

D R A F T

FOR DISCUSSION ONLY

**UNIFORM PROTECTION OF GENETIC  
INFORMATION IN EMPLOYMENT AND INSURANCE  
ACT**

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NATIONAL CONFERENCE OF COMMISSIONERS

ON UNIFORM STATE LAWS

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MEETING IN ITS ONE-HUNDRED-AND-SEVENTEENTH YEAR  
BIG SKY, MONTANA  
JULY 18 - JULY 25, 2008

**UNIFORM PROTECTION OF GENETIC  
INFORMATION IN EMPLOYMENT AND INSURANCE  
ACT**

*WITH PREFATORY AND REPORTER'S NOTES*

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By

NATIONAL CONFERENCE OF COMMISSIONERS  
ON UNIFORM STATE LAWS

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**UNIFORM PROTECTION OF GENETIC INFORMATION IN EMPLOYMENT AND  
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# UNIFORM PROTECTION 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. This Act strikes a balance between making genetic information available for beneficial uses and preventing access to information that creates a risk of 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).

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 Drafting Committee has identified reasons why it is important to regulate genetic testing and access, use, retention, and disclosure of genetic information by employers and insurers. These include the need to prevent fears of adverse consequences associated with genetic testing; the tendency to overstate the predictive power of genetic information, which can lead to actions that are not justified by that information; and the growing availability of genetic information.

*Fear as a deterrent to genetic testing.* 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 by employers or insurers. Currently, the public is afraid of taking advantage of genetic testing. See, e.g., Amy

Harmon, *Fear of Insurance Trouble Leads Many to Shun or Hide DNA Tests*, N.Y. Times, Feb. 24, 2008, at A1. There is more than anecdotal evidence that these fears are widespread. 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.

*Exaggerated predictive power of genetic information.* 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 that lessens predictability.

The genetic causation of most diseases, and hence their predictability 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.

*Increased Availability of Genetic Information.* 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.

Recent developments are making genetic information far more available and increasing the risk that it can be misused. One development is in genetic testing offered directly to consumers. Companies such as 23andMe and Navigenics offer a genome scan of a saliva sample for as little as \$1,000. There are companies that purport to help clients find DNA-compatible mates based on differences in immune systems or use DNA samples to identify nutritional needs that can be met by purchases of dietary supplements. *See generally* Rick Weiss, *Genetic Testing Gets Personal: Firms Sell Answers on Health, Even Love*, Wash. Post, Mar. 25, 2008.

A second development that will vastly increase the amount of readily available genetic information is the ongoing transition within the practice of medicine to electronic medical records. In 2005, the Secretary of Health and Human Services, Michael Leavitt, established the American Health Information Community, a federal advisory committee, to make recommendations on how to accelerate a shift to electronic records with the goal of reducing costs and improving medical care. Genetic information is typically contained in a standard medical record. Such records could be linked to each other and available electronically.

*Scope of Regulation.* 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).

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), which covers health insurers and other health practitioners, and the recently enacted Genetic Information Nondiscrimination Act of 2008 (GINA), Pub. L. 110-233, which covers health insurers and employers.

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. 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.

Health insurers who are 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.

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.

Recent federal legislation has established specific privacy requirements for genetic information. GINA supplements privacy regulations for group, individual and medigap health insurers already covered by the HIPAA privacy regulations. It prohibits these health insurers from requesting, requiring or purchasing genetic information before an individual’s enrollment and from using genetic information in underwriting or determining eligibility.

The legislation also limits 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, disability-income, and long-term-care insurers. Like HIPAA, the GINA employment provisions do not preempt state legislation that provides equal or greater privacy protection to individuals.

## *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. These limitations are coupled 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.

## Employment

### *General Policy Issues*

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 recent federal legislation, the Genetic Information Nondiscrimination Act of 2008 (GINA), has increased the role of the federal government in regulating genetic testing and genetic information in employment. The employment provisions of this act do not, however, preempt state legislation that provides equal or greater protection to individuals. 42 U.S.C. § 2000ff-8(a)(1). In addition, 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.

Recent federal legislation now specifically regulates access to genetic information and its use by employers. 42 U.S.C. §§ 2000ff to 2000ff-11. GINA applies 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. In six years, a study group will make recommendations regarding whether or not to add a cause of action for disparate treatment. Remedies and enforcement are generally limited to those available under Title VII of the Civil Rights Act of 1964, which requires filing a claim with the Equal Employment Opportunity Commission.

GINA is supplemented by Title VII, which 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 Equal Employment Opportunity Commission (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.

### *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 imposes strict limitations on genetic testing and access to genetic information by employers, employment agencies, labor organizations, and credentialing authorities.

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. These employment entities' use of genetic information is also limited and they may not take an adverse employment action against an employee based on an employee's genetic information. An employment entity must treat an employee's genetic information as confidential and may not keep it or disclose it to others without employee authorization. Remedies are broadly available to individuals, who need not elect to exhaust administrative procedures.

## 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 employer-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.

Recent federal legislation more specifically regulates genetic tests and the use of genetic information in the health insurance industry. GINA extends the HIPAA protections against use of genetic information to determine eligibility or establish exclusions for pre-existing conditions to the individual and small group health insurance market. It also adds new protections. In terms of access, it prohibits a health insurer from requesting or requiring an individual to take a genetic test, with an exception for requests for research purposes, and from collecting genetic information by requesting, requiring, or purchasing it. In terms of use of genetic information, health insurers may not use genetic information adjust premium rates and may not use or disclose genetic information for use in underwriting health insurance.

#### *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, Va, WV, 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*

Life, disability-income, and long-term-care insurance are not covered by the recent federal Genetic Information Nondiscrimination Act of 2008.

*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 §§ 69O-128.001 to 69O-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                   **UNIFORM PROTECTION OF GENETIC INFORMATION IN EMPLOYMENT**  
2   **AND INSURANCE ACT**

3  
4   **[ARTICLE] 1**

5   **GENERAL PROVISIONS**

6                   **SECTION 101. SHORT TITLE.** This [act] may be cited as the Uniform Protection of  
7 Genetic Information in Employment and Insurance Act.

8   **Reporter’s Notes**

9  
10                   The Drafting Committee has asked the Chair to request that the Executive Committee  
11 authorize changing the name of the act to “Protection of Genetic Information in Employment and  
12 Insurance.” They believe that “Misuse” is a misnomer in the context of the act because many of  
13 the provisions of the act permit certain uses. In addition, the proposed title better reflects the  
14 scope of the act, which goes beyond use to include access, retention, and disclosure of genetic  
15 information, setting a balance that provides appropriate protection for genetic information in all  
16 these contexts. *(NOTE: this name change was approved by the Executive Committee via*  
17 *Conference Call on June 19, 2008.)*  
18

19                   **SECTION 102. DEFINITIONS.** In this [act]:

20                   (1) “Adverse insurance determination” means a denial of coverage or the offering of less  
21 favorable rates, terms, or conditions for insurance than would be available if the insurer did not  
22 use genetic information in making the determination.

23                   (2) “Applicant for employment” means an individual who is applying to become an  
24 employee.

25                   (3) “Applicant for insurance” means an individual who is applying for health, life,  
26 disability-income, or long-term-care insurance.

27                   (4) “Child” means a son or daughter of an individual, whether related by whole or half  
28 blood, affinity, adoption, or born as the result of assisted reproduction technology, who is

1 deemed to be a child of the individual under law other than this [act].

2 (5) “Credentialing authority” means a governmental or private entity that provides a  
3 license, registration, or credential or certifies competence that is necessary for an individual to  
4 qualify for employment or to participate in an occupation or profession.

5 (6) “Disability-income insurance” means insurance intended to protect against loss of  
6 occupational or professional earning capacity arising from injury, sickness, or disablement. The  
7 term includes insurance that provides benefits for overhead expenses of a business, occupation,  
8 or profession when the insured becomes disabled.

9 (7) “Employee” means an individual who works for compensation. The term includes an  
10 individual employed in a supervisory, managerial, or confidential position. The term does not  
11 include an independent contractor.

12 (8) “Employer” means a person that has an employee.

13 (9) “Employment entity” means an employer, employment agency, labor organization, or  
14 credentialing authority.

15 (10) “Family medical history” means information about a current or past medical  
16 condition of a family member of an individual.

17 (11) “Family member” means an individual’s spouse or [domestic partner], child, and all  
18 individuals related by whole or half blood within the fourth degree of consanguinity measured  
19 using the civil law method to the individual, the individual’s spouse or [domestic partner], or the  
20 individual’s child.

21 (12) “Genetic counseling” includes:

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

1 (B) providing nondirective education about the inheritance, testing, management,  
2 and prevention of a genetic condition;

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

6 (D) communicating and interpreting test results; and

7 (E) providing support, informational resources, and referrals as appropriate to help  
8 an individual adapt to the medical, psychological, and familial implications of having or being at  
9 risk of having a genetic condition.

10 (13) “Genetic education” means the process by which an individual acquires information  
11 about the individual’s or the individual’s family member’s existing or suspected genetic  
12 condition.

13 (14) “Genetic information” means:

14 (A) the results of a genetic test;

15 (B) information based on the genetic test of an individual or an individual’s family  
16 member; or

17 (C) information that an individual or an individual’s family member requested or  
18 received genetic services.

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

22 (16) “Genetic service” means a genetic test, genetic counseling, or genetic education.

23 (17) “Genetic test” means an analysis of human genetic material, including

1 deoxyribonucleic acid, ribonucleic acid, chromosomes, proteins, and metabolites, that is intended  
2 to detect:

3 (A) a genotype or genetic marker; or

4 (B) a mutation or chromosomal change.

5 (18) “Health insurance” means a health-care arrangement assuming financial risk to pay  
6 for, purchase, or furnish health-care services to patients, insureds, or beneficiaries.

7 (19) “Insured” means an individual who is covered by health, life, disability-income, or  
8 long-term-care insurance.

9 (20) “Insurer” means a person engaged in the business of health, life, disability-income,  
10 or long-term-care insurance in this state, regardless of where a contract of insurance is entered  
11 into or issued or a plan is administered. The term includes an insurance agent, broker,  
12 underwriter, and third-party administrator.

13 (21) “Life insurance” means insurance against the financial risk of death.

14 (22) “Long-term-care insurance” means insurance that provides coverage for not less than  
15 12 consecutive months for one or more necessary diagnostic, preventive, therapeutic,  
16 rehabilitative, maintenance, or personal-care services provided in a setting other than an acute  
17 care unit of a hospital. The term includes a policy or rider that provides for payment of benefits  
18 based upon cognitive impairment or inability to perform the activities of daily living.

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

22 (24) “Predisposing genetic characteristic” means a gene variant or genetic marker that is  
23 determined from genetic information and is associated with an individual’s increased risk of

1 developing a disease or medical condition for which the individual is presently asymptomatic.

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

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

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

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

8 (27) “Tribunal” means a court, arbitral tribunal, or administrative agency.

9 **Legislative Note:** *In the definition of “family member” states should insert for [domestic*  
10 *partner] the appropriate term for an unmarried partner who is eligible for benefit coverage such*  
11 *as health insurance in the workplace, such as “partner,” “significant other,” “domestic*  
12 *partner” or other term.*

### 13 **Reporter’s Notes**

14  
15  
16 *Paragraph (1). (Adverse insurance determination)* The use of genetic information makes  
17 an insurance determination adverse if it leads to denial of coverage or coverage on less favorable  
18 terms than would have been available absent the insurer’s consideration of the information. This  
19 definition is relevant to an individual’s ability to correct a faulty genetic test that has  
20 consequences for insurance eligibility or terms and conditions for issuance of insurance.

21  
22 *Paragraph (2). (Applicant for employment)* This definition is added at the request of  
23 members of the style committee to differentiate applicants from employees. Article 2 provides  
24 that applicants for employment and employees are to be treated identically in terms of an  
25 employer’s genetic testing and access, use, retention, and disclosure of genetic information.

26  
27 *Paragraph (3). (Applicant for insurance)* This definition is added to create a parallel  
28 structure for the insurance and employment articles by separating out applicants in both contexts.

29  
30 *Paragraph (4). (Child)* This definition acknowledges the many ways in which the  
31 relationship of parent-child is created, including by adoption and assisted reproductive  
32 techniques. This relationship is governed by other law, such as the Uniform Parentage Act.

33  
34 *Paragraph (5). (Credentialing authority)* Credentialing authorities serve as gatekeepers  
35 to certain types of employment by providing credentials that are required either under state law or  
36 by an employer. Examples include state bar and medical examination boards, which control  
37 entry to the practice of law and medicine, and state departments of motor vehicles, which issue  
38 commercial drivers licenses necessary for some employment. Access or use of genetic

1 information by a credentialing authority could have the same effects on employees and applicants  
2 for employment as access or use by an employer.

3  
4 *Paragraph (6). (Disability-income insurance)* This definition of disability-income  
5 insurance is used in several state statutes on genetic testing. *See, e.g.,* Cal. Ins. Code § 10147;  
6 N.H. Rev. Stat. Ann. § 141-H:1. The committee discussed substituting the term “income” for  
7 “earning capacity,” but decided not to make this substitution.

8  
9 *Paragraph (7). (Employee)* The definition of employee is adapted from the National  
10 Conference of Commissioners on Uniform State Law’s Model Employment Termination Act.  
11 The definition’s requirement for compensation is intended to exclude volunteers from the  
12 definition of employee.

13  
14 The drafting committee considered including independent contractors in the definition of  
15 employees, but decided to exclude this category of workers. This approach is not intended,  
16 however, to provide employers with an avenue to evade their obligations by classifying  
17 employees as independent contractors.

18  
19 *Paragraph (8). (Employer)* The definition of employer is linked to the definition of  
20 “person” in paragraph 16 and therefore encompasses all types of entities, including governmental  
21 and non-profit employers. “Employer” takes its meaning from the broad definition of  
22 “employee” in paragraph 7.

23  
24 As the definition of employer is currently drafted, the act would cover all employers  
25 regardless of size. One consideration is whether the requirements of the act would prove too  
26 burdensome for small employers. Many statutes specify a minimum size using the number of  
27 employees as a proxy for size. For example, Title VII of the Civil Rights Act of 1964 covers  
28 employers who had 15 or more employees for each working day in 20 or more weeks over the  
29 course of a year. The definition in the Uniform Law Commissioner’s Model Employment  
30 Termination Act requires five employees and extends the measurement period to two years.

31  
32 Another way to limit the types of employers that are covered would be to exclude  
33 immediate family members from the count of employees, as is done in the Fair Labor Standards  
34 Act and the National Conference of Commissioners on Uniform State Law’s Model Employment  
35 Termination Act. In addition, some state statutes exclude particular employee groups, such as  
36 household workers or farm workers, in determining employer status.

37  
38 *Paragraph (9). (Employment entity)* Employment entity is the term used in the act to  
39 collectively indicate an employer, an employment agency, a labor organization, or a credentialing  
40 authority.

41  
42 *Paragraph (10). (Family medical history)* Family medical history is often a source of  
43 genetic information in that it is used to evaluate the likelihood that an individual carries an  
44 inherited trait. The act’s definition of “genetic information” does not encompass medical history,  
45 so a separate definition is needed when the act’s provisions apply to this category of information.

1            *Paragraph (11). (Family member)* A family member is defined broadly to encompass all  
 2 individuals whose own genotype could influence an employment or insurance decision. The  
 3 term includes (1) biological relations whose genetic information might provide information about  
 4 the genetic make-up of an individual employee or insured, (2) dependants whose risk of future  
 5 genetically-linked medical conditions could affect employer health care costs or family insurance  
 6 coverage and hence affect employment or insurance decisions, and (3) dependants’ biological  
 7 relations whose genetic information might provide information about the genetic make-up of a  
 8 dependant. The separately-defined term “child” includes both adopted and biologically-related  
 9 children because either can affect health-care costs or family insurance coverage.

10  
 11            Many employers provide health insurance for employees’ unmarried partners. Therefore,  
 12 an unmarried partner can be a dependent whose risk of a genetically-linked medical condition  
 13 could affect employment or insurance decisions. As a result, “domestic partner” is included in  
 14 the definition of family member for purposes of obtaining, retaining, using, and disclosing  
 15 genetic information. The brackets around this term are not meant to indicate that a state may  
 16 drop the concept, but only that a state should substitute the term it uses for a person in this  
 17 relationship. This definition is not meant to affect other state law definitions of marriage or  
 18 family.

19  
 20            Genetic counselors typically collect information on genetic diseases of family members  
 21 related to the third degree of consanguinity and often to the fourth degree. The drafting  
 22 committee considered a provision that replaced the designation “fourth degree of consanguinity”  
 23 with a list of family members, but decided instead to include information in the notes that  
 24 designates which family members are included within the fourth degree of consanguinity.

25  
 26            Lineal consanguinity is the relationship between persons when one is directly descended  
 27 from the other. Each generation in this direct line constitutes a degree. Collateral consanguinity  
 28 refers to the relationship between persons who descend from the same common ancestor, but not  
 29 from each other. The civil law method of calculating degree of collateral consanguinity, used in  
 30 most states, is to count the number of generations from one person up to the common ancestor  
 31 and then down to the other person. The following table identifies the relatives within four  
 32 degrees of consanguinity from an individual, with each row representing a generation.

33

34				Great-great-grandparents (4)
35			Great-grandparents (3)	
36		Grandparents (2)	Grand Aunts and Grand Uncles (4)	
37	Parents (1)	Aunts and Uncles (3)		

1	Individual	Sisters and Brothers (2)	First Cousins (4)		
2	Children (1)	Nieces and Nephews (3)			
3	Grandchildren (2)	Grandnieces and Grandnephews (4)			
4					
5	Great-grandchildren (3)				
6					
7					
8	Great-great-grandchildren (4)				
9					
10					

11  
12 *Paragraph (12). (Genetic counseling)* Genetic counseling is a key to an individual’s  
13 informed decision making about getting a genetic test, understanding the result, and authorizing  
14 its use, retention, or disclosure. Most states that license genetic counselors have a definition of  
15 genetic counseling, but the majority of states do not license genetic counselors or regulate genetic  
16 counseling. Note that the definition does not require that genetic counseling be performed by a  
17 genetic counselor. Physicians and geneticists are also qualified to provide genetic counseling.  
18

19 The definition uses the term genetic “condition,” which is intended to have a broad  
20 interpretation. Genetic condition includes the concepts of genetic disease and disorder, but in  
21 some circumstances it may also refer to a positive or benign trait or characteristic that is linked to  
22 a particular genotype.  
23

24 Genetic counseling is usually a two-step process consisting of 1) counseling before a test  
25 about the decision whether or not to have the test and 2) counseling after the test if the test  
26 indicates the individual is at risk. In addition, for some conditions counseling may also be  
27 appropriate if the test indicates the individual is not at risk. The functions listed in (A)-(C) of the  
28 definition of genetic counseling take place before an individual decides whether or not to have  
29 the test. The functions in (D) and (E) take place after the test, if necessary.  
30

31 *Paragraph (13). (Genetic education)* Genetic education is one element of genetic  
32 services. It is typically less tailored to individual circumstances than a one-on-one genetic  
33 counseling session. The definition is meant to be broad enough to include information provided  
34 by support groups for genetic conditions to those who may have the condition. It is not meant to  
35 encompass general genetic education such as that received in biology class or medical school.  
36

37 *Paragraph (14). (Genetic information)* This definition of “genetic information” is  
38 modeled on state provisions that do not include family history in the definition. (Ark, Del, LA,  
39 Minn, Neb, NH, NY, OK, OR, UT, VT) This narrow definition of genetic information is  
40 important for Article 4 on life, disability-income, and long-term-care insurance, in which the



1 draft allows these insurers to continue to collect information on family history, even though  
2 family history is a major source of information to evaluate an individual’s genetic risks.  
3

4 Many states use a more comprehensive definition of “genetic information” that includes  
5 information on genetic characteristics broadly, whether obtained from genetic tests or family  
6 medical history. (Cal, Conn, Hawaii, LA, Maine, MD, Mass, Mich, NJ, NMex, NC, RI, SD, TX,  
7 WA). In addition, the federal Genetic Information Nondiscrimination Act of 2008 also uses a  
8 broad definition that includes family history. The federal definition provides that the term means  
9 “information about (i) an individual’s genetic tests; (ii) the genetic tests of family members of the  
10 individual; or (iii) the occurrence of a disease of disorder in family members of the individual.”  
11 Information about the sex or age of an individual is excluded from this definition.  
12

13 The drafting committee has decided to use the broader concept of information, including  
14 family history, for Articles 2 and 3 on employment and health insurance. This meaning is  
15 conveyed in these articles by using the narrowly-defined term “genetic information” in  
16 combination with the term “family medical history.”  
17

18 Information about an individual’s request for or receipt of genetic services is included in  
19 the category of genetic information for ease of drafting.  
20

21 *Paragraph (15). (Genetic monitoring)* The definition of “genetic monitoring” is drawn  
22 from the description in Office of Technology Assessment, *Genetic Monitoring and Screening in*  
23 *the Workplace* 4 (1990). The focus in monitoring is not on inherited characteristics, but on  
24 genetic alterations in a group of exposed individuals over time. Genetic monitoring is typically  
25 undertaken by employers to identify risks for groups of employees who have been exposed to  
26 hazardous substances or to target work sites for safety and health measures. Testing for this  
27 purpose is permitted in Section 202.  
28

29 *Paragraph (16). (Genetic service)* “Genetic service” is a broader category than genetic  
30 testing. The term includes activities associated with obtaining genetic information that could  
31 create assumptions about an individual’s genetic status even in the absence of information about  
32 genetic test results or medical history. “Counseling” implies a one-on-one consultation, so the  
33 definition also includes “genetic education” in order to capture group information sessions on  
34 genetic conditions. While the definition of a “genetic service” does not separately define the  
35 term “genetic,” the term should be interpreted to be consistent with the definitions of “genetic  
36 test” and “genetic information.”  
37

38 *Paragraph (17). (Genetic test)* “Genetic test” is defined in terms of (1) the material that  
39 the test analyzes and (2) the purpose of the test. This structure and the lists in the definition are  
40 consistent with the definition of “genetic test” in the medical insurance provisions of the federal  
41 Genetic Information Nondiscrimination Act of 2008, which prohibits discrimination on the basis  
42 of genetic information with respect to health insurance and employment.  
43

44 The first clause makes specific reference to the types of biological material that are  
45 currently analyzed in genetic tests. Note that genetic tests can be conducted not only on gene  
46 sequences, but also on biological products such as proteins or metabolites that can indicate

1 genetic make-up. The second clause specifies that the test must be for the purpose of  
2 determining an individual’s genetic make-up, either through the identification of a genotype or  
3 genetic marker or by looking for a mutation or chromosomal change.  
4

5 Both clauses are equally important to the definition. First, some of the materials listed in  
6 the first clause, especially proteins and metabolites, are tested for many medical purposes. A test  
7 of a protein or metabolite does not constitute a genetic test unless it is administered for the  
8 purpose of determining individual’s genetic make-up as specified in the second clause.  
9

10 Second, some genetic diagnoses are made without laboratory tests of the type listed in the  
11 first clause. For example, a doctor may identify a genetic condition based on specific physical  
12 features occurring in combination, or “dismorphology.” This physical diagnosis of an  
13 individual’s genetic-make-up does not constitute a genetic test under the draft because it is not a  
14 test of “genetic material.”  
15

16 Insurance industry representatives have expressed the fear that this definition is so broad  
17 that it will sweep in routine medical tests such as blood tests of lipoproteins to measure  
18 cholesterol levels. It is true that a cholesterol test analyzes proteins. A cholesterol test is not,  
19 however, given specifically to detect a genotype, genetic marker, mutation, or chromosomal  
20 change, so it would not be considered a genetic test under the draft. Instead, a high cholesterol  
21 reading may indicate a number of causal factors, including inappropriate diet, lack of exercise,  
22 and/or a condition called inherited familial high cholesterol. If the measurement of cholesterol  
23 leads a doctor or insurance company to do further testing to see if an individual has a specific  
24 genotype, then that would be a genetic test under the draft’s definition. Other common medical  
25 tests of proteins or metabolites that would not fall under the definition of “genetic test” include  
26 urine tests for kidney disease, blood protein and creatinin tests for diabetes, blood tests of liver  
27 enzyme proteins for liver function, urine tests measuring glucose to diagnose diabetes, blood  
28 tests measuring serum blood glucose for diabetes, and triglycerides for heart disease.  
29

30 The draft follows the example of states with definitions of genetic testing that are not  
31 limited to identifying genotypes associated with diseases or impairments. (Fla, Haw, Mass, NH,  
32 Ore, UT). In contrast, many other states statutes limit their definition of “genetic test” to testing  
33 for disease-related genes. (Ariz, Ark, Del, Ill, Iowa, Kan, LA, Maine, MD, Mich, Minn, Nev,  
34 MO, Neb, NJ, NM, NY, NC, OK, OR, RI, TX, VT, VA, WI). While most of the reasons that an  
35 employer or insurer might currently seek or use genetic information probably involve a disease,  
36 disorder, or impairment, this may not always be the case. One can imagine, for example, that the  
37 presence or absence of behavioral traits might also be a criterion for selecting an employee.  
38 While the current evidence linking behavior to genes is tenuous, this area continues to be the  
39 subject of investigation. Moreover, a broad definition of “genetic test” will facilitate extension to  
40 topics outside employment and insurance, if that is a direction the National Conference of  
41 Commissioners on Uniform State Laws takes in future uniform acts. For example, provisions  
42 governing the retention of samples used for research or identification would cover testing that is  
43 not necessarily linked to disease.  
44

45 *Paragraph (18). (Health insurance)* The definition of “health insurance” is meant to be  
46 broad. Definitions and terms of art vary greatly among the states. For example, a number of

1 states use the term “disability insurance” for what is commonly thought of as “health insurance.”  
2 The definition is written in terms of functions and is intended to capture the full range of  
3 organizational structures for health insurance without regard to specific state designations. These  
4 organizational structures include insurance that covers hospital, medical, or health expenses;  
5 employee welfare-benefit plans; health maintenance organizations; preferred-provider  
6 organizations; medical service organizations; physician-hospital organizations; self-insured  
7 health plans; and prepaid health-care service plans.  
8

9 *Paragraph (19). (Insured)* The definition of “insured” encompasses individuals with the  
10 types of insurance policies covered by the act.  
11

12 *Paragraph (20). (Insurer)* The definition of “insurer” is intended to cover broadly  
13 insurance companies and other persons and individuals that issue health, life, disability-income,  
14 or long-term-care insurance and all persons who might obtain, use, or disclose genetic  
15 information associated with that process. Nothing in this definition is intended to subject  
16 insurance agents, brokers, underwriters, or third-party administrators to insurance regulations to  
17 which they are not already subject.  
18

19 *Paragraph (21). (Life insurance)* “Life insurance” is intended to be defined broadly.  
20 This definition is drawn from N.H. Rev. Stat. § 401:1(III).  
21

22 *Paragraph (22). (Long-term-care insurance)* The starting point for the definition of  
23 “long-term-care insurance” is N.H. Rev. Stat. § 415-D:3(V). The definition is intended to  
24 include all coverage of this nature whether it is provided on an expense-incurred, indemnity,  
25 prepaid, or other basis.  
26

27 *Paragraph (23). (Person)* This draft uses the broad version of the standard National  
28 Conference of Commissioners on Uniform State Laws definition of “person.”  
29

30 *Paragraph (24). (Predisposing genetic characteristic)* A “predisposing genetic  
31 characteristic” refers to a genotype that signals an increased risk of a certain disease or condition.  
32 The term does not include symptomatic diseases or conditions or genetic characteristics that are  
33 manifest in a disease, medical condition, or disability. The broader terms “genetic test” and  
34 “genetic information” may include both predisposing and manifest genetic characteristics as well  
35 as genetic information that does not necessarily pertain to health.  
36

37 While the terms “propensity” or “susceptibility” are often used, the actual manifestation  
38 of a disease or condition may depend on a complex chain of events and the degree to which risk  
39 is elevated may be quite small. The use of the term “predisposing” is meant to signal the tenuous  
40 connection between a genotype or marker and a physical manifestation.  
41

42 *Paragraph (25). (Record)* The definition of “record” is the standard National Conference  
43 of Commissioners on Uniform State Laws definition.  
44

45 *Paragraph (26). (Sign)* The definition of “sign” is the standard National Conference of  
46 Commissioners on Uniform State Laws definition.

1                    *Paragraph (27). (Tribunal)* The term “tribunal” refers collectively to the potential  
2 decision-makers in a litigation or arbitration context.  
3

1 [ARTICLE] 2

2 EMPLOYMENT

3 SECTION 201. APPLICANT FOR EMPLOYMENT. For purposes of this [article]  
4 an applicant for employment shall be treated the same as an employee.

5 Reporter’s Notes

6  
7 *Applicability of Article 2.* This article is intended to apply broadly in the employment  
8 setting to any employment entity. Employment agencies, labor organizations, and credentialing  
9 authorities are included within the scope of the article in addition to employers because they  
10 control access to employment through referrals or licensing.

11  
12 *Applicants.* For simplicity, the article refers only to employees. The provisions apply  
13 equally to applicants for employment.  
14

15 SECTION 202. GENETIC TESTING.

16 (a) Except as otherwise provided in this section or by law other than this [act], an  
17 employment entity may not require, offer, or provide a genetic test to an employee.

18 (b) An employment entity may offer a genetic test and, with prior authorization for the  
19 test by an employee that meets the requirements of Section 203, may provide the genetic test:

20 (1) to determine the employee’s predisposing genetic characteristics that may  
21 create susceptibility to harm to the employee from a workplace condition;

22 (2) to monitor the effects of the employee’s exposure to a workplace condition as  
23 part of a genetic monitoring program; or

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

25 (c) An employment entity that offers a genetic test to an employee shall provide and pay  
26 for genetic counseling for the employee about the risks and benefits of the genetic test before the  
27 employee considers authorizing the test unless the employee knowingly and voluntarily waives  
28 counseling in a signed record that informs the employee of the benefits of genetic counseling;

1 (d) An employment entity that provides a genetic test to an employee shall:

2 (1) pay for the genetic test;

3 (2) require the testing organization to report the test result to the employee and a  
4 health-care professional designated by the employee unless the employee directs otherwise;

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

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

10 (e) If a tribunal orders an employee to take a genetic test under Section 204(d), the  
11 employment entity shall provide and pay for the genetic test.

### 12 **Reporter’s Notes**

13  
14 *Relationship between genetic testing and access to genetic information.* Genetic testing  
15 is a means by which an employer or other employment entity can obtain genetic information, but  
16 it is also possible for employers to supply testing without gaining access to individualized test  
17 results. Therefore the draft separates provisions on access to genetic information, treated in  
18 Section 204, from the provisions in this section on genetic testing. An employment entity that  
19 provides genetic testing should supply it through an outside medical organization. *See* Mark A.  
20 Rothstein, *Genetics and the Workforce of the Next Hundred Years*, 2000 Colum. Bus. L. Rev.  
21 371 (2000).

22  
23 *Genetic testing.* Many states broadly prohibit employers from subjecting employees to  
24 genetic testing. *See, e.g.*, Iowa Code Ann. § 729.6 (employer may not “solicit, require, or  
25 administer” a genetic test as a condition of employment); Kan. Stat. Ann. § 44-1009(a)(9)  
26 (employer may not subject, directly or indirectly, any employee to any genetic screening or test);  
27 Md. Code Art. 49B § 16(a) (employer may not “request or require” genetic tests as a condition  
28 for hiring or determining benefits); Mass. Gen. L. Art. 151B § 4(19) (unlawful to “solicit  
29 submission to, require, or administer a genetic test” as a condition of employment); Mich. Comp.  
30 Laws § 37.1202 (no employer may require a genetic test as a condition of employment); Minn.  
31 Stat. Ann. § 181.974(subd. 2) (employer may not “administer a genetic test” as a condition of  
32 employment); Neb. Rev. Stat. § 48-236 (employer may not require a genetic test as a condition or  
33 employment or promotion); Nev. Rev. Stat. § 613.345 (unlawful employment practice to “require  
34 or administer” a genetic test as a condition of employment); N.H. Rev. Stat. § 141-H (may not  
35 “solicit, require, or administer” genetic testing as a condition of employment); RI Stat. § 28-6.7-1

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

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

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

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

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

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

40 The utility of testing for susceptibility to workplace exposures is illustrated by chronic  
41 beryllium disease. Beryllium is a lightweight metal used in many industries that poses the threat  
42 of this disease when dust or fumes are inhaled. Industry protections have greatly reduced  
43 exposure, but a small portion of the population can contract the disease even after a very brief  
44 exposure. A genetic marker has reportedly been identified for this extreme sensitivity that  
45 purports to show with certainty which individuals will contract beryllium disease and die from  
46 short exposure. Cynthia Nance, Paul Miller, & Mark Rothstein, *Discrimination in Employment*

1 *on the Basis of Genetics*, 6 Employee Rights & Employment Policy Journal 57, 63-64 (2002). If  
2 so, testing could provide information that could define an individual's risk from workplace  
3 exposure to beryllium.

4  
5 The draft allows an employment entity to supply testing for such susceptibilities, but  
6 unless the employee volunteers the test results under Section 204(b), the employment entity is  
7 not authorized to obtain them.

8  
9 *Subsection (b)(2) Genetic monitoring program.* Monitoring for damage to employees'  
10 genes from workplace exposure to harmful substances is another possible justification for testing.  
11 The states that permit an employer to screen for genetic susceptibility to harmful workplace  
12 substances also permit monitoring for exposure provided that the employee requests testing,  
13 provides informed consent or authorization, and the employer does not terminate the employee or  
14 take other adverse action as a result of testing. Iowa Code Ann. § 729.6(7); N.H. Rev. Stat. §  
15 141-H:3; N.Y. Exec. Law § 296; Wis. Stat. Ann. § 111.372. In addition, Louisiana authorizes  
16 monitoring of biological effects of toxic substances in the workplace if the employee has  
17 provided authorization and is notified of the results. La. Rev. Stat. § 23:368. More generally, the  
18 definitions and prohibitions in many state's statutes do not appear to restrict monitoring for  
19 genetic damage, or are ambiguous on this issue.

20  
21 Genetic damage is caused by mutagens, that is, substances that are capable of triggering  
22 change in the genetic material of a cell. Genetic damage appears in the form of recessive and  
23 dominant mutations, large rearrangements of DNA, point mutations, or loss of genetic material.  
24 Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace* 71  
25 (1990).

26  
27 There are multiple genetic tests for exposure to mutagens at both the chromosomal and  
28 molecular level. The most common indicators of chromosomal (cytogenic) damage are  
29 chromosomal aberrations (CAs) and sister chromatid exchanges (SCEs). CAs are chromosomes  
30 with breakage or rearrangements. *Id.* at 62. CAs are more likely to be induced by ionizing  
31 radiation than chemical agents, but there are notable exceptions. For example, vinyl chloride  
32 exposure results in increased CAs and places workers at risk of developing a form of liver  
33 cancer. Workers exposed to benzene show elevated CAs and are at increased risk of leukemia.  
34 *Id.* at 65. Sister chromatids are the two daughter strands of a duplicated chromosome. An  
35 exchange results when apparently equivalent sections of the sister chromatids of the same  
36 chromosome are switched during cell division. SCE is a sensitive marker for DNA damage and  
37 repair that results only from chemical mutagens, not from radiation. *Id.* at 63.

38  
39 As of 1990, no occupational studies had directly connected chromosomal abnormalities to  
40 increased individual risk for disease. Thus, while CA and SCE monitoring may have predictive  
41 value for a group, it is not a reliable way to predict health risks for an individual. *Id.* at 66.  
42 Monitoring can, however, be used by employers to reduce exposures to known mutagens to a  
43 level that does not affect individuals' chromosome morphology or DNA. Data on CAs are  
44 routinely used by regulatory agencies in the process of setting exposure standards for industry.  
45 *Id.*



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

10  
11           This draft recognizes the utility of monitoring in the workplace using such tests, and  
12 permits employment entities to supply genetic testing as part of a genetic monitoring program.  
13 Employment entities may not, however, have access to test results except in the aggregate, non-  
14 individually identifiable form prescribed in Section 204(c).

15  
16           *Subsection (b)(3) Employee health plan.* An employer that provides preventative health  
17 services to encourage a healthy workplace may include genetic testing as part of those services.  
18 The test results would not be available to the employer unless the employee volunteers them  
19 under section 204(b).

20  
21           *Subsection (c) Genetic counseling when an employment entity offers a test.* The draft  
22 requires employers to provide genetic counseling about the risks and benefits of the test before  
23 signing the authorization for testing, so that the employee can make an informed decision about  
24 whether or not to have the test. The committee decided that an employee may, however, decline  
25 the counseling.

26  
27           Employer-provided genetic counseling should normally be conducted by professionals –  
28 typically genetic counselors, geneticists, or physicians – from outside the employer organization.

29  
30           *Subsection (d) Requirements when an employment entity provides a genetic test.*

31  
32           *Subsection (d)(1) Payment.* This subsection imposes a payment obligation on the  
33 employment entity that provides a genetic test.

34  
35           *Subsection (d)(2) Reporting test results.* This subsection provides for reporting genetic  
36 test results to the employee when an employment entity supplies testing. The reporting  
37 obligation is incurred whether or not the employer may obtain the test results under Section 204.  
38 An employer must be sensitive, however, to the fact that not all individuals wish to know their  
39 genetic information. The draft recognizes an employee’s right to decline to know the results of a  
40 genetic test. An employee may not wish to be informed of the result because of the  
41 psychological burdens that may accompany such knowledge.

42  
43           *Subsection (d)(3) Genetic counseling.* Along with reporting test results to a health care  
44 professional, the draft mandates the availability of genetic counseling so that the results can be  
45 interpreted for the employee if the result is positive.

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

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

13            *Subsection (e) Legal proceedings.* This subsection requires an employer to supply the  
14 genetic testing when a tribunal has ordered that an employer may obtain genetic information  
15 relevant to a claim or defense in a legal proceeding under subsection 204(d).  
16

17            **SECTION 203. EMPLOYEE AUTHORIZATION FOR A GENETIC TEST.**

18            (a) Except as otherwise provided by law other than this [act], an employee’s authorization  
19 for a genetic test must be knowing and voluntary and indicated in a record signed by the  
20 employee that complies with subsection (b) of this section. An employment entity that receives a  
21 valid authorization for genetic testing may provide a test only in accordance with the  
22 authorization. An authorization may not expand the genetic testing permitted by this [article] and  
23 may not include exculpatory language waiving any of the employee’s legal rights.

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

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

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

28                    (3) inform the employee that the employment entity is obligated to provide and  
29 pay for genetic counseling about the risks and benefits of the test before the employee decides to  
30 authorize the test;

31                    (4) inform the employee that the employment entity is obligated to provide and

1 pay for genetic counseling about the test result unless the employee waives genetic counseling;

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

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

6 (7) inform the employee that the employee's biological sample will be destroyed  
7 as soon as permitted by law after the test is completed unless the employee authorizes retention  
8 of the sample or unless otherwise ordered by a tribunal; and

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

10 (c) The use of the following form complies with this section.

11 AUTHORIZATION FOR GENETIC TESTING

12  
13 Limited Authorization. Only the genetic tests that you authorize on this form will be  
14 performed on your biological sample. These tests are voluntary.

15  
16  
17  
18 Availability of Genetic Counseling. Before you complete this authorization, it is highly  
19 recommended that you meet with a genetic counselor who will help you understand and evaluate  
20 the risks, benefits, and consequences for you and your family of having the tests listed below.  
21

22  
23  
24 \_\_\_\_\_ will provide and pay for this genetic counseling.  
25 [Name of employment entity]

26  
27  
28 Proposed Genetic Tests. \_\_\_\_\_ proposes to provide the following  
29 [Name of employment entity]  
30 genetic tests:

31  
32  \_\_\_\_\_  
33 [Name of test]

34  
35 The purpose of this test is to determine if you have a genetic characteristic that  
36

1 predisposes you to harm from \_\_\_\_\_ . \_\_\_\_\_  
2 [workplace condition] [Name of employment entity]  
3 may not request or require you to disclose this test result and it will not have access to the  
4  
5 test result unless you authorize it. If you authorize \_\_\_\_\_ to have access to the  
6 [employment entity]  
7 test result, it will be used only for the following purposes: \_\_\_\_\_ .  
8  
9

10  \_\_\_\_\_  
11 [Name of test]  
12

13 This test is provided as part of a genetic monitoring program. The purpose of this test is  
14  
15 to monitor the effect of your exposure to \_\_\_\_\_. The result of the test will be  
16 [workplace condition]  
17 used only for the following purposes: \_\_\_\_\_ . \_\_\_\_\_  
18 [Name of employment entity]  
19 will have access to the test results of all employees who authorize this test only in an  
20  
21 aggregate form that does not include individually identifiable information.  
22  
23

24  \_\_\_\_\_  
25 [Name of test]  
26

27 This test is provided as part of a confidential preventative health plan. The purpose of the  
28  
29 test is \_\_\_\_\_. \_\_\_\_\_ may not request or  
30 [Name of employment entity]  
31 require you to disclose this test result and it will not have access to the test result unless  
32  
33 you authorize it. If you authorize access to the test result, it will be used only for the  
34  
35 following purposes: \_\_\_\_\_ .  
36  
37

38 Reporting Test Results and Genetic Counseling. The test results will be reported to you and  
39  
40 to a health-care professional whom you designate unless you direct otherwise. It is  
41  
42 recommended that you receive genetic counseling about the test results. \_\_\_\_\_  
43 [Name of employment entity]  
44 will provide and pay for genetic counseling about the test results unless you decline genetic  
45  
46 counseling. Genetic counseling is important for understanding the test results in the context of

1 your medical and family history. It can also provide you with support, informational resources,  
2  
3 and referrals, as appropriate, that can help you adapt to the implications of being at risk of a  
4  
5 genetic condition.  
6

7  
8 Destruction of your Biological Sample. After the genetic test, your biological sample will be  
9  
10 destroyed as soon as permitted by law unless you agree to authorize otherwise in writing or a  
11  
12 court, arbitral tribunal, or administrative agency requires retention of the sample.  
13

14  
15 By signing this authorization, you do not lose any legal rights to which you are entitled. You are  
16  
17 entitled to a copy of this authorization.  
18

19  
20 I, \_\_\_\_\_, authorize the genetic test(s) I have checked above.  
21 [print name]  
22

23  I wish to receive test results.

24  I do not wish to receive test results.  
25

26  Report test results to the following health care professional:

27 Name: \_\_\_\_\_

28 Address: \_\_\_\_\_

29  Do not report test results to a health care professional.  
30  
31

32 \_\_\_\_\_  
33 Signature

\_\_\_\_\_ Date  
34

### 35 **Reporter's Notes**

36  
37 The Drafting Committee has chosen to maintain privacy for genetic testing and genetic  
38 information by establishing an authorization requirement that is coupled with statutory limits and  
39 duties imposed on employers, employment agencies, labor organizations, and credentialing  
40 authorities. Under this approach, before any genetic testing can be performed, an employee must  
41 affirmatively authorize any genetic testing or access, use, retention, or disclosure of genetic  
42 information. The authorization requirement is not simply a procedural step because Article 2  
43 establishes limitations on the situations in which employment entities may request authorization  
44 from employees.  
45

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

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

10 *Subsection (a) Requirement for authorization for genetic testing.* Under Section 202, an  
11 employment entity may supply genetic tests under certain circumstances but only with prior  
12 authorization from the employee.  
13

14 In order to meet the requirement of this subsection that an authorization be knowing and  
15 voluntary, an employee or insured should have genetic counseling before signing the  
16 authorization. Genetic counseling provides employees or insureds with adequate information to  
17 make an informed decision about genetic testing. It also makes them aware of their options  
18 regarding reporting of test results and help in interpreting them through genetic counseling. An  
19 employment entity that offers a genetic test has an obligation to provide genetic counseling at the  
20 entity’s cost under Section 202(c). Genetic counseling may be provided by a genetic counselor,  
21 but may also be provided by a qualified physician or geneticist. An employee may waive genetic  
22 counseling, but must first be made aware of the benefits of genetic counseling.  
23

24 The Drafting Committee anticipated that there might be circumstances in which an  
25 individual is incapacitated or incapable of authorizing a genetic test. This situation is left to  
26 existing law of the state that provides for power of attorney, guardianship, or other substitute  
27 decision makers.  
28

29 *Subsection (b) Content of authorization for testing.* The section draws on N.Y. Civ.  
30 Rights Law § 79-1 (McKinney), which establishes requirements for consent for a genetic test.  
31

32 The limitation in (b)(2) to the authorized test is consistent with the requirements for prior  
33 authorization in Section 202.  
34

35 The requirements in subsection (b)(3)-(6) reflect the obligation of the employment entity  
36 to provide genetic counseling under Section 202(c).  
37

38 The notification provision for retention of the sample in (b)(7) is consistent with the  
39 employment entity’s obligation to ensure that the sample is destroyed under Section 202(c)(3),  
40 which recognize that the testing laboratory may be required to retain the sample for certification  
41 purposes.  
42

43 *Subsection (c) Authorization form.* The use of a form following the pattern in this  
44 subsection would comply with the requirements of the section.  
45



1           *Existing state law.* An employment entity gets health information in a variety of ways  
2 including applications, interviews, references, post-offer medical exams, post-offer releases of  
3 medical records, Family and Medical Leave Act requests, workers' compensation claims, health  
4 insurance claims to self-insured employers, and voluntary disclosures by employees. Many states  
5 have tried to limit employer access to genetic information. There are statutes that prohibit an  
6 employer from requiring, requesting, or administering genetic testing, obtaining genetic  
7 information, making inquiries about genetic information, or some combination of these methods  
8 of accessing genetic information. (Conn, Del, Iowa, Kan, MD, Mass, Mich, Minn, Neb, Nev,  
9 NH, NY, OR, RI, Tex, UT, VT, VA, WA, WI).

10  
11           *Privacy rationale.* One rationale for limiting employer access to genetic information is  
12 the view that an employee should be able to keep genetic information private. At least one state  
13 has a constitutional right of privacy that appears to be relevant to genetic information. (Alaska)  
14 Another rationale is to make genetic discrimination less likely. Unlike discrimination based on  
15 sex or race, an employer cannot discriminate on the basis of genetic characteristics unless it has  
16 access to genetic information.

17  
18           Scholars have argued that a privacy rationale makes more sense for protecting genetic  
19 information in the employment context than an anti-discrimination rationale. Statutory  
20 protections based on anti-discrimination rationales are designed for socially-recognized groups  
21 that have been historically disadvantaged. Genetic variations do not fit especially well within  
22 this paradigm. *See, e.g.,* Pauline T. Kim, *Genetic Discrimination, Genetic Privacy: Rethinking*  
23 *Employee Protections for a Brave New Workplace*, 96 NW U. L. Rev. 1497 (2002).

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

44  
45           The draft also allows employees to keep private information that could lead to  
46 discrimination based on assumptions about genetics, even in the absence of genetic information.



1 It does this by including information about requests for or receipt of genetic services in the  
2 definition of genetic information. If an individual is unable to keep private his use of genetic  
3 services such as counseling, the individual may be deterred from obtaining this service for fear  
4 that an employer will assume the employee has reason to think he has a genetic disorder.  
5

6 The draft follows a number of state statutes that prohibit employers from accessing or  
7 using information about an employee's request for or use of genetic services. *See, e.g.,* La. Rev.  
8 Stat. § 23:368 (employer may not "require, collect, or purchase" information about an  
9 employee's request for or use of genetic services); Maine Rev. Stat. Ann. § 19302 (employer may  
10 not discriminate on basis that an individual received a genetic test or genetic counseling except  
11 when based on a bona fide occupational qualification); N.C. Gen. Stat. Ann. § 95-28.1A  
12 (unlawful to deny employment of account of request for genetic testing or counseling services);  
13 Utah Code Ann. § 26-45-103 (employer may not inquire into whether an individual or blood  
14 relative has taken or refused to take a genetic test); Vt. Stat. Ann. § 9333 (employer may not use  
15 the fact that genetic counseling or tested services have been requested or performed).  
16

17 The draft's approach to employer access is in contrast to that of anti-discrimination  
18 statutes, which typically allow employers to compel testing or to require employees to provide  
19 genetic information under certain circumstances. Most of the states that rely on disability  
20 statutes to regulate genetic information follow the Americans with Disabilities Act (ADA),  
21 which permits an employer to test an applicant and access an applicant's medical records after a  
22 conditional offer of employment. 29 C.F.R. § 1630.14(b). This approach opens the door broadly  
23 to genetic information once an employer has made a conditional offer of employment. In  
24 addition, under the ADA and most state statutes modeled on it, after an employee is hired, an  
25 employer can obtain medical information if it has a reasonable belief that the employee is unable  
26 to perform the essential functions of his or her job due to a medical condition. 29 C.F.R. §  
27 1630.14(c). States that have amended their employment discrimination statutes to include  
28 genetics usually follow the rubric of these statutes and permit genetic testing or collection of  
29 genetic information when it is relevant to "job-related qualifications" or justified by "business  
30 necessity." However, members of the drafting committee were concerned that tying the Act's  
31 protections to the concept of "job-related" medical information would not provide adequate  
32 protection for genetic information. In interpreting the ADA, some courts have interpreted that  
33 category broadly to permit employers to access medical information, thus narrowing the scope of  
34 protection.  
35

36 The draft's approach also contrasts with California's and Minnesota's more  
37 comprehensive limitations on employer access, which prohibit employers from accessing non-  
38 job-related medical information at any time. An advantage of California's and Minnesota's  
39 approach is that it does not depend on how "genetic information" is defined. In addition, it does  
40 not rely on custodians of medical files to make a distinction between genetic information and  
41 medical information more generally, which are usually mixed in medical files. Practically  
42 speaking, when an employee signs a release permitting employer access to medical records,  
43 everything in the records is included. There are those who maintain that legislation is needed to  
44 limit an employer's ability to obtain any non-job-related health information during the hiring  
45 process or employment. *See* Mark A. Rothstein, *Genetic Exceptionalism and Legislative*  
46 *Pragmatism*, 35 Hastings Center Report No. 4 (2005), at 35. The drafting committee discussed

1 this approach, but declined to adopt it because it extends beyond the scope granted to the  
2 committee.

3  
4 The prohibition on seeking or inquiring about genetic information is not intended to  
5 prevent an employer from informing an employee about the availability of a genetic test that is  
6 relevant to conditions in the workplace or from informing an employee about a genetic  
7 monitoring program.

8  
9 If an employee authorizes employer access to genetic information, the conditions under  
10 which an employee grants that authorization are important. Some states permit employers to  
11 request genetic information under the apparent assumption that an employee's consent to an  
12 employer's request is voluntary. It is possible, however, to argue that in the context of at-will  
13 employment, the need to retain one's job may turn an employer's request for genetic information  
14 into a demand that an employee dare not refuse. Thus some statutes prohibit even requests or  
15 inquiries. *See, e.g.,* Mass. Gen. L. Art. 151B § 4(19) (unlawful to "question a person about their  
16 genetic information or genetic information concerning their family members"); Nev. Rev. Stat. §  
17 613.345 (unlawful employment practice to "ask or encourage" an employee to submit to a  
18 genetic test). This draft follows that approach.

19  
20 A more stringent level of protection could protect workers from ever providing genetic  
21 information or authorizing access, even on their own initiative. But a blanket prohibition on any  
22 disclosure arguably goes too far. It would prevent an employee from sharing information that  
23 could be used to protect the person from situations in which the employee is genetically  
24 susceptible to harm. In addition, it would make it easy to violate the act inadvertently by  
25 disclosing information an employee does not realize is genetic information. Instead, this draft  
26 follows a middle approach that permits employees to volunteer genetic information, but does not  
27 generally permit employers to require it.

28  
29 *Subsection (b) Voluntary provision.* Employees who provide genetic information  
30 voluntarily may do so directly, through oral statements or by turning over reports of test results.  
31 They may also do so by permitting an employment entity to see medical records held by a third  
32 party. In the case of disclosures made by a third party to an employer, the draft requires prior  
33 authorization by the employee. The prohibition on employer inquiries is intended to apply to  
34 inquiries directed to other entities as well as to inquiries directed to the employee.

35  
36 A complication is that employers who have access to medical records (which is permitted  
37 under the ADA after a conditional offer of employment or during employment for job-related  
38 purposes) will in practical terms also have access to genetic information because it is interspersed  
39 throughout medical records. An employer that requests any medical information is likely to  
40 receive the entire file, including genetic information. The committee considered the fact that  
41 mental health records are kept separate from medical records and HIPAA requires a separate  
42 authorization before they can be disclosed. However, mental health records are not determined  
43 by the content of the record, but as those kept by a psychologist or psychiatrist. The committee  
44 considered, but rejected, requiring genetic tests to be kept in a separate record. An alternative  
45 solution would be to develop technologies that can limit the scope of information disclosed by  
46 health care providers. Mark A. Rothstein & Meghan Talbott, *Compelled Disclosure of Health*

1 *Information: Protecting Against the Greatest Potential Threat to Privacy*, 295 JAMA 2882  
2 (2006).

3  
4 *Subsection (c) Genetic monitoring programs.* Genetic monitoring programs are typically  
5 undertaken by employers to identify risks for groups of employees who have been exposed to  
6 hazardous substances or to target work sites for safety and health measures. Monitoring is testing  
7 designed to detect whether the genetic material of a group of individuals has changed over time.  
8 The premise is that such changes could indicate increased risk of future illness. Aggregated data  
9 from tests for genetic damage is sufficient to allow an employer to reduce exposures to levels that  
10 do not affect individuals' chromosome morphology or DNA. Office of Technology Assessment,  
11 *Genetic Monitoring and Screening in the Workplace* 66 (1990). However, while monitoring may  
12 have predictive value for a group, the techniques that are used do not currently measure increased  
13 individual health risks.

14  
15 This subsection permits employers to access genetic information as part of a genetic  
16 monitoring program. Section 202 permits an employer to offer employees genetic tests as part of  
17 a monitoring program and section 206 permits employers to use genetic information for  
18 monitoring purposes. The rationale for genetic monitoring programs is discussed in more depth  
19 in the Reporter's notes to section 202.

20  
21 *Subsection (d) Legal proceedings.* This draft provides for an employer to obtain an  
22 employee's genetic information if the employee places the employee's health at issue in a legal  
23 proceeding. This right is limited in that it applies only if the employer has satisfied the burden of  
24 proof to show compelling need and that the information is otherwise unavailable. Only that  
25 portion of an employee's genetic information that is relevant to a claim or defense may be  
26 provided. This subsection is meant to operate in conjunction with subsection 206(a)(2), which  
27 permits an employer to use genetic information in a legal proceeding. Subsection 202(a) requires  
28 the employer to pay for this test. These procedures provide more protection than Rule 35 of the  
29 Federal Rules of Civil Procedure or state equivalents, which provide that a court may order a  
30 physical examination on motion for good cause shown. The drafting committee considered a  
31 requirement that the genetic test results be sealed or placed under a protective order, but decided  
32 to leave this to existing law.

33  
34 The substance of the subsection follows Utah's statute, which authorizes genetic testing  
35 when an employee has placed his or her health at issue in a proceeding, but only by order of a  
36 court or administrative agency after finding compelling need and that the information is  
37 otherwise unavailable. Utah Code Ann. § 26-45-103(2). Other states have more narrowly  
38 authorized employer testing to investigate a workers' compensation claim. (NH, NY).

39  
40 **SECTION 205. PROHIBITION ON USE OF GENETIC INFORMATION.** An  
41 employment entity may not take an adverse employment action against an employee based on the  
42 employee's genetic information or family medical history.

## Reporter's Notes

1  
2  
3 Many state statutes limit use of genetic information by prohibiting discrimination among  
4 employees or applicants for employment on the basis of genetic information. (Ark, Ill, Kan, LA,  
5 Maine, MD, Mass, Mich, MO, Neb, Nev, NJ, NY, NC, OK, OR, RI, SD, Tex). Others more  
6 generally ban any use of genetic information in employment. For example, New Mexico's 2005  
7 statute provides simply that "[i]t is unlawful for a person to use genetic information in  
8 employment, . . . ." In Utah, employers may not take into account genetic information about an  
9 individual in connection with an employment decision. Similarly, in Iowa, an employer may not  
10 use genetic information to "affect the terms, conditions, or privileges of employment" of a person  
11 who gets a genetic test. Iowa Code Ann. § 729.6(2).  
12

13 This draft follows the example of Minnesota and Wisconsin, which prohibit adverse  
14 employment actions based on genetic information. Minn. Stat. § 181.974 subd. 2(a)(2) (may not  
15 "affect the terms or conditions of employment or terminate the employment of any person based  
16 on protected genetic information"); Wis. Stat. § 111.375 (may not "affect terms, conditions or  
17 privileges of employment, labor organization membership or licensure or terminate the  
18 employment labor organization membership or licensure").  
19

20 The term used in the draft, "adverse employment decision" is a term of art in employment  
21 law that does not need to be defined in this act. The drafting committee decided not to list  
22 adverse employment actions in the black letter law because of the risk that something would be  
23 left off the list and the list would be treated as limiting. The committee intends, however, for the  
24 term to be interpreted broadly. One example of a broad statement of adverse employment actions  
25 can be found in the District of Columbia Human Rights Act, which makes it a discriminatory  
26 practice for an employer "[t]o fail or refuse to hire, or to discharge, any individual; or otherwise  
27 to discriminate against any individual, with respect to his compensation, terms, conditions, or  
28 privileges of employment, including promotion; or to limit, segregate, or classify his employees  
29 in any way which would deprive or tend to deprive any individual of employment opportunities  
30 or otherwise adversely affect his status as an employee." D.C. Code § 2-1402.11. The term  
31 "adverse employment action" is consistent with and intended to include the actions listed in the  
32 federal Genetic Information Nondiscrimination Act of 2008, which makes it an unfair  
33 employment practice for an employer "(1) to fail to hire, or to discharge, any employee, or  
34 otherwise to discriminate against any employee with respect to the compensation, terms,  
35 conditions, or privileges of employment of the employee, because of genetic information with  
36 respect to the employee; or (2) to limit, segregate, or classify the employees of the employer in  
37 any way that would deprive or tend to deprive any employee of employment opportunities or  
38 otherwise adversely affect the status of the employee as an employee, because of genetic  
39 information with respect to the employee." 42 U.S.C. § 2000ff-1(a).  
40

41 The restriction on employment actions in this Act is particularly important because of  
42 uncertainty about how courts will apply federal statutes to decisions based on genetic information  
43 that predicts employee susceptibility to harm from workplace exposures. On one hand, in 1991  
44 the United States Supreme Court held that a chemical company's policy barring women of child-  
45 bearing age from employment opportunities that involved exposure to lead violated Title VII  
46 prohibitions on gender discrimination. *International Union v. Johnson Controls*, 499 U.S. 187

1 (1991). On the other hand, the ADA allows employers to act on health information, even in the  
2 case of disability, when there is a direct threat to the health or safety of others in the workplace.  
3 The Equal Employment Opportunity Commission (EEOC) has interpreted this ADA provision to  
4 apply when there is no risk to others but when an employer can show that an individual's  
5 disability poses a significant risk of harm to the individual. The United States Supreme Court  
6 upheld this interpretation. *Chevron v. Echazabal*, 122 S. Ct. 2045 (2002). Although the  
7 *Echazabal* case did not involve a genetic characteristic, but rather a worker's liver damage due to  
8 exposure to workplace solvents, the implication of the case is that in the absence of a prohibition  
9 in a state statute, an employer may make adverse employment decisions based on genetic  
10 screening or monitoring requested by an employee even if there is no threat to others. Section  
11 205 does not permit an employer to take an adverse employment action under these  
12 circumstances. Harm to the employee or to others is not a justification. As a result, employers  
13 would not be able to use an employee's genetic information in the way the employee's health  
14 information was used in the *Echazabal* case.

15  
16 Note that the section does not necessarily prevent an employer from making decisions  
17 based on the effects of an employee's manifest genetic condition or disease in the workplace.  
18 This is because the section uses the term "genetic information," which is defined with reference  
19 to a "genetic test." Some employees with manifest genetic conditions would be covered under  
20 the ADA if the condition limits a major life activity, but there is no comprehensive protection for  
21 individuals with medical conditions that result from genetic traits. While some maintain that  
22 attempts to prevent genetic discrimination are mostly meaningless without protection for people  
23 who have genetic diseases, see Mark A. Rothstein, *Genetic Privacy and Confidentiality: Why*  
24 *They are so Hard to Protect*, 26 J. L. Med. & Ethics 181 (1998), others emphasize the  
25 difficulties with either policy choice, see Henry T. Greely, *Genotype Discrimination: The*  
26 *Complex Case for Some Legislative Protection*, 149 U. Pa. L. Rev. 1483, 1503 (2001).

## 27 28 **SECTION 206. AUTHORIZED USE OF GENETIC INFORMATION.**

29 (a) An employment entity that obtains genetic information or family medical history in  
30 compliance with Section 204 may use the genetic information or family medical history to:

31 (1) monitor the effects of an employee's exposure to a workplace condition as  
32 part of a genetic monitoring program; or

33 (2) defend a claim in a proceeding before a tribunal in which an employee has  
34 placed the employee's health at issue.

35 (b) An employment entity that obtains genetic information or family medical history in  
36 compliance with Section 204 about an employee's predisposing genetic characteristic that may

1 create susceptibility to harm to the employee from a workplace condition may use the genetic  
2 information or family medical history only to reduce the employee's exposure to the workplace  
3 condition but not to take adverse employment action against an employee.

#### 4 **Reporter's Notes**

5  
6 The draft selectively authorizes ways that an employment entity may use genetic  
7 information in employment decisions about individual employees.

8  
9 The drafting committee considered a provision that would have allowed adverse  
10 employment actions in the case of an employee with a predisposing genetic characteristic that  
11 poses a direct threat of harm to others. It decided not to include this provision because the  
12 drafting committee was unable to identify any known genetic trait that would qualify and if  
13 testing is permitted for this purpose it could be abused.

14  
15 *Subsections (a)(1) and (a)(2). Monitoring programs or legal proceedings.* This  
16 subsection permits an employment entity to use genetic information for a monitoring program or  
17 defending a legal proceeding, which is consistent with the purposes for which an employment  
18 entity may access an employee's genetic information under Section 204.

19  
20 *Subsection (b). Employee susceptibility to harm in the workplace.* This subsection, in  
21 combination with section 205, follows the lead of the states that permit genetic testing to  
22 determine susceptibility to harm from a workplace substance only when an employer does not  
23 use the information to terminate or take other adverse action against the employee. *See* Iowa  
24 Code Ann. § 729.6(7); N.H. Rev. Stat. § 141-H:3; N.Y. Exec. Law § 296; Wis. Stat. Ann. §  
25 111.372. An employer may offer genetic testing to screen for susceptibility to harm under  
26 section 202, but may not access the results of the testing without authorization from the  
27 employee. If an employee volunteers genetic information about susceptibility to harm from  
28 workplace exposures under section 204, the draft permits the employer to reduce the potentially  
29 harmful exposure, but not to make an employment decision that would adversely affect the  
30 employee.

31  
32 The Brush-Wellman company in Cleveland, Ohio, developed a program (since  
33 discontinued) that provides a model for permissible use of screening or monitoring information.  
34 Brush-Wellman conducted genetic tests for its employees who work with beryllium, but the  
35 testing was voluntary and confidential. Moreover, the test results were provided to the employee,  
36 who made the decision on what action to take. The company took no action against the  
37 employee as a result of the genetic testing. Cynthia Nance, Paul Miller, & Mark Rothstein,  
38 *Discrimination in Employment on the Basis of Genetics*, 6 Employee Rights & Employment  
39 Policy Journal 57, 64-65 (2002).

40  
41 **SECTION 207. ACCESS TO GENETIC INFORMATION BY EMPLOYEE.** An

1 employee may inspect, request correction of, or obtain a copy of the employee’s genetic  
2 information or family medical history in any record of an employment entity which contains the  
3 information. If an employee requests correction of genetic information or family medical history,  
4 the employment entity shall include the request for correction and supporting data in the  
5 employee’s record.

6 **Reporter’s Notes**  
7

8 This section is based on the conclusion that an employee ought to be able to find out what  
9 genetic information an employer knows about an employee and to have the same information. It  
10 is based on 16 Del. Code § 1223. It also provides a mechanism for an employee to correct  
11 genetic information contained in employer records.  
12

13 If the employer supplied the genetic testing, information may also be kept in files at the  
14 laboratory that performed the testing. The employer’s responsibility to correct errors does not  
15 extend to the testing laboratory, which is regulated under the Clinical Laboratory Improvement  
16 Amendments, (CLIA), 42 U.S.C. § 263a.  
17

18 The drafting committee considered but rejected an exception that would have prohibited  
19 employee access to information compiled for litigation. This situation will be governed by  
20 normal discovery rules, which are unaffected by this section.  
21

22 **SECTION 208. CONFIDENTIALITY; RETENTION AND DISCLOSURE OF**  
23 **GENETIC INFORMATION.**

24 (a) An employment entity shall treat an employee’s genetic information and family  
25 medical history as a confidential record.

26 (b) If an employee authorizes an employment entity to keep a record of an employee’s  
27 genetic information or family medical history, the employment entity shall keep the record or  
28 require the record to be kept separately from the employee’s personnel file.

29 (c) Except as necessary to defend a claim in a proceeding before a tribunal, an  
30 employment entity may not disclose an employee’s individually identifiable genetic information  
31 to a person other than the employee unless the employee authorizes the disclosure or unless

1 otherwise ordered by a tribunal.

2 (d) Notwithstanding this section, an employment entity may keep and disclose genetic  
3 information obtained in aggregate form pursuant to Section 204(c) for use in a genetic  
4 monitoring program.

#### 5 **Reporter’s Notes**

6  
7 *Subsection (a) Confidentiality.* This subsection declares that genetic information, family  
8 medical history, and authorizations concerning genetic tests or information is confidential in the  
9 employment context. “Genetic information” is a category that includes information about use of  
10 or request for genetic services.

11  
12 *Subsection (b) Retention of genetic information or family medical history.* If an  
13 employment entity obtains any genetic information or family medical history under Section 204,  
14 it needs the employee’s authorization under Section 209 to retain the information. The separate  
15 storage requirement serves to protect the employee’s privacy and is modeled on La. Rev. Stat. §  
16 23:368(B). Under Section 210, an employee may revoke this authorization.

17  
18 *Subsection (c) Disclosure of genetic information or family medical history.* The draft is  
19 consistent with disclosure provisions in a number of states that have enacted (1) general privacy  
20 protections for genetic information that prohibit disclosure without informed consent or  
21 authorization (Alaska, Cal, Del, Fla, Maine, Mass, Nev, NH, NJ, NMex, NY, OR) or (2) specific  
22 protections against the disclosure of genetic information by employers (Ariz, Fla, LA, Mass,  
23 NH, NJ, Or, RI).

24  
25 *Subsection (d) Genetic monitoring program.* An employer may retain and disclose  
26 genetic information without an employee’s specific authorization for a genetic monitoring  
27 program. An employer is allowed access to this information only in an aggregate form that does  
28 not identify individual employees, which should minimize the effects of retaining monitoring  
29 information for an employee’s privacy. An employer may need to disclose aggregate monitoring  
30 information in order to analyze trends or take action to reduce risk in the workplace.

### 31 32 **SECTION 209. AUTHORIZATION FOR ACCESS, USE, RETENTION, OR** 33 **DISCLOSURE OF GENETIC INFORMATION OR FAMILY MEDICAL HISTORY.**

34 (a) Except as otherwise provided by this [act] or by law other than this [act], an  
35 employment entity may not access, use, keep or disclose an employee’s genetic information or  
36 family medical history without the employee’s knowing and voluntary authorization indicated in



1 a record signed by the employee that complies with subsection (c). An employment entity that  
2 receives a valid authorization may access, use, keep or disclose genetic information or family  
3 medical history only in accordance with the authorization. An authorization may not expand the  
4 access, use, retention, or disclosure of genetic information or family medical history permitted by  
5 this [article] and may not include exculpatory language waiving any of the employee’s legal  
6 rights.

7 (b) Except as otherwise provided by this [act] or law other than this [act], a person who  
8 receives genetic information disclosed by an employment entity must maintain the confidentiality  
9 of the employee’s genetic information and may not disclose the information without the  
10 employee’s knowing and voluntary authorization indicated by a record signed by the employee  
11 that complies with subsection (c). A recipient that receives the employee’s valid authorization to  
12 disclose genetic information may disclose the information only in accordance with the  
13 authorization. An authorization may not expand the disclosure of genetic information permitted  
14 by this [article] and may not include exculpatory language waiving any of the employee’s legal  
15 rights. When an employment entity discloses an employee’s genetic information, it must notify  
16 the recipient of the information about these obligations.

17 (c) An authorization to access, use, keep, or disclose an employee’s genetic information  
18 or family medical history must:

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

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

23 (3) if the authorization is for access to genetic information or family medical

1 history through disclosure by another person to an employment entity, identify or describe the  
2 person authorized to make the disclosure;

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

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

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

11 (7) indicate the duration of the authorization with an expiration date if any or  
12 expiration event that relates to the employee or to the purpose of the access, use, retention, or  
13 disclosure;

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

17 (9) state that the employee is entitled to a copy of the authorization.

18 (d) The use of the following forms comply with this section:

19 Authorization for Access and Use

20 \_\_\_\_\_ seeks your authorization to access the following genetic test  
21 [Name of employment entity]  
22 results or family medical history and use it for the purposes identified:  
23

24  \_\_\_\_\_. The purpose of this test is to determine if you have  
25 [Name of test and condition tested for]  
26 a genetic characteristic that predisposes you to harm from \_\_\_\_\_.  
27 [workplace condition]  
28

1 \_\_\_\_\_ will use this information only for the following purposes: \_\_\_  
2 [Name of employment entity]  
3 \_\_\_\_\_.

4  
5  
6  Family medical history information about \_\_\_\_\_.  
7 [name of medical condition] [Name of  
8 \_\_\_\_\_ will use this information only for the following purposes: \_\_\_\_\_.  
9 employment entity]

10  
11  
12  Disclosure by \_\_\_\_\_ of genetic information about \_\_\_\_\_  
13 [name of person to disclose] [name of test and  
14 \_\_\_\_\_ will use this information only for the following  
15 condition] [Name of employment entity]  
16 purposes: \_\_\_\_\_.

17  
18 You may revoke this authorization for access and use at any time by sending a letter to  
19 \_\_\_\_\_ unless \_\_\_\_\_ has \_\_\_\_\_  
20 [name and address] [name of employment entity] [description of action that  
21 \_\_\_\_\_  
22 \_\_\_\_\_].  
23 would be taken based on the information]

24  
25 You are entitled to a copy of this authorization. By signing this authorization, you do not lose  
26 any legal rights to which you are entitled.

27  
28 This authorization is valid until \_\_\_\_\_.  
29 [date or event]

30  
31 I, \_\_\_\_\_, authorize \_\_\_\_\_ to access the genetic information  
32 [print name] [name of employment entity]  
33 and family medical history checked above for use for the purposes indicated.

34  
35  
36 \_\_\_\_\_  
Signature Date

37  
38  
39 Authorization for Retention of Genetic Information

40  
41 \_\_\_\_\_ seeks your authorization to keep the following genetic  
42 [Name of employment entity]  
43 information or family medical history to which you have granted \_\_\_\_\_  
44 [name of employment entity]  
45 access. This information will be treated as a confidential record and kept separately from the rest  
46

1 of your personnel records.

2  
3  \_\_\_\_\_  
4 [Name of test and condition tested for]

5  
6  Family medical history information about \_\_\_\_\_  
7 [name of medical condition]

8  
9 The purpose for keeping this information is \_\_\_\_\_.

10  
11 You may revoke this authorization for retention at any time by sending a letter to  
12 \_\_\_\_\_ unless \_\_\_\_\_ has \_\_\_\_\_  
13 [name and address] [name of employment entity] [description of action that  
14 \_\_\_\_\_].  
15 would be taken based on the information]

16  
17 You are entitled to a copy of this authorization. By signing this authorization, you do not lose  
18 any legal rights to which you are entitled.

19  
20 This authorization is valid until \_\_\_\_\_.  
21 [date or event]

22  
23 I, \_\_\_\_\_, authorize \_\_\_\_\_ to keep the information checked  
24 [print name] [name of employment entity]  
25 above.

26  
27 \_\_\_\_\_  
28 Signature

\_\_\_\_\_ Date

29  
30  
31 Authorization for Disclosure of Genetic Information

32  
33 \_\_\_\_\_ seeks your authorization to disclose the following genetic  
34 [Name of employment entity]  
35 information or family medical history to \_\_\_\_\_.

36 [name of recipient of the information]  
37 \_\_\_\_\_ will notify \_\_\_\_\_ that  
38 [Name of employment entity] [name of recipient of the information]  
39 \_\_\_\_\_ is legally obligated to maintain the confidentiality  
40 [name of recipient of the information]  
41 of this information and that if may not make further disclosures without your authorization.

42  
43  
44  \_\_\_\_\_  
45 [Name of test and condition tested for]



1 Committee decided that regulation of the initial disclosure is ineffective without a continuing  
2 obligation of confidentiality that is binding on the recipient. Hence under this subsection a  
3 recipient may not redisclose the genetic information without the insured’s authorization. This  
4 provision extends beyond the privacy protections provided by HIPAA. States are permitted to  
5 depart from HIPAA privacy provisions if they impose more stringent protections. 45 C.F.R. §  
6 160.203(b).

7  
8 The Committee considered and rejected several approaches to the issue of redisclosures,  
9 including 1) a notice to the insured that the genetic information disclosed by the authorized  
10 person may be subject to redisclosure by the recipient and not longer protected, and 2) a  
11 provision that an insured could enter into a confidentiality agreement with recipients of their  
12 genetic information.

13  
14 *Subsection (c) Content of authorization.* The provision on authorization for access, use,  
15 retention, or disclosure of genetic information or family medical history is adapted from the  
16 HIPAA Privacy Rule regulations for “uses and disclosures for which an authorization is  
17 required.” 45 C.F.R. §§ 164.508 (a) and (c), 164.512(a). The subsection adapts these regulations  
18 to apply to genetic information and family medical history, and expands them to include  
19 authorization for access and retention as well as for use and disclosure.

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

32  
33 *Subsection (d) Authorization forms.* The subsection includes forms that could be used for  
34 an employee to authorize an employment entity to access and use genetic information, to keep  
35 genetic information, or to disclose genetic information. The use of a form following this pattern  
36 would comply with the requirements of the section.

## 37 38 **SECTION 210. REVOCATION OF AUTHORIZATION.**

39 (a) Except as otherwise provided in subsection (b) or by law other than this [act], an  
40 employee may revoke an authorization provided under this [article] at any time in a signed  
41 record.

1 (b) An employee’s revocation of an authorization under subsection (a) has no effect to the  
2 extent that an employment entity has taken action in reliance on the authorization.

3 **Reporter’s Notes**  
4

5 This section is adapted from the HIPAA regulation that governs revocation of an  
6 authorization. 45 C.F.R. § 164.508(b)(5). It is similar to provisions governing health care  
7 information that have been adopted by some of the states.  
8

9 The Drafting Committee considered expanding this section to give employees the ability  
10 to amend their authorizations short of revoking them, but decided that it would be preferable for  
11 employees to revoke one authorization and execute a new one.  
12

13 Other law of the state may provide for a substitute decisionmaker or signer if the  
14 employee is incapacitated or incompetent. Revocation by a substitute is left to existing law of  
15 the state that governs power of attorney, guardianship, or other substitute decision makers.  
16

17 **SECTION 211. RETENTION OF AUTHORIZATION.** An employment entity that  
18 receives an employee’s authorization under this [article] shall treat the authorization as a  
19 confidential record and keep the authorization or require the authorization to be kept separately  
20 from the employee’s personnel records. The employment entity shall keep a record of the  
21 authorization for six years from the expiration date of the authorization or, if the authorization  
22 does not have an expiration date, for six years from the date the authorization was created.

23 **Reporter’s Notes**  
24

25 An employee’s authorization for genetic testing or employer access, retention, or  
26 disclosure of genetic information under Sections 203 or 209 is a confidential record that must be  
27 kept separate from the employee’s personnel files. The provision that the authorization must be  
28 retained for six years is adapted from the HIPAA regulations that govern documentation and  
29 retention of a signed authorization. 45 C.F.R. § 164.508 (b) (6), § 164.530(j).  
30

31 **SECTION 212. REMEDIES; LIMITATION OF ACTIONS.**

32 (a) An individual aggrieved by a violation of this [article] may file a civil action without  
33 exhausting arbitral procedures or administrative remedies provided by an agreement of the

1 parties or by law other than this [act]. This section does not prohibit an employee from pursuing  
2 administrative remedies or other remedies available under law other than this [act].

3 (b) All remedies at law and in equity are available to enforce this [article], including  
4 compensatory damages, back pay, front pay, reassignment, reinstatement, injunctive relief,  
5 punitive damages, expungement of records, and the right to a jury trial.

6 (c) A court shall award a prevailing employee reasonable attorney's fees and costs unless  
7 justice requires otherwise.

8 (d) An individual may file the civil action authorized in subsection (a) not later than two  
9 years after the individual discovers the violation of this [article] or an individual exercising  
10 reasonable care should have discovered the violation.

### 11 **Reporter's Notes**

12  
13 The draft is intended to provide remedies for privacy violations, employment  
14 determinations based on misuse of genetic information, and other harms. Privacy violations  
15 involve access, retention, or disclosure of genetic information that does not comply with the Act.  
16 Employment determinations could include failure to license, hire, refer for employment,  
17 promote, or decisions to terminate, demote, reduce pay, reassign, or to take any other adverse  
18 action. Other harms could include torts such as intentional infliction of emotional distress. The  
19 appropriate remedy will vary with the type of violation.

20  
21 The draft provides for a civil cause of action that will supercede limitations in union  
22 contracts, arbitration agreements, and administrative processes that otherwise apply in the  
23 employment context. At the same time, the draft preserves existing remedies. The cause of  
24 action created by the statute is cumulative and available in addition to existing remedies.

25  
26 The section does not increase the enforcement burden on state agencies. The primary  
27 remedy for a violation of the article is a private civil action. Fee and cost shifting are included to  
28 compensate prevailing employees for their costs to enforce the statute.

29  
30 The drafting committee considered a tolling provision, but rejected this approach because  
31 they did not want to impose a long period of potential liability on employment entities.

32  
33 States with genetic statutes tend to provide relief for violations using a mixture of  
34 administrative and civil processes, and a few have even enacted criminal penalties. Many state  
35 statutes that emphasize discrimination require employees to submit claims of unlawful  
36 employment discrimination based on use of genetic information to a state agency or the federal



1 Equal Opportunity Employment Commission. Using a state employment discrimination agency  
2 makes sense for enforcement of provisions related to employment decisions because such  
3 agencies already have the apparatus in place to enforce state civil rights and disability statutes.  
4 The draft does not prevent that avenue of enforcement. For privacy violations, however, other  
5 avenues are desirable. Discrimination agencies do not have expertise in privacy violations and  
6 the typical remedies for employment discrimination are not necessarily appropriate for a privacy  
7 violation. Enforcement could be turned over to an agency with that expertise, but the drafting  
8 committee wish to avoid the cost of creating and funding a new agency. Moreover, the drafting  
9 committee did not want to impose the delay associated with administrative processes on an  
10 aggrieved employee.

11  
12 A privacy rights perspective assumes an intrinsic harm from the invasion of privacy,  
13 whether or not consequential damages are incurred. Because of difficulties in measuring damage  
14 to privacy interests, several states that provide a private right of action for privacy violations  
15 involving genetic information also specify statutory damages, with higher amounts when the  
16 violation is willful or leads to monetary gain for the violator. Alaska Stat. § 18.13.020 (actual  
17 damages plus \$5,000, or plus \$1,000 if there is monetary gain); N.H. Rev. Stat. § 141-H:6 (not  
18 less than \$1,000 per violation); NM Stat. Ann. § 24-21-6 (economic loss plus damages of up to  
19 \$5,000 if the violation results from willful or grossly negligent conduct). The drafting committee  
20 did not take this approach because statutory damages often become a limit on the recovery  
21 available.

1 [ARTICLE] 3

2 HEALTH INSURANCE

3 SECTION 301. APPLICANT FOR INSURANCE. For purposes of this [article] an  
4 applicant for health insurance shall be treated the same as an insured.

5 Reporter’s Notes

6  
7 *Applicability of Article 3.* The article is meant to apply broadly to health insurance,  
8 whether issued on an individual, group, or other basis. It does not apply to disability-income  
9 insurance or long-term-care insurance.

10  
11 This article closes the gaps left by Title I of HIPAA, which prohibits discrimination in  
12 enrollment and premiums based on health status related factors, including genetic information.  
13 Title I, however, does not apply to small group and individual coverage, which is covered by this  
14 article. In addition to individual and group health insurance policies, some state statutes  
15 reference health insurance issued on a franchise or blanket basis. These forms of health  
16 insurance are also subject to this article.

17  
18 The drafting committee intends that this article also applies to employee welfare plans  
19 unless there is a controlling judicial decision that the article is preempted by the Employee  
20 Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. § 1001 et seq. Federal preemption  
21 is relevant because the United States Supreme Court has held that ERISA applies to employee  
22 benefit plans such as health insurance as well as to employee pension plans. *Inter-Modal Rail*  
23 *Employees Ass’n v. Atchison, Topeka and Santa Fe Ry. Co.*, 520 U.S. 510 (1997). The United  
24 States Supreme Court has recognized three types of preemption under ERISA that are relevant to  
25 this draft act: express, complete, and conflict preemption. Complete preemption and conflict  
26 preemption are relevant to enforcement and civil remedies and are discussed in the notes to  
27 Section 307.

28  
29 In order to simplify the administration of plans by ensuring that they are subject to only  
30 one set of regulations, ERISA expressly preempts state regulation of the administration of  
31 employee benefit plans to the extent those regulations “relate to” employee benefit plans. 29  
32 U.S.C. § 1144(a). The statute contains a savings clause, however, that saves laws that regulate  
33 insurance from ERISA preemption. 29 U.S.C. § 1144(b)(2)(A). The issue of whether state  
34 regulations are preempted by ERISA has led to extensive litigation.

35  
36 Recently, the United States Supreme Court clarified the application of the savings clause.  
37 In order to fall under ERISA’s savings clause, a state law must first be “specifically directed  
38 toward” the insurance industry. *Kentucky Ass’n of Health Plans, Inc. v. Miller*, 123 S. Ct. 1471,  
39 1475 (2003). Laws of general application that merely have “some bearing on insurers” do not  
40 fall under the clause. *Id.* Second, the ERISA provision saves state laws that regulate  
41 “insurance,” not “insurers,” so a law must regulate insurers “with respect to their insurance  
42 practices.” *Id.* A state law regulates an insurer with respect to insurance practices if it controls

1 the terms of insurance policies, *id.* at 1476, or if it “substantially affect[s] the risk pooling  
2 arrangement between the insurer and the insured,” *id.* at 1477. This act regulates insurance  
3 practices and thus falls under ERISA’s savings clause.  
4

5 The preemption question is further complicated by that fact that ERISA also contains  
6 what is referred to as the “deemer clause,” which creates an exception to the savings clause. It  
7 provides that “neither an employee benefit plan . . . nor any trust established under such plan,  
8 shall be deemed to be an insurance company or other insurer . . . for purposes of any law of any  
9 State purporting to regulate insurance companies . . .” 29 U.S.C. § 1144(b)(2)(B). The United  
10 States Supreme Court has interpreted the deemer clause to exempt self-funded (i.e. uninsured)  
11 health plans from the savings clause. Thus the Court concluded that “self-funded ERISA plans  
12 are exempt from state regulation insofar as that regulation ‘relate[s] to’ the plans.” *FMC Corp. v.*  
13 *Holliday*, 498 U.S. 52, 61 (1990). Under this decision, this act is preempted as applied to self-  
14 funded employee benefit plans.  
15

16 The distinction in *FCM Corp.* between insured and self-insured health plans has not been  
17 overruled and continues to be applied by lower courts. *See, e.g., Daly v. Marriott International,*  
18 *Inc.*, 415 F.3d 889 (8th Cir. 2005) (“deemer clause” of ERISA preemption provision exempted  
19 employer funded health plan from application of state mental-health parity law); *Blue Cross Blue*  
20 *Shield of Alabama v. Sanders*, 138 F.3d 1347 (11th Cir. 1998).  
21

22 *Applicants.* For simplicity, the article refers only to insureds. The provisions apply  
23 equally to applicants for insurance.  
24

## 25 **SECTION 302. GENETIC TESTING; ACCESS TO GENETIC INFORMATION.**

26 (a) In determining eligibility for health-insurance coverage and in setting rates, terms,  
27 and conditions, a health insurer may not:

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

30 (2) require or request an insured’s genetic information [or family medical  
31 history]; or

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

34 (b) Except as otherwise prohibited by law other than this [act], a health insurer that  
35 receives a claim for payment for health-care services may access, without specific authorization

1 by the insured, genetic information and family medical history contained in the insured’s medical  
2 records that the insurer may use under Section 304 to determine a payment obligation.

3 (c) This [article] permits an insurer that directly provides health-care services to provide a  
4 genetic test to an insured or to access an insured’s genetic information or family medical history  
5 in the insured’s medical records for the purpose of providing health-care services for the insured.

### 6 **Reporter’s Notes**

7  
8 *Access to Genetic Information.* This section limits the ability of health insurers to access  
9 genetic information and family medical history consistent with the uses prohibited in Section 303  
10 and permitted in Section 304.

11  
12 *Subsection (a) Coverage decisions.* This subsection prohibits a health insurer from  
13 requiring genetic tests or obtaining genetic information for uses associated with the issuance of  
14 insurance. The draft prohibits those uses in Section 303.

15  
16 Recent state legislation that prohibits the use of genetic test results to set terms for  
17 medical insurance also prohibits the use of family medical history for this purpose. This is also  
18 the approach taken in the federal bill on genetic discrimination. The reference to family medical  
19 history is bracketed in this draft, however, because the drafting committee would like further  
20 reaction and input from the industry on this provision.

21  
22 *Subsection (b) Claims processing.* This subsection allows health insurers to access  
23 genetic information for use in determining an insured’s payment obligations, as permitted in  
24 Section 304. The exception for other legal requirements is included to avoid conflict with  
25 HIPAA regulations on using and disclosing medical information for payment operations.

26  
27 *Subsection (c) Medical treatment.* For health insurers such as HMOs, which also provide  
28 health care services, access to genetic information for functions that involve determining  
29 eligibility and terms of insurance need to be separated from access for health care provider  
30 functions. These insurers may provide genetic tests to patients or access genetic information or  
31 family medical history for therapeutic purposes as part of the practice of medicine, but not as part  
32 of determining eligibility for insurance or for underwriting. Specific conditions for access to  
33 genetic information for diagnosis or treatment are not covered by this draft because those uses  
34 constitute the practice of medicine. Likewise, the draft does not cover authorization for genetic  
35 testing because that is treated as a matter of informed consent, with standards set as a matter of  
36 the practice of medicine.

37  
38 **SECTION 303. PROHIBITED USE OF GENETIC INFORMATION.** A health  
39 insurer may not consider an insured’s genetic information [or family medical history] in

1 determining eligibility for health-insurance coverage or in setting rates, terms, and conditions for  
2 health-insurance.

### 3 **Reporter's Notes**

4  
5 This section reflects and combines the approaches of many states that prohibit the use of  
6 genetic information for setting eligibility requirements and for underwriting in health insurance.  
7 It partially closes the gaps left by HIPAA and is consistent with the federal Genetic Information  
8 Nondiscrimination Act (GINA) in that it extends beyond merely prohibiting complete denial of  
9 coverage; the section also prohibits use of genetic information in determining rates, terms, and  
10 conditions.

11  
12 Recent state legislation that prohibits the use of genetic test results to set terms for  
13 medical insurance also prohibits the use of family medical history for this purpose. This is also  
14 the approach taken in GINA. The reference to family medical history is bracketed in this draft,  
15 however, because the drafting committee would like further reaction and input from the industry  
16 on this provision.

17  
18 A determination of eligibility for coverage is meant to include decisions made in  
19 connection with the offer, sale, continuation, or renewal of a health insurance policy. A  
20 determination of rates, terms, and conditions includes establishing premiums, limiting coverage,  
21 limiting or conditioning benefits, or making any other underwriting decisions. The prohibition  
22 on using genetic information for these purposes also precludes an insurer from treating a  
23 predisposing genetic characteristic as a preexisting condition for purposes of limiting or  
24 excluding benefits or coverage. This is consistent with statutes in several states that do not  
25 permit health insurers to impose preexisting condition exclusions based on predictive genetic  
26 information in the absence of a diagnosis based on symptoms of the disease or condition.  
27 (Alaska, Conn, Idaho, Iowa, Ky, OR).

28  
29 There are many alternative approaches to regulating the use of genetic information in  
30 health insurance. Some other states take an approach like that of HIPAA and use a non-  
31 discrimination provision that prohibits higher premiums than those charged to similarly situated  
32 individuals. (Alaska, Ark, Ill, Iowa). Yet other states prohibit the use of genetic information for  
33 underwriting health insurance without actuarial justification. (Ariz, WVa). In some states, use  
34 of genetic information for risk selection is permitted if an individual submits the information  
35 voluntarily or if the information is favorable to the individual. (Ill, Ind, Mass, Mo, NY). Yet  
36 other states regulate this use by prohibiting insurers from increasing policy rates based on genetic  
37 information. (Md, Mont, Or, Tex). The Drafting Committee decided that a more comprehensive  
38 limitation on use to determine eligibility or for any form of underwriting is the appropriate course  
39 to take for health insurance.

40  
41 It is often permissible for insurers to consider existing medical conditions in determining  
42 coverage and premiums under other law so long as they treat like situations alike. This section  
43 would impose a different standard by prohibiting consideration of genetic information, which  
44 includes conditions revealed by a genetic test. The language chosen by the Drafting Committee

1 creates a different standard for genetic illnesses than for other medical conditions, thus raising  
2 the practical question of which conditions are “genetic.” The prohibition on considering genetic  
3 information is broader than if it were limited to an insured’s predisposing genetic characteristics.  
4 Some analysts endorse this approach by maintaining that attempts to prevent genetic  
5 discrimination are mostly meaningless without protection for people who have genetic diseases.  
6 *See* Mark A. Rothstein, *Genetic Privacy and Confidentiality: Why They are so Hard to Protect*,  
7 26 J. L. Med. & Ethics 181 (1998). Others think that this would place too great a burden on  
8 insurers. *See, e.g.*, Henry T. Greely, *Genotype Discrimination: The Complex Case for Some*  
9 *Legislative Protection*, 149 U. Pa. L. Rev. 1483, 1503 (2001).

#### 11 **SECTION 304. AUTHORIZED USE OF GENETIC INFORMATION.**

12 (a) A health insurer that receives a claim for payment for a genetic test or genetic  
13 counseling may use genetic information and family medical history contained in the insured’s  
14 medical records regarding the need for a genetic test to determine the insurer’s payment  
15 obligation. The insurer is not entitled to use the results of the test.

16 (b) A health insurer that receives a claim for payment for health-care services rendered  
17 because of a genetic condition or predisposing genetic characteristic may use the genetic  
18 information or family medical history that is necessary to determine the insurer’s payment  
19 obligation.

20 (c) This [article] permits an insurer that directly provides health-care services to use an  
21 insured’s genetic information or family medical history for the purpose of providing health-care  
22 services for the insured.

#### 23 **Reporter’s Notes**

24  
25 *Subsections (a) and (b) Payment obligations.* This subsection highlights the potential  
26 role for genetic information in providing payment for genetic tests and health care services. First,  
27 genetic information such as family history may be necessary for preauthorization for a genetic  
28 test or service or for approval of payment for a genetic test or service. Second, health care  
29 services may be medically justified by a predisposing genetic characteristic or a genetic  
30 condition. In this context, genetic “condition” should be interpreted broadly to include the full  
31 range of health effects influenced by a genotype, including a disease or disorder.

32  
33 These subsections are modeled on a Utah provision.



1 disclose the insured's genetic information to a person other than the insured if the recipient has  
2 obtained the insured's authorization under Section 307.

3 (c) This [article] permits an insurer that directly provides health-care services to disclose  
4 an insured's genetic information or family medical history in the insured's medical record to the  
5 extent appropriate for the purpose of providing health-care services for the insured.

### 6 **Reporter's Notes**

7  
8 This section conditions the disclosure of an insured's genetic information on the  
9 authorization of the insured. In some jurisdictions, however, health care providers may have a  
10 common-law duty to inform others of a genetic disorder. This case law creates malpractice  
11 liability that may require disclosure by a health insurer without the insured's consent.  
12

13 New Jersey's court has recognized a physician's duty to warn those "known to be at risk  
14 of avoidable harm from a genetically transmissible condition." *Safer v. Pack*, 677 A.2d 1188  
15 (N.J. Super. Ct. App. Div. 1996). The defendant in the case was the physician who had treated  
16 the plaintiff's father for colorectal cancer that led to the father's death when the plaintiff was a  
17 child. The plaintiff inherited multiple polyposis, an inherited condition that if undiscovered and  
18 untreated, leads to metastatic colorectal cancer. The court found a duty to "take reasonable  
19 steps" to warn that "extends beyond the patient to members of the immediate family of the  
20 patient who may be adversely affected by a breach of that duty." It noted, but did not determine,  
21 the issue that would arise if the father had instructed the doctor not to disclose details of the  
22 illness or the genetic risk. In that event, it would be necessary to resolve the conflict between  
23 physician-patient confidentiality and the duty to warn.  
24

25 Minnesota has also recognized a duty regarding genetic testing and diagnosis that reaches  
26 beyond the patient. The plaintiff alleged that her daughter's physicians were negligent in failing  
27 to diagnose a genetic disorder in the daughter that led the mother to conceive another child with  
28 the same genetic disorder. *Molloy v. Meier*, 679 N.W.2d 711 (Minn. 2004). The court noted that  
29 genetic testing and diagnosis affect not only the patient, but can benefit or harm both the patient  
30 and her family. The Fragile X disorder is one that physicians ordinarily report to parents and it  
31 was foreseeable that a negligent diagnosis of the disorder would cause harm to the family as well  
32 as the patient. The court held that the duty to warn extends to "biological parents who  
33 foreseeably may be harmed by a breach of that duty." It did not consider whether it should  
34 extend to additional family members.  
35

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



1

2           **SECTION 307. AUTHORIZATION FOR DISCLOSURE OF GENETIC**  
3 **INFORMATION.**

4           (a) Except as otherwise provided by this [act] or law other than this [act], a health insurer  
5 may not disclose an insured's genetic information without the insured's knowing and voluntary  
6 authorization indicated by a record signed by the insured that complies with subsection (c) of this  
7 section. A health insurer that receives a valid authorization to disclose genetic information may  
8 disclose the information only in accordance with the authorization. An authorization may not  
9 expand the disclosure of genetic information permitted by this [article] and may not include  
10 exculpatory language waiving any of the insured's legal rights.

11           (b) Except as otherwise provided by this [act] or law other than this [act], a person who  
12 receives genetic information disclosed by a health insurer must maintain the confidentiality of the  
13 insured's genetic information and may not disclose the information without the insured's  
14 knowing and voluntary authorization indicated by a record signed by the insured that complies  
15 with subsection (c) of this section. A recipient that receives the insured's valid authorization to  
16 disclose genetic information may disclose the information only in accordance with the  
17 authorization. An authorization may not expand the disclosure of genetic information permitted  
18 by this [article] and may not include exculpatory language waiving any of the insured's legal  
19 rights. When a health insurer discloses an insured's genetic information, it must notify the  
20 recipient of the information about these obligations.

21           (c) An authorization to disclose an insured's genetic information must:

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

1 (2) identify or describe the person that may disclose the genetic information;

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

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

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

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

11 (d) The use of the following form complies with this section.

12 Authorization for Disclosure of Genetic Information

13  
14 \_\_\_\_\_ requests your authorization to disclose the following  
15 [Name of person seeking to make disclosure]  
16 genetic information to \_\_\_\_\_.

17 [name of recipient of the information] [Name of person seeking  
18 \_\_\_\_\_ will notify \_\_\_\_\_ that \_\_\_\_\_  
19 to make disclosure] [name of recipient of the information] [name of  
20 \_\_\_\_\_ is legally obligated to maintain the confidentiality of this  
21 recipient of the information]  
22 information and that it may not make further disclosures without your authorization.

23  
24  
25  \_\_\_\_\_  
26 [Name of test and condition tested for]

27  
28 You may revoke this authorization for disclosure at any time by sending a letter to  
29 \_\_\_\_\_ unless \_\_\_\_\_ has already disclosed the information.  
30 [name and address] [name of insurer]

31  
32  
33  
34 You are entitled to a copy of this authorization. By signing this authorization, you do not lose  
35

1 any legal rights to which you are entitled.

2  
3 This authorization is valid until \_\_\_\_\_.  
4 [date or event]

5  
6 I, \_\_\_\_\_, authorize \_\_\_\_\_ to disclose  
7 [print name] [name of person authorized to make disclosure]  
8 the genetic information I have checked above to \_\_\_\_\_.  
9 [name of recipient of the information]

10  
11 \_\_\_\_\_  
12 Signature

\_\_\_\_\_ Date

### 13 14 **Reporter's Notes**

15  
16 This section requires an insured to provide an authorization before a health insurer may  
17 disclose genetic information.

18  
19 The draft does not disturb existing law that allows a minor to seek repudiation of consent  
20 and expunge records when the minor reaches the age of majority.

21  
22 *Subsection (a) General requirement for authorization.* This subsection would establish a  
23 requirement that an insurer must be authorized by the insured before it may disclose genetic  
24 information, except as provided elsewhere in the act. In order to give a valid authorization, the  
25 insured must be informed as provided in the following subsections and must act voluntarily.  
26 Subsection (a) also includes a requirement that an authorization must be indicated by a signed  
27 record. The authorization requirement is coupled with limitations on disclosure in Section 306.  
28 It establishes a statutory confidential relationship. In some states this might support a cause of  
29 action for breach of confidence. *See, e.g., Munzer v. Blaisdell*, 183 Misc. 773, 49 N.Y.S.2d 915  
30 (NY Sup. Ct. 1944), *aff'd mem.*, 269 A.D. 970, 58 N.Y.S.2d 359 (1945) (common law remedy  
31 implicit in statutory prohibition of disclosure of treatment information by mental hospital).

32  
33 Other law of the state may provide for a substitute decisionmaker or signer if the  
34 employee is incapacitated or incompetent. This situation is left to existing law of the state that  
35 governs power of attorney, guardianship, or other substitute decision makers. Again, the  
36 Drafting Committee has indicated that it wishes to consider whether or not to include a provision  
37 for incapacitation or incompetence into the text of the draft.

38  
39 *Subsection (b) Obligation of recipient of authorized disclosure.* One of the difficulties in  
40 authorizing disclosure is control over the information once it has been disclosed. The Drafting  
41 Committee decided that regulation over the initial disclosure is ineffective without a continuing  
42 obligation of confidentiality that is binding on the recipient. Hence under this subsection a  
43 recipient may not redisclose the genetic information without the insured's authorization. This  
44 provision extends beyond the privacy protections provided by HIPAA. States are permitted to  
45 depart from HIPAA privacy provisions if they impose more stringent protections. 45 C.F.R. §

1 160.203(b).

2  
3 The Committee considered and rejected several approaches to the issue, including 1) a  
4 notice to the insured that the genetic information disclosed by the authorized person may be  
5 subject to redisclosure by the recipient and not longer protected, and 2) a provision that an  
6 insured could enter into a confidentiality agreement with recipients of their genetic information.

7  
8 *Subsection (c) Content of authorization.* The provision on authorization for disclosure of  
9 genetic information is adapted from the HIPAA Privacy Rule regulations for “uses and  
10 disclosures for which an authorization is required.” 45 C.F.R. §§ 164.508 (a) and (c),  
11 164.512(a).

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

24  
25 *Subsection (d). Authorization form.* This subsection provides a form that a health insurer  
26 may use for an insured to authorize disclosure of genetic information. The use of a form  
27 following this pattern would comply with the requirements of the section.

28  
29 **SECTION 308. REMEDIES; ENFORCEMENT; LIMITATION OF ACTIONS.**

30 (a) An individual aggrieved by a violation of this [article] may initiate an appropriate  
31 proceeding with the [state commissioner of insurance] for whatever action the [commissioner]  
32 may be authorized to take under the [state unfair practice insurance law] or may file a civil action  
33 without exhausting administrative remedies.

34 (b) All remedies at law and in equity are available to enforce this [act], including punitive  
35 damages and a right to a jury trial. In addition, a court may order expungement of records.

36 (c) A court shall award a prevailing insured reasonable attorney’s fees and costs unless  
37 justice requires otherwise.

1 (d) An individual may initiate the administrative action or file the civil action authorized  
2 in subsection (a) not later than two years after the individual discovers the violation of this  
3 [article] or an individual exercising reasonable care should have discovered the violation.

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

### 7 8 **Reporter’s Notes** 9

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

18  
19 The committee considered and rejected statutory damages as a remedy for a privacy  
20 violation for the reason that statutory damages often serve primarily to limit recovery. The  
21 absence of statutory damages, however, makes the availability of punitive damages particularly  
22 important.

23  
24 This section is identical to the enforcement provision for life insurance, income-disability  
25 insurance and long-term-care insurance in Article 4.

26  
27 Certain enforcement and remedies may be preempted by ERISA. “Complete preemption”  
28 occurs when Congress has “so completely [preempted] a particular area that any civil complaint  
29 raising this select group of claims is necessarily federal in character.” *Metropolitan Life Ins.*  
30 *Corp. v. Taylor*, 481 U.S. 58, 63-64 (1987). In *Taylor*, the United States Supreme Court held  
31 that the civil enforcement provision of ERISA, 29 U.S.C. § 1132(a), completely preempts  
32 common law breach of contract and tort claims for wrongful termination of disability benefits.  
33 *See also Prudential Ins. Co. of Amer. v. Nat’l Park Med. Center, Inc.*, 413 F.3d 897 (8th Cir.  
34 2005) (with respect to suits that could be brought under ERISA, civil enforcement provision  
35 preempts Arkansas Patient Protection Act civil penalties).

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

1 (statute providing attorney's fees and costs for external review of insurer's denial of coverage  
2 preempted by conflict with ERISA).

1 [ARTICLE] 4

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

4 SECTION 401. APPLICANT FOR INSURANCE. For purposes of this [article], an  
5 applicant for life insurance, disability-income insurance, or long-term-care insurance shall be  
6 treated the same as an insured.

7 Reporter’s Notes

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

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

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

31  
32 *Applicants.* For simplicity, the article refers only to insureds. The provisions apply  
33 equally to applicants for insurance.  
34

35 SECTION 402. GENETIC TESTING.

36 (a) If an insurer files information on a genetic test that meets the standards of Section  
37 406, an insurer may request or require an insured to take the genetic test in connection with the

1 provision of life insurance, disability-income insurance, or long-term-care insurance and, with  
2 prior authorization of the insured that meets the requirements of Section 403, may provide the  
3 test to the insured.

4 (b) An insurer that requests or requires a genetic test in connection with the provision of  
5 life insurance, disability-income insurance, or long-term-care insurance shall provide and pay for  
6 genetic counseling for the insured about the risks and benefits of the genetic test before the  
7 insured decides to authorize the test. The insured may knowingly and voluntarily waive  
8 counseling in a signed record that informs the insured of the benefits of genetic counseling.

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

11 (1) pay for the genetic test;

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

15 (3) provide and pay for genetic counseling for the insured about a test result  
16 unless the insured knowingly and voluntarily waives counseling in a signed record that informs  
17 the insured of the benefits of genetic counseling; and

18 (4) require the destruction of the insured's biological sample obtained for a  
19 genetic test as soon as permitted by law after the test is completed unless retention of the sample  
20 is authorized by the insured, permitted by law other than this [act], or ordered by a tribunal.

### 21 **Reporter's Notes**

22  
23 *Genetic testing and genetic information.* This section and the section 404 limit access to  
24 genetic information by insurers that provide life, disability-income, or long-term-care insurance.  
25 This section limits genetic testing and section 404 limits access to genetic information in general.  
26 The limitations are based on the philosophy that insurers may continue current information



1 gathering practices, but may not expand their collection of genetic information unless and until  
2 there is a strong scientific basis for its use to predict mortality and morbidity. It is the drafting  
3 committee's understanding that life, disability-income and long-term-care insurers do not at  
4 present require applicants to take genetic tests, but do collect family history information for use  
5 in determining eligibility and in underwriting.  
6

7 The drafting committee considered, but did not adopt, an approach to regulating genetic  
8 information for life, disability-income or long-term-care insurance based on the amount of the  
9 insurance policy. The suggestion was to prohibit genetic testing and consideration of genetic  
10 information for policies worth less than a specified monetary threshold. Above that value,  
11 insurers would be permitted to consider genetic information freely.  
12

13 The arguments for restricting access to genetic information by the insurance industry are  
14 that this information is particularly private and its predictive power is easily exaggerated. There  
15 are privacy concerns with commercial access to sensitive genetic information and predictions that  
16 individuals will avoid genetic testing for fear of adverse effects on their insurability. There is  
17 also a possibility that insurers may require applicants to take genetic tests and then deny  
18 insurance or charge more based on genetic characteristics, unfairly making coverage unavailable  
19 to people who are not sick from the genetic condition and never will become sick from that  
20 condition. From the industry perspective, as with health insurance, insurers worry about adverse  
21 selection. If applicants seek coverage because a genetic characteristic exposes them to risk, but  
22 the insurer does not have this information, this puts the insurer at a financial disadvantage. *See*  
23 *generally* Mark A. Rothstein, ed., *Genetics and Life Insurance: Medical Underwriting and Social*  
24 *Policy* (2004).  
25

26 A 1997 study by the Human Genetics Advisory Commission in the United Kingdom  
27 concluded that it is unlikely that actuarially-sound genetic predictions of adult death will be  
28 validated and available anytime in the near future. Genetic tests need to be connected to medical  
29 and epidemiological research to establish what consequences for health and life-span can be  
30 inferred from a given genetic test. The Commission concluded that a requirement to disclose  
31 genetic tests as a condition of obtaining insurance would be acceptable only after research has  
32 established an association between a given pattern of test results and life events that are relevant  
33 for the insurance product. It recommended continuing a moratorium on requiring test results.  
34 Human Genetics Advisory Commission, *The Implications of Genetic Testing for Insurance*  
35 (1997).  
36

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

1 Ann. § 9334 (any insurance).

2  
3 The section also sets forth requirements similar to those imposed on employers who  
4 provide genetic tests.

5  
6 *Genetic Counseling.* This section requires insurers who have applicants take genetic tests  
7 to provide genetic counseling. The counseling occurs in two stages: before the test to assist in  
8 the decision to take the genetic test and after the test to interpret results if the test indicates the  
9 individual is at risk. Counseling is an important component of the testing process in the field of  
10 genetics for several reasons. Tests may indicate a risk of a condition for which there is no  
11 treatment and the information may have implications for family members who are not tested  
12 directly. The outcomes require interpretation of complex probabilities which can be easily  
13 misunderstood. The genetic counseling that is required before the test is covered in subsection  
14 (b) and the counseling that is appropriate after a test is covered in subsection (c).

15  
16 The committee received differing opinions from industry participants on this issue which  
17 ranged from opposition to any obligation to provide counseling to a view that if insurance  
18 companies request the tests they should provide and pay for counseling in conjunction with the  
19 test.

20  
21 **SECTION 403. AUTHORIZATION FOR GENETIC TEST.**

22 (a) An insured's authorization for the genetic test requested or required under Section 402  
23 must be knowing and voluntary and indicated in a record signed by the insured that complies  
24 with subsection (b) of this section. An insurer that receives a valid authorization for genetic  
25 testing may provide a test only in accordance with the authorization. An authorization may not  
26 expand the genetic testing permitted by this [act] and may not include exculpatory language  
27 waiving any of the insured's legal rights.

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

- 30 (1) describe the genetic test to be performed, its purpose, and its permitted uses;  
31 (2) state that only the authorized genetic test will be performed on the insured's  
32 biological sample;  
33 (3) inform the insured that the insurer is obligated to provide and pay for genetic

1 counseling about the risks and benefits of the test before the insured decides to authorize the test;

2 (4) inform the insured that the insurer is obligated to provide and pay for genetic  
3 counseling about the test result unless the insured waives genetic counseling;

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

6 (6) include an opportunity for the insured to provide directions about reporting  
7 test results;

8 (7) inform the insured that the insured's biological sample will be destroyed as  
9 soon as permitted by law after the test is completed unless the insured authorizes retention of the  
10 sample or unless otherwise ordered by a tribunal; and

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

12 (c) The use of the following form complies with this section.

13 Authorization for Genetic Testing

14 Limited Authorization. Only the genetic tests that you authorize on this form will be performed  
15 on your biological sample. These tests are voluntary, but refusing a test requested by  
16 \_\_\_\_\_ may mean that your application for insurance will be denied.  
17 [name of insurer]

18  
19  
20  
21  
22  
23 Availability of Genetic Counseling. Before you complete this authorization, it is highly  
24 recommended that you meet with a genetic counselor who will help you understand and evaluate  
25 the risks, benefits, and consequences for you and your family of having the tests listed below.  
26

27 \_\_\_\_\_ will provide and pay for this genetic counseling.  
28 [Name of insurer]

29  
30  
31  
32  
33 Proposed Genetic Tests. Based on a review of your family medical history, \_\_\_\_\_  
34 [name of insurer]

1 requests the following genetic test:

2  
3  
4  \_\_\_\_\_  
5 [Name of test]

6  
7 The purpose of this test is to determine if you have a predisposition for \_\_\_\_\_ .  
8 [genetic condition]

9 If you authorize \_\_\_\_\_ to have access to the test result, it will be used only for the  
10 [insurer]  
11 following purposes: \_\_\_\_\_.

12  
13 Reporting Test Results and Genetic Counseling. The test results will be reported to you and to a  
14 health-care professional whom you designate unless you direct otherwise. It is recommended that  
15 you receive genetic counseling about the test results. Genetic counseling is important for  
16 understanding the test results in the context of your medical and family history. It can also  
17 provide you with support, informational resources, and referrals, as appropriate, that can help you  
18 adapt to the implications of being at risk of a genetic condition. \_\_\_\_\_  
19 [Name of insurer]  
20 will provide and pay for genetic counseling about the test results unless you decline genetic  
21 counseling.  
22  
23  
24  
25  
26  
27  
28  
29  
30

31 Destruction of your Biological Sample. After the genetic test, your biological sample will be  
32 destroyed as soon as permitted by law unless a court, arbitral tribunal, or administrative  
33 agency requires retention of the sample or you sign a written authorization for \_\_\_\_\_  
34 [name of insurer]  
35 to keep the sample.  
36  
37

38 Retention of Legal Rights. By signing this authorization, you do not lose any legal rights to  
39 which you are entitled.  
40

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

43 I, \_\_\_\_\_, authorize the genetic test(s) I have checked above.  
44  
45  
46

1 [print name]

- 2
- 3  I wish to receive test results.
- 4  I do not wish to receive test results.

5

6  Report test results to the following health care professional:

7 Name: \_\_\_\_\_

8 Address: \_\_\_\_\_

9

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

11

12 \_\_\_\_\_

13 Signature

14 \_\_\_\_\_

Date

15 **Reporter’s Notes**

16

17 The Drafting Committee selected a method for protection privacy for genetic testing and

18 genetic information by establishing an authorization requirement that is coupled with statutory

19 limits and duties imposed on insurers. Under this approach, an insured must affirmatively

20 authorize any genetic testing or access, use, retention, or disclosure of genetic information. The

21 authorization requirement is not simply a procedural step because Article 4 establishes

22 limitations on the situations in which insurers may request authorization from insureds.

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 insurance.

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 402, an

34 insurer may require a genetic test as a condition of obtaining life, disability-income, or long-

35 term-care insurance if the test has been filed and meets the standards of Section 406. This

36 subsection adds an additional requirement that genetic testing is permitted only with the prior

37 authorization of the insured.

38

39 In order to meet the requirement that an authorization be knowing and voluntary, an

40 employee or insured should have genetic counseling before signing the authorization. Genetic

41 counseling provides insureds with adequate information to make an informed decision about

42 genetic testing. It also makes them aware of their options regarding reporting of test results and

43 help in interpreting them through genetic counseling. Genetic counseling may be provided by a

44 genetic counselor, but may also be provided by a qualified physician or geneticist.

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 for testing.* The section draws on N.Y. Civ.  
6 Rights Law § 79-1 (McKinney), which establishes requirements for consent for a genetic test.  
7

8 The limitation in (b)(2) to the authorized test is consistent with the requirements for prior  
9 authorization in Section 402.  
10

11 The notification provision regarding destruction of the sample in (b)(7) is consistent with  
12 the insurer's obligation to ensure the sample is destroyed under Section 402(c)(4), which  
13 recognizes that the testing laboratory may be required to retain the sample for certification  
14 purposes.  
15

16 *Subsection (c). Authorization form.* The subsection provides a form that may be used to  
17 authorize an insurance company to provide a genetic test. The use of a form following this  
18 pattern would comply with the requirements of the section.  
19

#### 20 **SECTION 404. ACCESS TO GENETIC INFORMATION.**

21 (a) Unless an insurer has filed information on a genetic test that meets the standards of  
22 Section 405, an insurer may not knowingly obtain or directly or indirectly inquire about, request,  
23 or require an insured to provide the insured's genetic information based on a genetic test in  
24 connection with the provision of life insurance, disability-income insurance, or long-term-care  
25 insurance.

26 (b) Nothing in this [article] prohibits an insurer from obtaining medical records of an  
27 applicant for insurance that contain genetic information in connection with the provision of life  
28 insurance, disability-income insurance, or long-term-care insurance.

29 (c) An insurer may request or require an insured to provide family medical history in  
30 connection with the provision of life insurance, disability-income insurance, or long-term-care  
31 insurance.

#### 32 **Reporter's Notes**

33

1 This section limits the extent to which an insurance company may access genetic  
2 information or the results of genetic testing based on the rationale discussed in the reporter’s  
3 notes to Section 402. Subsection (a) permits access to genetic information if it is based on a  
4 genetic test that meets the standards set forth in Section 406.  
5

6 Subsection (b) is included to reassure the industry that its traditional access to medical  
7 records is preserved, despite the fact that medical records may contain genetic information.  
8

9 The prohibition on access to genetic information does not apply to family medical history,  
10 which is not included in the definition of “genetic information.” Subsection (c), moreover,  
11 explicitly permits insurers to seek information about family medical history, which they have  
12 traditionally used for underwriting.  
13

14 **SECTION 405. PROHIBITION ON USE OF GENETIC INFORMATION.** Unless  
15 genetic information is based on a genetic test that has been filed and meets the standards  
16 provided in Section 406, an insurer may not use the genetic information about an insured’s  
17 predisposing genetic characteristics to determine eligibility for or rates, terms, and conditions of  
18 life insurance, disability-income insurance, or long-term-care insurance.

### 19 **Reporter’s Notes**

20  
21 The determination of eligibility for coverage includes decisions made in connection with  
22 the offer, sale, continuation, or renewal of an insurance policy. The determination of rates,  
23 terms, and conditions includes establishing premiums, limiting coverage, limiting or conditioning  
24 benefits, or making any other underwriting decisions.  
25

26 This section prohibits the use of genetic information for determining eligibility or  
27 underwriting of life, disability-income, and long-term-care insurance unless the genetic test has  
28 been filed and meets that standards provided in Section 406. Traditional insurance underwriting  
29 has been based on medical histories and tests that indicate existing medical conditions. The draft  
30 permits those practices to continue. Using predictions based on predisposing genetic  
31 characteristics that have not been expressed as a disease or condition would be a new step,  
32 however, and there is a great risk that such predictions would not be reliable in the context of  
33 insurance.  
34

35 Unlike the draft’s treatment of genetic information in employment or health insurance,  
36 the restriction on use of genetic information in life, disability-income & long-term-care insurance  
37 is narrower in that it applies only to predisposing genetic characteristics. Therefore, insurers are  
38 not restricted from using genetic information with regard to a medical condition that has been  
39 diagnosed.  
40

1 The section ties use of genetic information about predisposing characteristics to the  
2 process in Section 406 for ensuring that the genetic test provides a reliable prediction of  
3 individual mortality or morbidity. Otherwise, life, disability-income and long-term-care insurers  
4 may not use genetic information about predisposing characteristics for determining eligibility or  
5 in underwriting.  
6

7 This prohibition is consistent with regulation in a number of states. Because genetic tests  
8 are not yet routine in medical care and few individuals have previously taken genetic tests when  
9 they apply for insurance, the prohibitions on requiring tests in California, Massachusetts, and  
10 Vermont have the effect of preventing the use of genetic information in insurance  
11 determinations. In addition, a number of states directly prohibit insurers from using genetic  
12 information to determine eligibility or in underwriting. *See* Colo. Rev. Stat. § 10-3-1104.7(3)(b)  
13 (group disability-income & long-term-care); Kan. Stat. Ann. § 40-2259(d) (disability-income &  
14 long-term-care); Or. Rev. Stat. § 746.135 (genetic information from a blood relative for life,  
15 disability-income & long-term-care insurance); Vt. Stat. Ann. tit. 18, § 9334(a) (same). *See also*  
16 Ariz. Rev. Stat. Ann. § 20-448(F) (permitting disability-income and long-term-care insurers to  
17 use genetic information only if there is an actual diagnosis of a genetic condition).  
18

19 The insurance industry maintains that any restrictions on their ability to use genetic  
20 information will undermine the availability and pricing structure of life, disability-income &  
21 long-term-care insurance. However, there is broad international consensus that the use of genetic  
22 information in life insurance should be restricted. Numerous countries have enacted restrictions,  
23 as have the states noted above. There is no evidence, moreover, that these restrictions have been  
24 associated with adverse selection, increased pricing, reduced availability of policies, or decreased  
25 profitability of the insurance industry. Without some supporting evidence, these industry  
26 concerns do not outweigh the importance of protecting against new uses of information that  
27 would diminish privacy and that carry a high risk of irrational discrimination.  
28

29 With the draft's narrow definition of "genetic information," an insurer would be able to  
30 use genetic data revealed by an individual's family medical history to determine eligibility or to  
31 underwrite without restriction. One member of the subcommittee raised the question of whether  
32 there should be any limits on insurers' use of family medical history. The question was  
33 motivated by a concern that even if disclosures to insurers do not change, insurers may be able to  
34 do more with those disclosures using ever more sophisticated computer technology. The drafting  
35 committee may want to consider whether it is desirable to prevent new uses of family history  
36 information that may become possible and if so, what limits would be appropriate.  
37

38 **SECTION 406. REQUIRED DETERMINATION AND FILING FOR GENETIC**  
39 **TESTING AND ACCESS AND USE OF GENETIC INFORMATION.** A life insurer,  
40 disability-income insurer, or long-term-care insurer may request or require a genetic test or  
41 access and use genetic information based on the results of a genetic test if the insurer files with



1 the [state commissioner of insurance] the test and documentation supporting to a reasonable  
2 degree of scientific certainty the test’s analytical validity, clinical validity, and a scientific  
3 association between the test and an increased risk of morbidity or mortality. The insurer’s use of  
4 genetic information about an insured’s predisposing genetic characteristic to determine eligibility  
5 or rates, terms, or conditions for life insurance, disability-income insurance, or long-term-care  
6 insurance without a filing by the insurer that meets this standard is a violation of the [state unfair  
7 practices insurance law].

8 **Legislative Note:** *[State unfair practices insurance law] should be replaced with the title of the*  
9 *relevant statute and [state commissioner of insurance] should be replaced with the appropriate*  
10 *title.*

#### 11 **Reporter’s Notes**

12  
13  
14 The risk of misuse of genetic information is increasing because of the explosion of  
15 genetic tests available, the general lack of governmental oversight for these tests, and common  
16 misperceptions about the extent to which a genetic test can predict a future medical disease or  
17 condition. In addition, the pathways for gene expression remain uncertain. Links between most  
18 genetic characteristics and the incidence of disease are extremely complex and depend on the  
19 interrelation of many factors, both genetic and environmental.

20  
21 Even with draft’s restrictions on genetic testing by insurance companies, access to genetic  
22 information in medical records will increase. More than 1,000 genetic tests are available  
23 clinically as of early 2007; hundreds more are available to researchers. Some are marketed  
24 directly to consumers with claims that they can be used to individually customize vitamins and  
25 diet as well as test for future disease. There is no government oversight of the validity of the  
26 tests used for research or available through medical professionals. Through the mechanisms of  
27 this section that protect against the premature or improper use of predictions based on genetic  
28 information, the draft provides assurance that insurance companies are permitted to use genetic  
29 information, but not misuse it.

30  
31 The insurance industry has expressed a view that it must be able to develop its use of  
32 genetic information along with the rapid development of knowledge in the genetic field. The  
33 section provides a mechanism that will allow use of genetic information to evolve, in response to  
34 new scientific information that may justify the use of genetic information for eligibility and  
35 underwriting determinations as determined by an evidence-based review process.

36  
37 The drafting committee considered and rejected an approach that would have established  
38 regulatory oversight of the use of genetic information by insurers by requiring a prior finding of  
39 an association with mortality or morbidity by state insurance regulators in consultation with state

1 public health authorities. The committee also considered and rejected an approach that would  
2 have required that the appropriate finding be made by a geneticist or genetic counselor. Instead,  
3 the drafting committee decided that the insurance industry should be responsible for determining  
4 the accuracy and completeness of the data on a genetic test and the reliability of the prediction  
5 possible with the genetic information.  
6

7 The approach selected by the committee requires an insurance company to identify  
8 genetic tests that it plans to use and to file documentation supporting the validity of the test with  
9 the state insurance commissioner. This documentation would then be open to public scrutiny,  
10 creating transparency that can provide a check on a company's determination. This process will  
11 allow an insurer's use of genetic information to change as research develops reliable connections  
12 between genetic characteristics and risk of mortality or morbidity.  
13

14 The process required here contemplates the type of evidence-based review of genetic tests  
15 conducted by the Evaluation of Genomic Applications in Practice and Prevention (EGAPP)  
16 Working Group formed under the auspices of the Centers for Disease Control National Office of  
17 Public Health Genomics. See <http://www.cdc.gov/genomics/gtesting/EGAPP/about.htm>.  
18

19 As explained in the following excerpt from the Final Report of the Task Force on Genetic  
20 Testing, Promoting Safe and Effective Genetic Testing in the United States (1997) (available at  
21 <http://www.genome.gov/10001733>), before relying on a genetic test, there must be scientific  
22 evidence to (1) establish a reliable relationship between a disease, genes, and inherited mutations;  
23 (2) establish the analytical validity of the test; and (3) establish the clinical validity of the test.  
24

#### 25 Establishing Associations Between a Disease, Genes, and Inherited Mutations 26

27 In developing genetic tests, scientists must first be confident that the DNA  
28 segments under investigation play a role in the disease in question. These  
29 segments might be apparently functionless markers that appear to be spatially  
30 linked on a chromosome to a disease-related gene. Linkage is demonstrated  
31 when, within families, one form of the marker is found in those with the disease  
32 more often than in blood relatives in whom the disease is absent. Because such  
33 associations might be due to chance, as was the case for the linkage claimed  
34 between bipolar affective disorder and markers on chromosome 11, and between  
35 schizophrenia and markers on chromosome 5, stringent statistical standards must  
36 be satisfied before accepting linkage, and the findings must be confirmed in  
37 additional families with the disease. . . .  
38

39 Further research leads scientists from the linked, functionless marker to a nearby  
40 gene suspected of being casually related to the diseases in question. The proof  
41 depends on finding mutations in the gene that are only present (in gene dosage  
42 sufficient to cause disease) in family members with disease. Further proof that a  
43 gene is causally related to disease comes from demonstrating that the protein  
44 encoded by the gene is absent, not synthesized in adequate amounts, or manifests  
45 a structural or functional aberration that plausibly accounts for symptoms and  
46 signs of the disease.

1 Another approach to identifying a disease-related gene does not depend on linkage  
2 but on suspecting that a gene that has been previously identified (“candidate  
3 gene”) plays a role in a specific disease. Here too, mutations must be found only  
4 in those with the disease.  
5

6 The DNA segments associated with a disease might be functional, common,  
7 polymorphic gene variants. Recently, attention has been given to the association  
8 between the apolipoprotein E polymorphism and Alzheimer disease (AD). A  
9 higher proportion of people with apoE4 will develop AD than those with other  
10 forms of the polymorphism. Some people with AD, however, will not inherit  
11 apoE4 and other with apoE4 will never develop AD; the polymorphism is neither  
12 a necessary nor sufficient cause for the disease. It is not clear whether  
13 polymorphic variants themselves predispose to the disease, whether the  
14 association is spurious (unlikely in the case of apoE4 and AD), or whether a  
15 marker linked to both the polymorphic gene and the disease-related gene is  
16 responsible. The following criterion must be satisfied before either linked  
17 markers or putative disease-related mutations are used as the basis of a genetic  
18 test. **The genotypes to be detected by a genetic test must be shown by**  
19 **scientifically valid methods to be associated with the occurrence of a disease.**  
20 **The observations must be independently replicated and subject to peer**  
21 **review.**  
22

### 23 Analytical Validity

24  
25 For DNA-based tests, analytical validity requires establishing the probability that  
26 a test will be positive when a particular sequence (analyte) is present (analytical  
27 sensitivity) and the probability that the test will be negative when the sequence is  
28 absent (analytical specificity). In contrast to DNA-based tests, enzyme and  
29 metabolite assays measure continuous variables (enzyme activity or metabolic  
30 concentration). One key measure of their analytical validity is accuracy, or the  
31 probability that the measured value will be within a predefined range of the true  
32 activity or concentration. Another measure of analytical validity is reliability, or  
33 the probability of repeatedly getting the same result.  
34

35 [V]alidation includes performing replicate determinations to ensure that a single  
36 observation is not spurious, and “blind” testing of coded positive samples (from  
37 patients with the disease in whom the alteration is known to be present) and  
38 negative samples (from controls). Organizations engaged in new test  
39 development should have access to a sufficient number of patient samples to have  
40 statistical confidence in the validation. In validating a new test analytically, the  
41 laboratory techniques should be as similar as possible to those used when the test  
42 will be performed clinically once it is validated.  
43

44 **Analytical sensitivity and specificity of a genetic test must be determined**  
45 **before it is made available in clinical practice.**  
46

## Clinical Validity

Clinical validity involves establishing several measures of clinical performance including (1) the probability that the test will be positive in people with the disease (clinical sensitivity), (2) the probability that the test will be negative in people without the disease (clinical specificity), and (3) the probability that people with positive test results will get the disease (positive predictive value (PPV)) and that people with negative results will not get the disease (negative predictive value.) Predictive value depends on the prevalence of the disease in the group or populations being studied, as well as on the clinical sensitivity and specificity of the test.

Two intrinsic features of genetic diseases, heterogeneity and penetrance, affect clinical validity.

*Heterogeneity.* The same genetic disease might result from the presence (in the necessary gene dosage) of any of several different variants (alleles) of the same gene (allelic diversity) or of different genes (locus heterogeneity). With current technology, all disease-related alleles cannot always be identified, particularly when there are many of them, which is often the case. This failure to detect all disease-related mutations reduces a test's clinical sensitivity.

*Penetrance.* The probability that disease will appear when a disease-related genotype is present is the penetrance of the genotype. When penetrance is incomplete, PPV is reduced. Penetrance is incomplete when other genetic or environmental factors must be present. In high-risk breast cancer families, 10 to 15 percent of women with inherited susceptibility mutations of the BRCA1 gene will never develop breast cancer. Environmental factors and possibly other inherited factors are required as well. In women without a family history of breast cancer, the penetrance of a BRCA1 or BRCA2 is even lower. Alleles at other gene loci and similar environments are more likely to be shared by relatives than by people in the general population.

\* \* \*

Parameters of clinical validity will depend in part on the group or population in which the test will be used. For instance, the frequency of disease-related alleles might differ between ethnic groups, making it difficult if not impossible to extrapolate the test sensitivity from one group to another. This is the case for cystic fibrosis and breast cancer in which certain alleles can predominate in one ethnic group or geographical area but not in others. Penetrance can also differ among ethnic groups. The prevalence of allele frequencies will have a marked effect on PPV; the greater the prevalence, the higher the PPV. Age will also affect allele prevalence; in a population older than the age at which the disease usually causes death, the allele frequency will be lower than in a younger population. For all these reasons, validation studies should be conducted in a

1 group representative of the one in which the test is intended for clinical use.

2  
3 When tests are developed for one purpose are used for another, there is no  
4 assurance that the sensitivity or PPV will be the same. . . .

5  
6 The three following criteria help ensure that appropriate data on the clinical  
7 validity of genetic tests will be collected during the developmental stages.

- 8  
9 • **Data to establish the clinical validity of genetic tests (clinical**  
10 **sensitivity, specificity, and predictive value) must be collected under**  
11 **investigative protocols.**  
12 • **In clinical validation, the study sample must be drawn from a group**  
13 **of subjects representative of the population for whom the test is**  
14 **intended.**  
15 • **Formal validation for each intended use of a genetic test is needed.**

16  
17 (emphasis in original, citations omitted)

18  
19 **SECTION 407. CORRECTION OPTION FOR GENETIC INFORMATION.** If an

20 insurer uses an insured's genetic information to make an adverse determination regarding  
21 eligibility or rates, terms, or conditions for life insurance, disability-income insurance, or long-  
22 term-care insurance, the insurer shall provide notice of that use to the insured. The insured may  
23 choose to repeat a genetic test to verify the analysis used in the adverse determination. If the  
24 initial test was performed at the request of the insurer, the insurer shall pay for a repeat test  
25 requested by the insured. If the first analysis is found to be inaccurate, the insurer shall  
26 reconsider the adverse determination.

27 **Reporter's Notes**

28  
29 Under this section, an insured is provided an opportunity to correct mistakes in genetic  
30 information. The section is modeled on Florida procedures which require the DNA analysis to  
31 be repeated in the event of an adverse determination. Fla. Stat. § 760.40(3). Delaware also has a  
32 special provision that allows an individual to access his genetic records and to correct those  
33 records. 16 Del. Code Ann. § 1223.  
34



1 The insurance industry argues that disclosures are necessary for business purposes and  
2 that a special disclosure provision for genetic information is unnecessary because a number of  
3 states have adopted statutes based on National Association of Insurance Commissioners' model  
4 laws dealing with general privacy of information. In the Drafting Committee's view, disclosures  
5 of genetic information are not protected adequately when there are broad exceptions that allow  
6 this information to be shared for business purposes.

7  
8 *Subsection (b).* Under this subsection, an insured is allowed to access an insurer's  
9 records of his genetic information. In combination with the procedure in Section 407, this  
10 enables an insured to correct those records.  
11

12 **SECTION 410. AUTHORIZATION FOR ACCESS, USE, RETENTION, OR**  
13 **DISCLOSURE OF GENETIC INFORMATION.**

14 (a) Except as otherwise provided by this [act] or law other than this [act], an insurer may  
15 not access, use, keep, or disclose an insured's genetic information without the insured's knowing  
16 and voluntary authorization indicated by a record signed by the insured that complies with  
17 subsection (c) of this section. An insurer that receives a valid authorization may access, use,  
18 keep, or disclose genetic information only in accordance with the authorization. An  
19 authorization shall not expand the access, use, retention, or disclosure of genetic information  
20 permitted by this [article] and may not include exculpatory language waiving any of the insured's  
21 legal rights.

22 (b) Except as otherwise provided by this [act] or law other than this [act], a person who  
23 receives genetic information disclosed by an insurer must maintain the confidentiality of the  
24 insured's genetic information and may not disclose the information without the insured's  
25 knowing and voluntary authorization indicated by a record signed by the insured that complies  
26 with subsection (c) of this section. A recipient that receives the insured's valid authorization to  
27 disclose genetic information may disclose the information only in accordance with the  
28 authorization. An authorization may not expand the disclosure of genetic information permitted

1 by this [article] and may not include exculpatory language waiving any of the insured's legal  
2 rights. When an insurer discloses an insured's genetic information, it must notify the recipient of  
3 the information about these obligations.

4 (c) An authorization to access, use, keep, or disclose an insured's genetic information  
5 must:

6 (1) describe the genetic information to be accessed, used, kept, or disclosed in a  
7 specific and meaningful fashion;

8 (2) identify or describe the person that is authorized to access, use, keep, or  
9 disclose the genetic information;

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

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

14 (5) if the authorization is for retention of genetic information, describe where the  
15 information will be kept and identify or describe the custodian of the information;

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

18 (7) indicate the duration of the authorization with an expiration date if any or  
19 expiration event that relates to the insured or to the purpose of the access, use, retention, or  
20 disclosure;

21 (8) state that the insured may revoke the authorization at any time in a signed  
22 record, subject to the right of an insurer or other person that acted in reliance on the authorization  
23 before receiving notice of revocation, and provide instructions on how to revoke an



1 authorization; and

2 (9) state that the insured is entitled to a copy of the authorization.

3 (d) The use of the following forms complies with this section.

4  
5 Authorization for Access and Use of Genetic Information

6  
7 \_\_\_\_\_ requests your authorization to access the following genetic test results and  
8 [Name of insurer]  
9 use them for the purposes identified:

10  
11  
12  Access to the results of the test for \_\_\_\_\_. The purpose  
13 [name of test and condition tested for]  
14 of this test is to determine if you have a genetic characteristic that predisposes you towards the  
15 following medical condition: \_\_\_\_\_. \_\_\_\_\_ will use this information  
16 [Name of insurer]  
17 only for the following purposes: \_\_\_\_\_.

18  
19  
20  
21  Disclosure by \_\_\_\_\_ of genetic information about \_\_\_\_\_  
22 [name of person to disclose] [name of test]  
23 \_\_\_\_\_ to \_\_\_\_\_. \_\_\_\_\_ will use this information  
24 and condition] [name of insurer] [Name of insurer]  
25 only for the following purposes: \_\_\_\_\_.

26  
27  
28 You may revoke this authorization for access and use at any time by sending a letter to  
29 \_\_\_\_\_ unless \_\_\_\_\_ has \_\_\_\_\_  
30 [name and address] [name of insurer] [description of action that would  
31 \_\_\_\_\_  
32 be taken based on the information]

33  
34  
35  
36 You are entitled to a copy of this authorization. By signing this authorization, you do not lose  
37 any legal rights to which you are entitled. This authorization is valid until \_\_\_\_\_.  
38 [date or event]  
39

40  
41  
42  
43 I, \_\_\_\_\_, authorize \_\_\_\_\_ to access and use my genetic

1 [print name] [name of insurer]  
2 information as checked above.

3  
4  
5 \_\_\_\_\_  
6 Signature Date

7  
8  
9 Authorization for Retention of Genetic Information

10  
11 \_\_\_\_\_ requests your authorization to keep the following genetic information:  
12 [Name of insurer]

13  
14  
15  \_\_\_\_\_  
16 [Name of test and condition tested for]

17  
18  
19 You may revoke this authorization for \_\_\_\_\_ to keep your genetic information at  
20 [name of insurer]  
21 any time by sending a letter to \_\_\_\_\_ unless \_\_\_\_\_  
22 [name and address] [name of insurer]  
23 has \_\_\_\_\_.  
24 [description of action that would be taken based on the information]

25  
26  
27 You are entitled to a copy of this authorization. By signing this authorization, you do not lose  
28  
29 any legal rights to which you are entitled. This authorization is valid until \_\_\_\_\_.  
30 [date or event]

31  
32  
33 I, \_\_\_\_\_, authorize \_\_\_\_\_ to keep the genetic information  
34 [print name] [name of insurer]  
35 checked above.

36  
37 \_\_\_\_\_  
38 Signature Date

39  
40  
41 Authorization for Disclosure of Genetic Information

42  
43  
44 \_\_\_\_\_ seeks your authorization to disclose the following genetic information to  
45 [Name of insurer]  
46 \_\_\_\_\_ will notify \_\_\_\_\_

1 [name of recipient of the information] [Name of insurer] [name of recipient  
2  
3 \_\_\_\_\_ that \_\_\_\_\_ is legally obligated  
4 of the information] [name of recipient of the information]  
5 to maintain the confidentiality of this information and that if may not make further disclosures  
6  
7 without your authorization.

8  
9  
10  \_\_\_\_\_  
11 [Name of test and condition tested for]  
12

13  
14 You may revoke this authorization for disclosure at any time by sending a letter to  
15  
16 \_\_\_\_\_ unless \_\_\_\_\_ has already disclosed the information.  
17 [name and address] [name of insurer]  
18

19  
20 You are entitled to a copy of this authorization. By signing this authorization, you do not lose  
21  
22 any legal rights to which you are entitled. This authorization is valid until \_\_\_\_\_.  
23 [date or event]  
24

25  
26 I, \_\_\_\_\_, authorize \_\_\_\_\_ to  
27 [print name] [name of person authorized to make disclosure]  
28 disclose my genetic information checked above to \_\_\_\_\_.  
29 [name of recipient of the information]  
30

31  
32 \_\_\_\_\_  
33 Signature Date  
34

### 35 Reporter's Notes

36  
37 This section requires an insured to provide an authorization before an insurer may access,  
38 use, keep, or disclose genetic information. The provisions differ from those in the employment  
39 context in that insurers are permitted to continue their traditional use of family medical history  
40 without special authorization requirements.  
41

42 The draft does not disturb existing law that allows a minor to seek repudiation of consent  
43 and expunge records when the minor reaches the age of majority.  
44

45 *Subsection (a) General requirement for authorization.* This subsection would establish a

1 requirement that an insurer must be authorized by the insured before it may access, keep, or  
2 disclose genetic information, except as provided elsewhere in the act. In order to give a valid  
3 authorization, the insured must be informed as provided in the subsection (b) and must act  
4 voluntarily. Subsection (a) also includes a requirement that an authorization must be indicated  
5 by a signed record. The authorization requirement is coupled with limitations on access, use,  
6 retention, and disclosure in Sections 404, 405, 406, 408, and 409.

7  
8 Other law of the state may provide for a substitute decisionmaker or signer if the  
9 employee is incapacitated or incompetent. This situation is left to existing law of the state that  
10 governs power of attorney, guardianship, or other substitute decision makers.

11  
12 *Subsection (b) Obligation of recipient of authorized disclosure.* One of the difficulties in  
13 authorizing disclosure is control over the information once it has been disclosed. The Drafting  
14 Committee decided that regulation over the initial disclosure is ineffective without a continuing  
15 obligation of confidentiality that is binding on the recipient. Hence under this subsection a  
16 recipient may not redisclose the genetic information without the insured’s authorization. This  
17 provision extends beyond the privacy protections provided by HIPAA. States are permitted to  
18 depart from HIPAA privacy provisions if they impose more stringent protections. 45 C.F.R. §  
19 160.203(b).

20  
21 The Committee considered and rejected several approaches to the issue, including 1) a  
22 notice to the insured that the genetic information disclosed by the authorized person may be  
23 subject to redisclosure by the recipient and not longer protected, and 2) a provision that an  
24 insured could enter into a confidentiality agreement with recipients of their genetic information.

25  
26 *Subsection (c) Content of authorization.* The provision on authorization for access, use,  
27 retention, or disclosure of genetic information is adapted from the HIPAA Privacy Rule  
28 regulations for “uses and disclosures for which an authorization is required.” 45 C.F.R. §§  
29 164.508 (a) and (c), 164.512(a). The subsection adapts these regulations to apply to genetic  
30 information and expands them to include authorization for access and retention as well as for use  
31 and disclosure.

32  
33 An advantage of using the HIPAA regulations as the foundation for the authorization  
34 requirements is that the requirements to authorize a disclosure by a health care provider to an  
35 insurer would be similar to the requirements that health care provider must follow as a covered  
36 entity under HIPAA. The context of the HIPAA regulations is different enough, however, that  
37 they cannot be transported directly into the Act without modification. Moreover, states are  
38 permitted to impose their own, more stringent, privacy requirements. 45 C.F.R. § 160.203(b).  
39 Some have enacted statutes with different requirements for disclosing health care information,  
40 which reduces the uniformity that would theoretically be achieved by using the HIPAA format.  
41 Therefore, while the structure of this subsection is modeled on the HIPAA regulations, it  
42 includes some additional provisions from various state statutes. *See, e.g.,* Me. Rev. Stat. Ann. tit.  
43 22 § 1711-C.

44  
45 *Subsection (d). Authorization form.* This subsection provides forms that may be used for  
46 an insured to provide authorization for use, retention or disclosure of genetic information. Forms

1 following these examples would comply with this section.  
2

3 **SECTION 411. REVOCATION OF AUTHORIZATION.**

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

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

7 (1) to the extent that an insurer or other person has taken action in reliance on the  
8 authorization; or

9 (2) if the authorization was granted as a condition of obtaining insurance and  
10 other law provides the insurer with a right to contest a claim under, or the validity of, the policy.

11 **Reporter's Notes**

12  
13 This section is adapted from the HIPAA regulation that governs revocation of an  
14 authorization. 45 C.F.R. § 164.508 (b) (5). It is similar to provisions governing health care  
15 information that have been adopted by some of the states. Long-term-care insurers are subject to  
16 HIPAA, but life insurers and disability-income insurers are not, so this section extends the law in  
17 order to give an insured greater control over his genetic information.  
18

19 Other law of the state may provide for a substitute decisionmaker or signer if the  
20 employee is incapacitated or incompetent. This situation is left to existing law of the state that  
21 governs power of attorney, guardianship, or other substitute decision makers.  
22

23 Subsection (b)(2) is included because Section 402 permits an insurer to condition the  
24 availability of life, disability-income, or long-term-care insurance on an applicant's authorization  
25 for a genetic test or access to genetic information about the test, if the test meets the standards of  
26 Section 406 for providing a reliable prediction of mortality or morbidity. An insurer needs to  
27 continue to access this information in order to protect against fraud or misrepresentation in an  
28 insurance application; it has two years in which to contest the validity of the insurance contract.  
29 Records are also kept for reinsurance purposes and for reapplications by the insured.  
30

31 **SECTION 412. RETENTION OF AUTHORIZATION.** An insurer that receives an  
32 authorization under this [article] shall keep a record of the authorization for six years after the  
33 expiration date of the authorization or, if the authorization has no expiration date, for six years

1 from the date the authorization was created.

2 **Reporter’s Notes**  
3

4 This section on the length of the obligation to keep an authorization is adapted from the  
5 HIPAA regulations that govern documentation and retention of a signed authorization. 45 C.F.R.  
6 §§ 164.508 (b) (6), § 164.530(j).  
7

8 **SECTION 413. REMEDIES; ENFORCEMENT; LIMITATION OF ACTIONS.**

9 (a) An individual aggrieved by a violation of this [article] may initiate an appropriate  
10 proceeding with the [state commissioner of insurance] for whatever action the [commissioner]  
11 may be authorized to take under the [state unfair practice insurance law] or may file a civil action  
12 without exhausting administrative remedies.

13 (b) All remedies at law and in equity are available to enforce this [article], including  
14 punitive damages and a right to a jury trial. In addition, a court may order expungement of  
15 records.

16 (c) A court shall award a prevailing insured reasonable attorney’s fees and costs unless  
17 justice requires otherwise.

18 (d) An individual may initiate the administrative action or file the civil action authorized  
19 in subsection (a) not later than two years after the individual discovers the violation of this  
20 [article] or an individual exercising reasonable care should have discovered the violation.

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

25 **Reporter’s Notes**  
26

27 The draft’s remedy section is written to respond to privacy violations as well as  
28 discrimination or misuse of genetic information in insurance. It provides a private right of action  
29 for an aggrieved individual. Alternatively, an aggrieved individual may seek enforcement  
30 through the State Commissioner of Insurance. An administrative remedy such as this is typical in  
31 state statutes that prohibit discrimination in health insurance based on genetic testing or

1 information. These statutes declare that a violation is an unfair and deceptive insurance act or  
2 practice under the state insurance code. They often provide that the State Commissioner of  
3 Insurance shall enforce the prohibitions.  
4

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

10 This section is identical to the enforcement provision for health insurance in Article 3.

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 . . . .