insurer’s
2 payment obligation.

3 (b) An insurer that receives a claim for payment under a health-insurance policy for
4 health-care services rendered because of a genetic condition or predisposing genetic
5 characteristic may use the genetic information or family medical history that is necessary to
6 determine the insurer’s payment obligation.

7 (c) This [article] does not limit an insurer that directly provides health-care services in
8 using an insured’s genetic information or family medical history for the purpose of providing
9 health-care services for the insured.

10 **Reporter’s Notes**

11
12 *Subsection (a) Payment obligations.* This subsection highlights the potential role for
13 genetic information in providing payment for genetic tests and health care services. First, genetic
14 information such as family history may be necessary for preauthorization for a genetic test or
15 service or for approval of payment for a genetic test or service. Second, health care services may
16 be medically justified by a predisposing genetic characteristic or a genetic condition. In this
17 context, genetic “condition” should be interpreted broadly to include the full range of health
18 effects influenced by a genotype, including a disease or disorder.

19
20 This subsection is modeled on a Utah provision.

21
22 *Subsection (b) Health-care services.* Health insurers such as HMOs, which also provide
23 health care services, need to be able to use genetic information in order to function as health care
24 providers. These insurers may use genetic information or family medical history for therapeutic
25 purposes as part of the practice of medicine, but not as part of determining eligibility for
26 insurance or for underwriting. Specific conditions for use of genetic information for diagnosis or
27 treatment are not covered by this draft because those uses constitute the practice of medicine.
28

29 **SECTION 304. RETENTION OF GENETIC INFORMATION.** A health insurer
30 that retains genetic information or family medical history shall comply with the terms of the
31 regulations that govern Security Standards for the Protection of Electronic Protected Health
32 Information pursuant to the Health Insurance Portability and Accountability Act of 1996, 45

1 C.F.R. Part 164 Subpart C, as if the insurer were covered by that Act.

2 **Reporter’s Notes**

3
4 This section extends the protections of HIPAA regulations to all genetic information
5 retained by health insurers, whether covered by HIPAA or not. The health insurers that are not
6 covered by HIPAA’s Privacy Rule but would be brought under it by this provision are primarily
7 small employer-sponsored group health plans (less than 50 participants) or employer-sponsored
8 group health plans that are administered solely by the employer that established and maintains
9 the plan. *See* 45 C.F.R. § 160.202. The drafting committee noted that it would consider deleting
10 this section.
11

12 **SECTION 305. DISCLOSURE OF GENETIC INFORMATION BY HEALTH**
13 **INSURERS.**

14 (a) A health insurer may disclose an insured’s genetic information to a person other than
15 the insured if the health insurer has obtained the insured’s authorization under Section 306.

16 (b) This [article] does not limit an insurer that directly provides health-care services from
17 disclosing an insured’s genetic information or family medical history to the extent appropriate for
18 the purpose of providing health-care services for the insured.

19 **Reporter’s Notes**

20
21 This section conditions the disclosure of an insured’s genetic information on the
22 authorization of the insured. In some jurisdictions, however, health care providers may have a
23 common-law duty to inform others of a genetic disorder. This case law may require disclosure
24 by a health insurer without the insured’s consent.
25

26 New Jersey’s court has recognized a physician’s duty to warn those “known to be at risk
27 of avoidable harm from a genetically transmissible condition.” *Safer v. Pack*, 677 A.2d 1188
28 (N.J. Super. Ct. App. Div. 1996). The defendant in the case was the physician who had treated
29 the plaintiff’s father for colorectal cancer that led to the father’s death when the plaintiff was a
30 child. The plaintiff inherited multiple polyposis, an inherited condition that if undiscovered and
31 untreated, leads to metastatic colorectal cancer. The court found a duty to “take reasonable
32 steps” to warn that “extends beyond the patient to members of the immediate family of the
33 patient who may be adversely affected by a breach of that duty.” It noted, but did not determine,
34 the issue that would arise if the father had instructed the doctor not to disclose details of the
35 illness or the genetic risk. In that event, it would be necessary to resolve the conflict between
36 physician-patient confidentiality and the duty to warn.
37

1 Minnesota has also recognized a duty regarding genetic testing and diagnosis that reaches
2 beyond the patient. The plaintiff alleged that her daughter’s physicians were negligent in failing
3 to diagnose a genetic disorder in the daughter that led the mother to conceive another child with
4 the same genetic disorder. *Molloy v. Meier*, 679 N.W.2d 711 (Minn. 2004). The court noted that
5 genetic testing and diagnosis affect not only the patient, but can benefit or harm both the patient
6 and her family. The Fragile X disorder is one that physicians ordinarily report to parents and it
7 was foreseeable that a negligent diagnosis of the disorder would cause harm to the family as well
8 as the patient. The court held that the duty to warn extends to “biological parents who
9 foreseeably may be harmed by a breach of that duty.” It did not consider whether it should
10 extend to additional family members.

11
12 The Florida Supreme Court has similarly held there is a duty to warn of the likelihood
13 that a condition was inherited by a patient’s children but, in contrast to the Minnesota and New
14 Jersey courts, it found that the duty is satisfied by warning the patient. *Pate v. Threlkel*, 661
15 So.2d 278 (Fla. 1995). The court observed that a patient can normally be relied upon to pass on
16 the warning and emphasized the heavy burden that would be entailed in seeking out and warning
17 family members.

18
19 **SECTION 306. AUTHORIZATION FOR ACCESS, USE, RETENTION, OR**
20 **DISCLOSURE OF GENETIC INFORMATION.**

21 (a) Except as otherwise provided by this [act] or law other than this [act], an insurer may
22 not disclose an insured’s genetic information without the insured’s knowing and voluntary
23 authorization indicated by a record signed and dated by the insured. An insurer that receives a
24 valid authorization to disclose genetic information may disclose the information only in
25 accordance with the authorization.

26 (b) An authorization form to disclose an insured’s genetic information must:

27 (1) describe the genetic information or family medical history to be disclosed in a
28 specific and meaningful fashion;

29 (2) identify or describe the person that is authorized to disclose the genetic
30 information;

31 (3) identify or describe the third person to which the authorized person may
32 disclose the genetic information;

1 (4) state that the genetic information disclosed by the authorized person may be
2 subject to redisclosure by the recipient and no longer be protected;

3 (5) indicate the duration of the authorization with an expiration date or expiration
4 event that relates to the insured or to the purpose of the access, use, retention, or disclosure;

5 (6) state that the insured may revoke the authorization at any time in a signed
6 record, subject to the right of a person that acted in reliance on the authorization before receiving
7 notice of revocation, and provide instructions on how to revoke an authorization; and

8 (7) state that the insured is entitled to a copy of the authorization form.

9 **Reporter's Notes**

10 This section requires an insured to provide an authorization before a health insurer may
11 disclose genetic information.
12

13 The draft does not disturb existing law that allows a minor to seek repudiation of consent
14 and expunge records when the minor reaches the age of majority.
15

16 *Subsection (a) General requirement for authorization.* This subsection would establish a
17 requirement that an insurer must be authorized by the insured before it may disclose genetic
18 information, except as provided elsewhere in the act. In order to give a valid authorization, the
19 insured must be informed as provided in the following subsections and must act voluntarily.
20 Subsection (a) also includes a requirement that an authorization must be indicated by a signed
21 and dated record. The authorization requirement is coupled with limitations on disclosure in
22 Section 305.
23

24 Other law of the state may provide for a substitute decisionmaker or signer if the
25 employee is incapacitated or incompetent. This situation is left to existing law of the state that
26 governs power of attorney, guardianship, or other substitute decision makers. Again, the
27 Drafting Committee has indicated that it wishes to consider whether or not to include a provision
28 for incapacitation or incompetence into the text of the draft.
29

30 *Subsection (b) Content of authorization.* The provision on authorization for disclosure of
31 genetic information is adapted from the HIPAA Privacy Rule regulations for “uses and
32 disclosures for which an authorization is required.” 45 C.F.R. §§ 164.508 (a) and (c),
33 164.512(a).
34

35 An advantage of using the HIPAA regulations as the foundation for the authorization
36 requirements is that the requirements to authorize a disclosure by a health care provider to an
37 insurer would be similar to the requirements that health care provider must follow as a covered
38

1 entity under HIPAA. The context of the HIPAA regulations is different enough, however, that
2 they cannot be transported directly into the Act without modification. Moreover, states are
3 permitted to impose their own, more stringent, privacy requirements. 45 C.F.R. § 160.203(b).
4 Some have enacted statutes with different requirements for disclosing health care information,
5 which reduces the uniformity that would theoretically be achieved by using the HIPAA format.
6 Therefore, while the structure of this subsection is modeled on the HIPAA regulations, it
7 includes some additional provisions from various state statutes. *See, e.g.,* Me. Rev. Stat. Ann. tit.
8 22 § 1711-C.
9

10 **SECTION 307. REMEDIES; ENFORCEMENT; LIMITATION OF ACTIONS.**

11 (a) An individual aggrieved by a violation of this [article] may file a civil action not later
12 than two years after the individual discovers the violation of this [article] or a person exercising
13 reasonable care should have discovered the violation of this [article].

14 (b) If a court finds a violation of this [article], it may award compensatory damages,
15 injunctive relief, including expungement of records, or any other appropriate remedy, including
16 punitive damages. The court shall award a prevailing insured reasonable attorney's fees and
17 costs unless justice requires otherwise.

18 (c) A violation of this [article] is a violation of [the state unfair practices insurance law].
19 An individual aggrieved by a violation of this [article] may initiate an appropriate proceeding
20 with the [state commissioner of insurance] for whatever action the [commissioner] may be
21 authorized to take under the [state unfair practice insurance law] not later than two years after the
22 individual discovers the violation or a person exercising reasonable care should have discovered
23 the violation of this [article].

24 *Legislative Note:* States should insert for [state commissioner of insurance] the appropriate
25 title of this department. [The state unfair practices insurance law] should be replaced with the
26 title of the relevant statute.
27

28 **Reporter's Notes**

29
30 The draft's remedy section is written to respond to privacy violations as well as
31 discrimination or misuse of genetic information in insurance. It provides a private right of action

1 for an aggrieved individual. Alternatively, an aggrieved individual may seek enforcement
2 through the State Commissioner of Insurance, which is a typical provision in state statutes that
3 prohibit discrimination in health insurance based on genetic testing or information. These
4 statutes declare that a violation is an unfair and deceptive insurance act or practice under the state
5 insurance code. They often provide that the State Commissioner of Insurance shall enforce the
6 prohibitions.

7
8 The committee considered and rejected statutory damages as a remedy for a privacy
9 violation for the reason that statutory damages often serve primarily to limit recovery. The
10 absence of statutory damages, however, makes the availability of punitive damages particularly
11 important.

12
13 A comment from a style committee member states that the language would permit two
14 different dates for the statute of limitation and asks the drafting committee to resolve whether
15 intends the earlier or later of the dates the individual discovered or should have discovered the
16 violation.

17
18
19 This section is identical to the enforcement provision for life insurance, income-disability
20 insurance and long-term-care insurance in Article 4.

21
22 Certain enforcement and remedies may be preempted by ERISA. “Complete preemption”
23 occurs when Congress has “so completely [preempted] a particular area that any civil complaint
24 raising this select group of claims is necessarily federal in character.” *Metropolitan Life Ins.*
25 *Corp. v. Taylor*, 481 U.S. 58, 63-64 (1987). In *Taylor*, the United States Supreme Court held
26 that the civil enforcement provision of ERISA, 29 U.S.C. § 1132(a), completely preempts
27 common law breach of contract and tort claims for wrongful termination of disability benefits.
28 *See also Prudential Ins. Co. of Amer. v. Nat’l Park Med. Center, Inc.*, 413 F.3d 897 (8th Cir.
29 2005) (with respect to suits that could be brought under ERISA, civil enforcement provision
30 preempts Arkansas Patient Protection Act civil penalties).

31
32 A separate type of preemption, “conflict preemption,” comes into play with civil
33 remedies. The United States Supreme Court has held that Congress intended to make the ERISA
34 civil enforcement remedy exclusive and that therefore a state-law cause of action that
35 “duplicates, supplements, or supplants” the ERISA civil remedy conflicts with congressional
36 intent. *Aetna Health, Inc. v. Davila*, 452 U.S. 200, 208 (2004) (Texas statute that created a cause
37 of action against HMOs for failure to exercise ordinary care in handling coverage decisions
38 preempted). *See also Hawaii Management Alliance v. Ins. Comm’n*, 100 P.3d 952 (Haw. 2004)
39 (statute providing attorney’s fees and costs for external review of insurer’s denial of coverage
40 preempted by conflict with ERISA).

1 [ARTICLE] 4

2 LIFE INSURANCE, DISABILITY-INCOME INSURANCE,
3 AND LONG-TERM-CARE INSURANCE

4 SECTION 401. GENETIC TESTING.

5 (a) If a genetic test is approved in accordance with Section 405, an insurer may request or
6 require an insured to take the genetic test in connection with the provision of life insurance,
7 disability-income insurance, or long-term-care insurance and, with prior authorization of the
8 insured that meets the requirements of Section 402, may provide the test to the insured.

9 (b) An insurer that requests or requires provides a genetic test in connection with the
10 provision of life insurance, disability-income insurance, or long-term-care insurance shall
11 provide and pay for genetic counseling for the insured about the risks and benefits of the genetic
12 test before the insured considers authorizing the test unless the insured knowingly and voluntarily
13 waives counseling in a signed record that informs the insured of the benefits of genetic
14 counseling;

15 (c) An insurer that provides a genetic test to an insured in connection with the provision
16 of life insurance, disability-income insurance, or long-term-care insurance shall:

17 (1) pay for the genetic test;

18 (2) require the testing organization to make a report of the test result to the
19 insured and a health-care professional designated by the insured unless the insured directs
20 otherwise;

21 (3) provide and pay for genetic counseling for the insured about a positive test
22 result unless the insured knowingly and voluntarily waives counseling in a signed record that
23 informs the insured of the benefits of genetic counseling; and

1 (4) require the destruction of the insured's biological sample obtained for a
2 genetic test as soon as permitted by law after the test is completed unless retention of the sample
3 is authorized by the insured, permitted by law other than this [act], or ordered by a court, arbitral
4 tribunal, or administrative agency.

5 **Reporter's Notes**

6
7 *Applicability of Article 4.* This article applies to life insurance, disability-income
8 insurance, and long-term-care insurance issued on an individual, group, or other basis. Including
9 individual policies is significant because individual insurance policies are subject to underwriting
10 and many life, disability-income, or long-term-care insurance policies are issued on an individual
11 basis. The draft does not distinguish between individual and group insurance, however, because
12 most of the states that regulate genetic testing or the use of genetic information for issuing life,
13 disability-income, or long-term-care insurance treat both individual and group insurance
14 identically.

15
16 The justification for including life, disability-income, and long-term-care insurance in a
17 separate article from health insurance is that these insurance policies tend to be viewed as
18 financial products that are less necessary than health insurance. That, however, is a contested
19 view. Life insurance plays a central role in the financial lives of many individuals and families.
20 Disability-income and long-term-care insurance are increasingly viewed as a necessary adjunct to
21 health insurance and many states regulate disability-income and long-term-care insurance as
22 health insurance.

23
24 There are differences in underwriting principles among the three types of insurance. Life
25 insurance underwriting is concerned with mortality and uses life expectancy tables. In contrast,
26 disability-income underwriting is concerned with morbidity and long-term-care underwriting is a
27 hybrid process. These differences do not seem to require different treatment in terms of genetic
28 information.

29
30 *Genetic testing and information.* This section and the following one limit access to
31 genetic information by insurers that provide life, disability-income, or long-term-care insurance.
32 This section limits genetic testing and the following section limits access to genetic information
33 in general. The limitations are based on the philosophy that insurers may continue current
34 information gathering practices, but may not expand their collection of genetic information
35 unless and until there is a strong scientific basis for its use to predict mortality and morbidity. It
36 is the drafting committee's understanding that life, disability-income and long-term-care insurers
37 do not at present require applicants to take genetic tests, but do collect family history information
38 for use in determining eligibility and in underwriting.

39
40 The drafting committee considered, but did not adopt, an approach to regulating genetic
41 information for life, disability-income or long-term-care insurance based on the amount of the
42 insurance policy. The suggestion was to prohibit genetic testing and consideration of genetic

1 information for policies worth less than a specified monetary threshold. Above that value,
2 insurers would be permitted to consider genetic information freely.

3
4 The arguments for restricting access to genetic information by the insurance industry are
5 that this information is particularly private and its predictive power is easily exaggerated. There
6 are privacy concerns with commercial access to sensitive genetic information and predictions that
7 individuals will avoid genetic testing for fear of adverse effects on their insurability. There is
8 also a possibility that insurers may require applicants to take genetic tests and then deny
9 insurance or charge more based on genetic characteristics, unfairly making coverage unavailable
10 to people who are not sick from the genetic condition and never will become sick from that
11 condition. From the industry perspective, as with health insurance, insurers worry about adverse
12 selection. If applicants seek coverage because a genetic characteristic exposes them to risk, but
13 the insurer does not have this information, this puts the insurer at a financial disadvantage. *See*
14 *generally* Mark A. Rothstein, ed., *Genetics and Life Insurance: Medical Underwriting and Social*
15 *Policy* (2004).

16
17 A 1997 study by the Human Genetics Advisory Commission in the United Kingdom
18 concluded that it is unlikely that actuarially-sound genetic predictions of adult death will be
19 validated and available anytime in the near future. Genetic tests need to be connected to medical
20 and epidemiological research to establish what consequences for health and life-span can be
21 inferred from a given genetic test. The Commission concluded that a requirement to disclose
22 genetic tests as a condition of obtaining insurance would be acceptable only after research has
23 established an association between a given pattern of test results and life events that are relevant
24 for the insurance product. It recommended continuing a moratorium on requiring test results.
25 Human Genetics Advisory Commission, *The Implications of Genetic Testing for Insurance*
26 (1997).

27
28 *Genetic testing.* This section prohibits insurers from requiring applicants to have genetic
29 testing as a condition of obtaining life, disability-income or long-term-care insurance unless a test
30 has been certified as providing a relevant prediction. The section is consistent with the
31 moratorium recommended by the UK Human Genetics Advisory Commission because there is no
32 research establishing an association between a pattern of genetic test results and life events
33 relevant to insurance coverage.

34
35 The section is also consistent with genetic testing prohibitions in force in California,
36 Massachusetts, and Vermont, except that it allows the prohibition to be modified as justified by
37 scientific developments. Vermont and Massachusetts prohibit insurers from requiring applicants
38 to take a genetic test as a condition of obtaining or renewing a policy. California prohibits long-
39 term-care insurers from requiring genetic testing for use in determining insurability or in
40 underwriting. *See* Cal. Ins. Code § 10233.1 (long-term-care insurance); Mass. Gen. L. Ann. 175
41 § 120E (life insurance); Mass. Gen. L. Ann. 175 § 108I (disability and long-term-care
42 insurance); Vt. Stat. Ann. § 9334 (any insurance).

43
44 The section also sets forth requirements similar to those imposed on employers who
45 provide genetic tests.

1 **SECTION 402. AUTHORIZATION FOR GENETIC TEST.**

2 (a) An insured’s authorization for the genetic test requested or required under Section 401
3 must be knowing and voluntary and indicated in a record signed by the insured.

4 (b) An authorization form for a genetic test for life insurance, disability-income
5 insurance, or long-term-care insurance must:

6 (1) describe the genetic test to be performed, its purpose, and its permitted uses;

7 (2) inform the insured that only the authorized genetic test will be performed on
8 the insured’s biological sample;

9 (3) inform the insured that the insured is obligated to provide and pay for genetic
10 counseling about the risks and benefits of the test before the insured considers the authorization;

11 (4) inform the insured that the test result will be reported to the insured and a
12 health-care professional designated by the insured, unless the insured directs otherwise;

13 (5) include an opportunity for the insured to provide directions about reporting
14 test results;

15 (6) inform the insured that the insured’s biological sample will be destroyed as
16 soon as permitted by law after the test is completed unless the insured authorizes retention of the
17 sample or unless otherwise ordered by a court, arbitral tribunal, or administrative agency; and

18 (7) state that the insured is entitled to a copy of the authorization form.

19 **Reporter’s Notes**

20
21 The Drafting Committee requested alternative approaches for maintaining privacy for
22 genetic testing and genetic information. The alternative chosen by the drafting committee at the
23 November meeting protects privacy by establishing an authorization requirement that is coupled
24 with statutory limits and duties imposed on insurers. Under this approach, an insured must
25 affirmatively authorize any genetic testing or access, use, retention, or disclosure of genetic
26 information. The authorization requirement is not simply an extra procedural step because
27 Article 4 establishes limitations on the situations in which employers and insurers may request
28 authorization from insureds .

1
2 The drafting committee considered, but did not adopt alternatives that would (1) establish
3 a general property right in a biological sample an individual provides for genetic testing and in
4 the resulting genetic information or (2) establish a limited property applicable only to the context
5 of insurance.
6

7 This section deals with genetic testing. It sets forth an authorization requirement and the
8 elements that must be contained in an authorization form. The term “authorization” is used
9 instead of “informed consent” to avoid confusion with the use of that term in medical practice.
10

11 *Subsection (a) Requirement for authorization for genetic testing.* Under Section 401, an
12 insurer may require a genetic test as a condition of obtaining life, disability-income, or long-
13 term-care insurance if the test has been approved under Section 405. Under this subsection,
14 genetic testing allowed by these sections is permitted only if an employee or insured first
15 authorizes the genetic test.
16

17 In order to meet the requirement that an authorization be knowing and voluntary, an
18 employee or insured should have genetic counseling before signing the authorization. Genetic
19 counseling provides insureds with adequate information to make an informed decision about
20 genetic testing. It also makes them aware of their options regarding reporting of test results and
21 help in interpreting them through genetic counseling. Genetic counseling may be provided by a
22 genetic counselor, but may also be provided by a qualified physician or geneticist.
23

24 Other law of the state may provide for a substitute decisionmaker or signer if the
25 employee is incapacitated or incompetent. This situation is left to existing law of the state that
26 governs power of attorney, guardianship, or other substitute decision makers.
27

28 *Subsection (b) Content of authorization for testing.* The section draws on N.Y. Civ.
29 Rights Law § 79-1 (McKinney), which establishes requirements for consent for a genetic test.
30

31 The insurance provision in subsection (c) does not require the insurer to provide genetic
32 counseling, but to inform the insured that it is desirable.
33

34 The limitation in (b)(2) to the authorized test is consistent with the requirements for prior
35 authorization in Section 401.
36

37 The notification provision for retention of the sample in (b)(6) is consistent with the
38 insurer’s obligation to ensure the sample is destroyed under Section 401(b)(3), which recognizes
39 that the testing laboratory may be required to retain the sample for certification purposes.
40

41 The following is a sample form that may be used to authorize an insurance company to
42 provide a genetic test.
43

44 Authorization for Genetic Testing

45
46 Limited Authorization

1 Only the genetic tests that you authorize on this form will be performed on your biological
2 sample. These tests are voluntary, but refusing a test requested by [name of insurer] may mean
3 that your application for insurance will be denied.
4

5 Availability of Genetic Counseling

6 Before you complete this authorization form, it is highly recommended that you meet with a
7 genetic counselor who will help you understand and evaluate the risks and benefits of having the
8 tests listed below. _____ [Name of insurer] will provide and pay for this genetic counseling.
9

10 Proposed Genetic Tests

11 Based on a review of your family medical history, _____ [name of insurer] requests the
12 following genetic test:
13

- 14 _____ [Name of test]
15 The purpose of this test is to determine if you have a predisposition for _____
16 [genetic condition]. If you authorize [insurer] to have access to the test result, it will be
17 used only for the following purposes: _____.
18

19 Reporting Test Results and Genetic Counseling

20 The test results will be reported to you and to a health-care professional who you designate
21 unless you direct otherwise. It is recommended that you receive genetic counseling about the test
22 results. _____ [Name of insurer] will provide and pay for genetic
23 counseling about the test results unless you decline genetic counseling.
24

- 25 I wish to receive test results.
26 I do not wish to receive test results.
27
28 Report test results to the following health care professional:
29 Name: _____
30 Address: _____
31 Do not report test results to a health care professional.
32
33 I wish to receive genetic counseling about the test results.
34 I decline genetic counseling about the test results.
35

36 Destruction of your Biological Sample

37 After the genetic test, your biological sample will be destroyed as soon as permitted by law
38 unless you choose to authorize otherwise in writing or a court, arbitral tribunal, or administrative
39 agency requires retention of the sample.
40

41 Copy of this form

42 You are entitled to a copy of this authorization form.
43

44 I _____ [print name] authorize the genetic test(s) I have checked above.
45
46

1
2 _____
3 Signature

_____ Date

4 **SECTION 403. ACCESS TO GENETIC INFORMATION.**

5 (a) Unless genetic information is based on a genetic test that is approved in accordance
6 with Section 405, an insurer may not knowingly obtain or directly or indirectly inquire about,
7 request, or require an insured to provide an insured's genetic information in connection with the
8 provision of life insurance, disability-income insurance, or long-term-care insurance.

9 (b) An insurer may request or require an insured to provide family medical history in
10 connection with the provision of life insurance, disability-income insurance, or long-term-care
11 insurance.

12 **Reporter's Notes**

13
14 This section limits the extent to which an insurance company may access genetic
15 information or the results of genetic testing based on the rationale discussed in the reporter's
16 notes to Section 401. Subsection (a) permits access to genetic information if it is based on a
17 genetic test that has been approved under Section 405. Otherwise access is prohibited. This
18 prohibition does not apply to family medical history, which is not included in the definition of
19 "genetic information." Subsection (b), moreover, explicitly permits insurers to seek information
20 about family medical history, which they have traditionally used for underwriting.
21

22 **SECTION 404. PROHIBITION ON USE OF GENETIC INFORMATION.** Unless
23 genetic information is based on a genetic test that is approved as provided in Section 405, an
24 insurer may not use genetic information about an insured's predisposing genetic characteristics to
25 determine eligibility or rates, terms, and conditions for life insurance, disability-income
26 insurance, or long-term-care insurance.

27 **Reporter's Notes**

28
29 The determination of eligibility for coverage includes decisions made in connection with
30 the offer, sale, continuation, or renewal of an insurance policy. The determination of rates,

1 terms, and conditions includes establishing premiums, limiting coverage, limiting or conditioning
2 benefits, or making any other underwriting decisions.
3

4 This section prohibits the use of genetic information for determining eligibility or
5 underwriting of life, disability-income, and long-term-care insurance unless the genetic test has
6 been certified using the procedure in Section 405. Traditional insurance underwriting has been
7 based on medical histories and tests that indicate existing medical conditions. The draft permits
8 those practices to continue. Using predictions based on predisposing genetic characteristics that
9 have not been expressed as a disease or condition would be a new step, however, and there is a
10 great risk that such predictions would not be reliable in the context of insurance.
11

12 The section ties use of genetic information about predisposing characteristics to the
13 process in Section 405 for ensuring that the genetic test provides a reliable prediction of
14 individual mortality or morbidity. Otherwise, life, disability-income and long-term-care insurers
15 may not use genetic information about predisposing characteristics for determining eligibility or
16 in underwriting.
17

18 This prohibition is consistent with regulation in a number of states. Because genetic tests
19 are not yet routine in medical care and few individuals have previously taken genetic tests when
20 they apply for insurance, the prohibitions on requiring tests in California, Massachusetts, and
21 Vermont have the effect of preventing the use of genetic information. In addition, a number of
22 states directly prohibit insurers from using genetic information to determine eligibility or in
23 underwriting. *See* Colo. Rev. Stat. § 10-3-1104.7(3)(b) (group disability-income & long-term-
24 care); Kan. Stat. Ann. § 40-2259(d) (disability-income & long-term-care); Or. Rev. Stat. §
25 746.135 (genetic information from a blood relative for life, disability-income & long-term-care
26 insurance); Vt. Stat. Ann. tit. 18, § 9334(a) (same).
27

28 Unlike the draft's treatment of genetic information in employment or health insurance,
29 the restriction on use of genetic information in life, disability-income & long-term-care insurance
30 is narrower in that it applies only to predisposing genetic characteristics. Therefore, insurers are
31 not restricted from using genetic information with regard to a medical condition that has been
32 diagnosed. The scope is similar to Arizona's statute, which permits disability-income and long-
33 term-care insurers to use genetic information only if there is an actual diagnosis of a genetic
34 condition. Ariz. Rev. Stat. Ann. § 20-448(F).
35

36 The insurance industry maintains that any restrictions on their ability to use genetic
37 information will undermine the availability and pricing structure of life, disability-income &
38 long-term-care insurance. However, there is broad international consensus that the use of genetic
39 information in life insurance should be restricted. Numerous countries have enacted restrictions,
40 as have the states noted above. There is no evidence, however, that these restrictions have been
41 associated with adverse selection, increased pricing, reduced availability of policies, or decreased
42 profitability of the insurance industry. Without some supporting evidence, these industry
43 concerns do not outweigh the importance of protecting against new uses of information that
44 would diminish privacy and that carry a high risk of irrational discrimination.
45

1 With the draft’s narrow definition of “genetic information,” an insurer would be able to
2 use genetic data revealed by an individual’s family medical history to determine eligibility or to
3 underwrite without restriction. One member of the subcommittee raised the question of whether
4 there should be any limits on insurers’ use of family medical history. The question was
5 motivated by a concern that even if disclosures to insurers do not change, insurers may be able to
6 do more with those disclosures using ever more sophisticated computer technology. The drafting
7 committee may want to consider whether it is desirable to prevent new uses of family history
8 information that may become possible and if so, what limits would be appropriate.
9

10 **SECTION 405. REQUIRED DETERMINATION FOR GENETIC TESTING AND**

11 **ACCESS AND USE OF GENETIC INFORMATION.** If a life insurer, disability-income
12 insurer, or long-term-care insurer determines to a reasonable degree of scientific certainty that a
13 positive genetic test or pattern of test results is reliably associated with an increased medical risk
14 of mortality and certifies the magnitude of the increase in risk, the insurer may request or require
15 a genetic test or access and use genetic information based on the results of the genetic test. This
16 determination must be made by a geneticist or a genetic counselor. The use of a genetic
17 information about an insured’s predisposing genetic characteristics to determine eligibility or
18 rates, terms, or conditions for life insurance without this determination is unfair discrimination in
19 violation of [state unfair practices insurance law].

20 *Legislative Note:* [State unfair practices insurance law] should be replaced with the title of the
21 relevant statute.
22

23 **Reporter’s Notes**
24

25 The risk of misuse of genetic information is increasing because of the explosion of
26 genetic tests available, the general lack of governmental oversight for these tests, and common
27 misperceptions about the extent to which a genetic test can predict a future medical disease or
28 condition. In addition, the pathways for gene expression remain uncertain. Links between most
29 genetic characteristics and the incidence of disease are extremely complex and depend on the
30 interrelation of many factors, both genetic and environmental.
31

32 Even with draft’s restrictions on genetic testing by insurance companies, access to genetic
33 information in medical records will increase. More than 1,000 genetic tests are available
34 clinically as of early 2007; hundreds more are available to researchers. Some are marketed
35 directly to consumers with claims that they can be used to individually customize vitamins and

1 diet as well as test for disease. There is no government oversight of the validity of the tests used
2 for research or available through medical professionals. Through the mechanisms of this section,
3 the draft provides assurance that insurance companies that are permitted to use genetic
4 information, but not misuse it by protecting against the premature or improper use of predictions
5 based on genetic information.
6

7 The insurance industry has expressed a view that it must be able to develop its use of
8 genetic information along with the rapid development of knowledge in the genetic field. The
9 section provides a mechanism that will allow use of genetic information to evolve in response to
10 new scientific information that may justify the use of genetic information for eligibility and
11 underwriting determinations.
12

13 The drafting committee considered and rejected an approach that would have established
14 regulatory oversight of the use of genetic information by insurers by requiring a prior finding by
15 state insurance regulators in consultation with state public health authorities. The committee
16 instead placed the responsibility for finding that there is a reliable relationship between a
17 predisposing genetic characteristic and the incidence of mortality on the insurance companies.
18 This finding must be made by a geneticist or genetic counselor. This expert would not make
19 actuarial determinations, but would evaluate the medical literature to determine the accuracy and
20 completeness of the data an actuary proposes to use and the reliability of the prediction possible
21 with the genetic information. The process would allow an insurer's use of genetic information to
22 change as research develops reliable connections between genetic characteristics and risk of
23 mortality.
24

25 The process required here may be informed by evidence-based review of genetic tests
26 conducted by the Evaluation of Genomic Applications in Practice and Prevention (EGAPP)
27 Working Group formed under the auspices of the Centers for Disease Control National Office of
28 Public Health Genomics. <http://www.cdc.gov/genomics/gtesting/EGAPP/about.htm>.
29

30 **SECTION 406. CORRECTION OPTION FOR GENETIC INFORMATION.** If an
31 insurer uses an insured's genetic information to make an adverse determination regarding
32 eligibility or rates, terms, or conditions for life insurance, disability-income insurance, or long-
33 term-care insurance, the insurer shall provide notice of that use to the insured. The insured may
34 choose to repeat a genetic test to verify the analysis used in the adverse determination. If the first
35 analysis is found to be inaccurate, the insurer shall reconsider the adverse determination.

36 **Reporter's Notes**

37

38 Under this section, an insured is provided an opportunity to correct mistakes in genetic
39 information. The sections is modeled on Florida procedures which require the DNA analysis to

1 be repeated in the event of an adverse determination. Fla. Stat. § 760.40(3). Delaware also has a
2 special provision that allows an individual to access his genetic records and to correct those
3 records. 16 Del. Code Ann. § 1223.
4

5 **SECTION 407. RETENTION OF GENETIC INFORMATION.** An insured's
6 genetic information is a confidential medical record that a life insurer, disability-income insurer,
7 or long-term-care insurer may retain only with authorization of the insured in accordance with
8 Section 409.

9 **Reporter's Notes**

10
11 This section permits insurers to retain genetic information under certain circumstances. It
12 follows the practice of the states with statutes that require authorization or informed consent for
13 the retention of genetic information and do not treat life, disability-income, or long-term-care
14 insurers differently than others who might retain such information. Other states, however,
15 exempt these insurers from their requirements for authorization or informed consent. (E.g.,
16 Mass., Nev., NH, NMex, Ok)
17

18 There are arguments that insurers should not be limited in retaining genetic information.
19 They typically have two years to rescind a policy for misrepresentation, and may need the
20 information submitted with the application in order to show misrepresentation. In addition,
21 reinsurers may audit underwriting practices several years after a policy issues. Insurance industry
22 representatives state that under current practice, information is retained indefinitely because of
23 the risk of class action suits.
24

25 **SECTION 408. DISCLOSURE OF GENETIC INFORMATION.**

26 (a) A life insurer, disability-income insurer, or long-term-care insurer may disclose an
27 insured's genetic information to a person other than the insured if the insurer has obtained the
28 insured's prior authorization for the disclosure in accordance with Section 409.

29 (b) An insured, upon request, may inspect and obtain a copy of genetic information from
30 the insurer's files on the insured.

31 **Reporter's Notes**

32
33 *Subsection (a).* This subsection restricts the ability of life, disability-income, and long-
34 term-care insurers to disclose genetic information without authorization of the insured. The

1 insurance industry argues that disclosures are necessary for business purposes and that a special
2 disclosure provision for genetic information is unnecessary because of the number of states that
3 have adopted statutes based on National Association of Insurance Commissioners' model laws
4 dealing with general privacy of information.

5
6 *Subsection (b).* Under this subsection, an insured is allowed to access an insurer's
7 records of his genetic information. In combination with the procedure in Section 406, this
8 enables an insured to correct those records.
9

10 **SECTION 409. AUTHORIZATION FOR ACCESS, USE, RETENTION, OR**
11 **DISCLOSURE OF GENETIC INFORMATION.**

12 (a) Except as otherwise provided by this [act] or law other than this [act], an insurer may
13 not access, use, retain, or disclose an insured's genetic information without the insured's
14 knowing and voluntary authorization indicated by a record signed and dated by the insured. An
15 insurer that receives a valid authorization to access, use, retain, or disclose genetic information
16 may do so only in accordance with the authorization.

17 (b) An authorization form to access, use, retain, or disclose an insured's genetic
18 information must:

19 (1) describe the genetic information to be accessed, used, retained, or disclosed in
20 a specific and meaningful fashion;

21 (2) identify or describe the person that is authorized to access, use, retain, or
22 disclose the genetic information;

23 (3) if the authorization is for access to genetic information through disclosure by
24 another person to an insurer, identify or describe the person authorized to make the disclosure;

25 (4) if the authorization is for use of genetic information, describe the permitted
26 uses;

1 (5) if the authorization is for retention of genetic information, describe where the
2 information will be retained and identify or describe the custodian of the information;

3 (6) if the authorization is for disclosure to a third person, identify or describe the
4 third person to which the authorized person may disclose the genetic information;

5 (7) if the authorization is for disclosure to a third person, state that the genetic
6 information disclosed by the authorized person may be subject to redisclosure by the recipient
7 and no longer be protected;

8 (8) indicate the duration of the authorization with an expiration date or expiration
9 event that relates to the insured or to the purpose of the access, use, retention, or disclosure;

10 (9) state that the insured may revoke the authorization at any time in a signed
11 record, subject to the right of a person that acted in reliance on the authorization before receiving
12 notice of revocation, and provide instructions on how to revoke an authorization; and

13 (10) state that the insured is entitled to a copy of the authorization form.

14 **Reporter's Notes**

15
16 This section requires an insured to provide an authorization before an insurer may access,
17 use, retain or disclose genetic information. The provisions differ from those in the employment
18 context in that insurers are permitted to continue their traditional use of family medical history
19 without special authorization requirements.
20

21 The draft does not disturb existing law that allows a minor to seek repudiation of consent
22 and expunge records when the minor reaches the age of majority.
23

24 *Subsection (a) General requirement for authorization.* This subsection would establish a
25 requirement that an insurer must be authorized by the insured before it may access, retain, or
26 disclose genetic information, except as provided elsewhere in the act. In order to give a valid
27 authorization, the insured must be informed as provided in the following subsections and must
28 act voluntarily. Subsection (a) also includes a requirement that an authorization must be
29 indicated by a signed and dated record. The authorization requirement is coupled with
30 limitations on access, use, retention, and disclosure in Sections 403, 404, 405, 406, and 407.
31

1 Other law of the state may provide for a substitute decisionmaker or signer if the
2 employee is incapacitated or incompetent. This situation is left to existing law of the state that
3 governs power of attorney, guardianship, or other substitute decision makers.
4

5 *Subsection (b) Content of authorization.* The provision on authorization for access, use,
6 retention, or disclosure of genetic information is adapted from the HIPAA Privacy Rule
7 regulations for “uses and disclosures for which an authorization is required.” 45 C.F.R. §§
8 164.508 (a) and (c), 164.512(a). The subsection adapts these regulations to apply to genetic
9 information and expands them to include authorization for access and retention as well as for use
10 and disclosure.
11

12 An advantage of using the HIPAA regulations as the foundation for the authorization
13 requirements is that the requirements to authorize a disclosure by a health care provider to an
14 insurer would be similar to the requirements that health care provider must follow as a covered
15 entity under HIPAA. The context of the HIPAA regulations is different enough, however, that
16 they cannot be transported directly into the Act without modification. Moreover, states are
17 permitted to impose their own, more stringent, privacy requirements. 45 C.F.R. § 160.203(b).
18 Some have enacted statutes with different requirements for disclosing health care information,
19 which reduces the uniformity that would theoretically be achieved by using the HIPAA format.
20 Therefore, while the structure of this subsection is modeled on the HIPAA regulations, it
21 includes some additional provisions from various state statutes. *See, e.g.,* Me. Rev. Stat. Ann. tit.
22 § 1711-C.
23

24 **SECTION 410. REVOCATION OF AUTHORIZATION.**

25 (a) Except as provided in subsection (b) or by law other than this [act], an insured may
26 revoke an authorization provided under this [article] at any time in a signed record.

27 (b) An insured may not revoke an authorization provided under this [article]:

28 (1) to the extent that an insurer has taken action in reliance on the authorization;

29 or

30 (2) if the authorization was granted as a condition of obtaining insurance and
31 other law provides the insurer with a right to contest a claim under the policy.

32 **Reporter’s Notes**

33
34 This section is adapted from the HIPAA regulation that governs revocation of an
35 authorization. 45 C.F.R. § 164.508 (b) (5). It is similar to provisions governing health care
36 information that have been adopted by some of the states. Long-term-care insurers are subject to

1 HIPAA, but life insurers and disability-income insurers are not, so this section extends the law in
2 order to give an insured greater control over his genetic information.

3
4 Other law of the state may provide for a substitute decisionmaker or signer if the
5 employee is incapacitated or incompetent. This situation is left to existing law of the state that
6 governs power of attorney, guardianship, or other substitute decision makers.

7
8 Subsection (b)(2) is included in because Section 401 permits an insurer to condition the
9 availability of life, disability-income, or long-term-care insurance on an applicant's authorization
10 for a genetic test or access to genetic information about the test, if the test has been certified
11 according to Section 405 as providing a reliable prediction of mortality or morbidity. An insurer
12 needs to continue to access this information in order to protect against fraud or misrepresentation
13 in an insurance application; it has two years in which to contest the validity of the insurance
14 contract. Records are also kept for reinsurance purposes and for reapplications by the insured.
15

16 **SECTION 411. RETENTION OF AUTHORIZATION.** An insurer that receives an
17 authorization under this [article] shall retain a record of the authorization for six years after the
18 date the authorization was created or the date the authorization expired, whichever is later.

19 **Reporter's Notes**

20
21 This section on the length of the obligation to retain an authorization is adapted from the
22 HIPAA regulations that govern documentation and retention of a signed authorization. 45 C.F.R.
23 §§ 164.508 (b) (6), § 164.530(j).
24

25 **SECTION 412. REMEDIES; ENFORCEMENT; LIMITATION OF ACTIONS.**

26 (a) An individual aggrieved by a violation of this [article] may file a civil action not later
27 than two years after the individual discovers the violation or a person exercising reasonable care
28 should have discovered the violation.

29 (b) If a court finds a violation of this [article], it may award compensatory damages,
30 injunctive relief, including expungement of records, or any other appropriate remedy, including
31 punitive damages. The court shall award a prevailing insured reasonable attorney's fees and
32 costs unless justice requires otherwise.

1 (c) A violation of this [article] is a violation of [the state unfair practices insurance law].
2 An individual aggrieved by a violation of this [article] may initiate an appropriate proceeding
3 with the [state commissioner of insurance] for whatever action the [commissioner] may be
4 authorized to take under the [state unfair practice insurance law] not later than two years after the
5 individual discovers the violation or a person exercising reasonable care should have discovered
6 the violation.

7 *Legislative Note: States should insert for [state commissioner of insurance] the appropriate*
8 *title of this department. [The state unfair practices insurance law] should be replaced with the*
9 *title of the relevant statute.*

10 **Reporter's Notes**

11
12
13 The draft's remedy section is written to respond to privacy violations as well as
14 discrimination or misuse of genetic information in insurance. It provides a private right of action
15 for an aggrieved individual. Alternatively, an aggrieved individual may seek enforcement
16 through the State Commissioner of Insurance, which is a typical provision in state statutes that
17 prohibit discrimination in health insurance based on genetic testing or information. These
18 statutes declare that a violation is an unfair and deceptive insurance act or practice under the state
19 insurance code. They often provide that the State Commissioner of Insurance shall enforce the
20 prohibitions.

21
22 The committee considered and rejected statutory damages as a remedy for a privacy
23 violation for the reason that statutory damages often serve primarily to limit recovery. The
24 absence of statutory damages, however, makes the availability of punitive damages particularly
25 important.

26
27 A comment from a style committee member states that the language would permit two
28 different dates for the statute of limitation and asks the drafting committee to resolve whether
29 intends the earlier or later of the dates the individual discovered or should have discovered the
30 violation.

31
32 This section is identical to the enforcement provision for health insurance.

1 [ARTICLE] 5

2 MISCELLANEOUS PROVISIONS

3 SECTION 501. UNIFORMITY OF APPLICATION AND CONSTRUCTION. In
4 applying and construing this uniform act, consideration must be given to the need to promote
5 uniformity of the law with respect to its subject matter among states that enact it.

6 SECTION 502. RELATION TO ELECTRONIC SIGNATURES IN GLOBAL
7 AND NATIONAL COMMERCE ACT. This [act] modifies, limits, and supersedes the federal
8 Electronic Signatures in Global and National Commerce Act, 15 U.S.C. Section 7001, et seq.,
9 but does not modify, limit, or supersede Section 101(c) of that act, 15 U.S.C. Section 7001(c), or
10 authorize electronic delivery of any of the notices described in Section 103(b) of that act, 15
11 U.S.C. Section 7003(b).

12 SECTION 503. EFFECTIVE DATE. This [act] takes effect