

THE NEW MASSACHUSETTS GENETIC PRIVACY ACT

In 2000, Massachusetts became the 37th state to adopt a law providing protections for the confidentiality and use of the results of genetic tests.

Many studies have found deep public concern about the privacy of genetic testing and fear of discrimination by employers and insurers based on genetic information. In Chapter 254 of the Acts of 2000 (referred to in this article as the "Act"), the Massachusetts legislature has addressed these concerns by providing protections for individuals who choose to receive genetic testing and for the confidentiality of genetic information. The Act also prohibits discriminatory conduct by employers, insurers and certain other businesses on the basis of genetic information. These protections became effective on November 20, 2000.

This article highlights the implications of the Act for physicians. It also provides a summary and analysis of the protections provided under the Act.

IMPLICATIONS FOR PHYSICIANS

Physicians will need to understand and implement the Act's protections in order for the law to achieve its goals.

Under the Act, physicians must obtain the required written consents both to conduct a genetic test and to release the test results to anyone other than the subject of the test. The required elements of a prior written consent for a genetic test, described in detail below, include a representation that the physician has discussed with the patient the reliability of the test and informed the patient of the availability of genetic counseling.

Physicians will have to identify patient records that contain genetic information subject to the heightened confidentiality protections of the Act. This task may be difficult. Genetic information generally is not segregated from other information in a medical record. The characterization of a test result as genetic information depends on the purpose of the test (e.g., a test of DNA, RNA, chromosomes or proteins is a genetic test only if the purpose is to identify genes, genetic abnormalities or characteristics of genetic material). A physician must be aware when a family history reveals the results of a genetic test that is protected genetic information and may not be disclosed without the informed consent of the subject of the test in the form specified in the Act. Otherwise, however, a family history, including family information pertaining to the presence, absence, alteration or modification of a human gene or genes, is not covered by the heightened confidentiality protections of the Act. Physicians will need to educate office staff and institute office procedures to assure that genetic information is appropriately handled.

Physicians must also be aware of the implications of the Act for patients and their families so that they can provide informed advice about the consequences of undergoing genetic testing. Physicians should know that undergoing a genetic test may impact a patient's ability to

obtain disability, long term care and life insurance because these insurers may ask whether an individual has had genetic testing.

SUMMARY AND ANALYSIS OF THE ACT

The Act regulates the confidentiality and uses of genetic test results and other genetic information. Provisions of the Act address: (1) protection of the confidentiality of genetic information through requirements for consent to genetic testing and consent to the disclosure of genetic test results; (2) discrimination in employment and employment related relationships; (3) discrimination in health insurance; and (4) discrimination in disability, long term care and life insurance.

The Act reflects the desire of the legislature to recognize the divergent interests and needs of different users of genetic information and the different purposes for which genetic information may be used. The definitions of the key terms "genetic test" and "genetic information" are different in the sections of the Act addressing confidentiality, discrimination in employment, discrimination in health insurance and discrimination in disability, long term care and life insurance. As a result, the statute is complex, notwithstanding its easily understood goals. Attachment 1 to this memorandum shows the different definitions of the key terms used in the Act.

1. Protection of Confidentiality

The provisions of the Act that protect the confidentiality of genetic information are of the greatest importance to physicians.

Summary. The Act provides heightened protection for the confidentiality of genetic testing by requiring a special form of written consent prior to the conduct of any genetic test, and informed written consent prior to the release of the results of any genetic test to any person other than the person tested and prior to identifying a person as the subject of a genetic test. A physician who requests that a genetic test be performed must provide a signed written statement to the laboratory that "warrants" that the required prior written consent has been obtained and authorizes the laboratory to perform the test and disclose the results to the physician.

The Act provides that a physician who orders a genetic test as "confidential research information" need not warrant to the testing laboratory that the person to be tested has given prior written consent in the form required by the Act and a health care facility or physician may disclose the results of a genetic test without the subject's written informed consent "where the results will be used only as confidential research information." The special rules applicable to confidential research information are discussed below.

Definitions. For the purposes of the confidentiality provisions of the Act, "genetic test" is defined as

a test of human DNA, RNA, mitochondrial DNA, chromosomes or proteins for the purpose of identifying genes, inherited or acquired genetic abnormalities or the presence or absence of inherited or acquired characteristics in genetic material.

"Genetic information" is defined as

any written or recorded individually identifiable result of a genetic test...or explanation of such a result.

There are important exclusions in the definitions of "genetic test" and "genetic information". Genetic tests do not include "tests given for drugs, alcohol, cholesterol or HIV", nor "any test for the purpose of diagnosing or detecting an existing disease, illness, impairment or disorder" (emphasis supplied). "Genetic information" does not include any information that is taken as

a biopsy, autopsy, or clinical specimen solely for the purpose of conducting an immediate clinical or diagnostic test that is not a test of DNA, RNA, mitochondrial DNA, chromosomes or proteins;

blood sample solely for blood banking;

a newborn screening mandated by law;

confidential research information for use in epidemiological and clinical research conducted for the purposes of generating scientific knowledge about genes, learning about genes, learning about the genetic basis of disease or for developing pharmaceutical and other treatments of disease; or

information pertaining to the abuse of drugs or alcohol which is derived from tests given for the exclusive purpose of determining the abuse of drugs or alcohol

By virtue of these exclusions, the confidentiality protections afforded by the Act are not as broad as the protections against discrimination in employment and health insurance. Physicians are not required to comply with the stringent consent requirements imposed by the Act for testing and the release of reports containing test results related to diagnosis and treatment of existing conditions which are part of standard clinical practice and not for the purpose of eliciting genetic information.

Prior written consent for genetic testing. Before ordering a genetic test for any purpose, the Act requires that a physician obtain the "prior written consent" of the person who is the subject of the test (or, if the subject is not competent to consent, the consent of someone authorized to provide such consent). A general consent is not adequate for this purpose. The Act requires that the prior written consent contain:

a statement of the purpose of the test;

a general description of the disease or condition being tested for;

a statement that the person has discussed with the ordering practitioner the reliability of the test and the level of certainty that a positive result serves as a predictor of the disease being tested for;

a statement that the person was informed of the availability of genetic counseling and received written information identifying a genetic counselor or medical geneticist from whom such counseling could be obtained; and

the identity of the person or persons to whom the test results may be disclosed.

Attachment 2 provides a sample form of consent to genetic testing that is intended to meet the requirements of the Act.

A health care facility or laboratory may perform a genetic test ordered by a physician only if the physician "warrants" that the required prior written consent has been obtained, except if the test is conducted for the purpose of generating confidential research information for certain purposes.

Informed consent for disclosure of genetic information. The records and reports of a physician, hospital, laboratory, insurer, commercial genetic testing company and certain other organizations that contain genetic information are not public records. Generally, the content of such records and reports may be disclosed only with the informed written consent of the subject of the information. The written consent form must state the purpose for which the information is being requested and must be distinct from the written consent for the release of any other medical information. Attachment 3 provides a sample form of consent to the release of genetic information intended to meet the requirements of the Act.

Other circumstances in which records and reports containing genetic information may be released are:

on proper judicial order;

to a person whose official duties entitle him to receive the information, as determined by the commissioner of the department of public health; and

in connection with life, disability or long term care insurance if the requirements of Massachusetts General Laws Chapter 175I are met.

Chapter 175I (the Insurance Information and Privacy Protection Act) permits an insurer and its representatives to obtain personal information (including medical information) about an insured or insurance applicant based on a written disclosure authorization form which is dated, specifies the types of persons authorized to disclose information about an individual, the specific nature of the information that may be disclosed and to whom it may be disclosed. Such forms must also specify the length of time the authorization shall remain valid. A disclosure authorization form that meets the requirements of Chapter 175I may meet the requirements for an informed written consent for the release of genetic information under the Act. If an insurer's disclosure authorization form does not clearly indicate the specific genetic information to be released, the purpose for which it is requested and the person(s) to whom it may be disclosed, a physician would be prudent to seek an additional informed written consent for the release of genetic information.

Confidential research information. The Act attempts to strike a balance between protecting the results of genetic testing so as to encourage testing when medically indicated and providing access to genetic information by researchers to advance scientific knowledge and the development of treatments for disease. To permit such access, the Act excludes "confidential research information for use in epidemiological or clinical research conducted for the purposes of generating scientific knowledge about genes or learning about genes or learning about the genetic basis of disease or for developing pharmaceutical and other treatments of disease" from the protections of "genetic information" contained in the confidentiality provisions of the Act.

"Confidential research information" is defined as

any results of a genetic test maintained pursuant to pharmacological or clinical research protocols which are subject to and conducted in accordance with the review and approval of an Institutional Review Board established pursuant to the provisions of [federal regulations] which protects the confidentiality of the individual who is the subject of the genetic test either by encryption, encoding or other means consistent with the requirements of said federal regulations or where the identity of the individual is unknown or protected from disclosure by encrypting or encoding or by other means consistent with the requirements of said federal regulations.¹

A physician who orders a genetic test as confidential research information for the designated purposes need not warrant to the testing laboratory that the person to be tested has given prior written consent in the form required by the Act and a physician may disclose the results of a genetic test without the subject's written informed consent in the form required by the Act where the results will be used only as confidential research information for the permitted purposes.

Enforcement. Violation of the provisions of the Act that prohibit genetic testing and the release of genetic information without appropriate consent are deemed to be violations of Section 2 of Massachusetts General Laws Chapter 93A (Regulation of Business Practices for Consumers Protection). If a person suffers financial injury as a result of a violation, Chapter 93A provides for payment of damages. If a violation is "willful and knowing", Chapter 93A provides for payment of treble damages and attorney's fees. A person whose rights have been violated may also seek injunctive and other equitable relief in a private right of action. The attorney general may also institute an action for such relief. In addition, an action to recover damages may be brought under Massachusetts law recognizing a general right of privacy, M.G.L. c. 214, §1B, and for breach of the common law obligation of a physician to obtain informed written consent to medical treatment.

¹ Subject to limited exceptions, all research involving human subjects supported by or subject to regulation by any federal department or agency must be reviewed by an Institutional Review Board constituted in accordance with federal regulations. The criteria for Institutional Review Board approval of research include a determination that an appropriate informed written consent will be obtained from each prospective subject and that, when appropriate, there are adequate protections for the privacy of subjects and the confidentiality of research data.

2. Protection Against Discrimination in Employment and Certain Other Commercial Transactions

The broadest definition of the term "genetic information" applies in the sections of the Act that prohibit discrimination on the basis of genetic testing and genetic information in employment and certain other commercial transactions. For the purposes of these sections only, genetic information includes not only the results of genetic tests and any explanation of such results, but also "family history pertaining to the presence, absence, variation, alteration, or modification of a human gene or genes" (emphasis added). No other provisions of the Act include family history in the definition of "genetic information".

The focus of these sections is the prohibition of discrimination by an employer, employment agency, labor organization or licensing agency on the basis of genetic information. Conduct that is expressly prohibited includes: refusal to hire or employ, represent, grant membership to or license or termination or refusal to renew employment, representation, membership or a license on the basis of a genetic test or other genetic information and the use of genetic information to affect the terms and conditions of employment, representation, membership or the ability to obtain a license; soliciting or requiring disclosure of genetic information as a condition of employment, representation, membership or licensure; offering any inducement for such disclosure; questioning a person about such information; or otherwise seeking to obtain or maintain such information for nonmedical purposes.

Individuals who are affected by a violation of Chapter 151B may bring a charge of discrimination before the Massachusetts Commission Against Discrimination ("MCAD") and seek damages and equitable relief from the MCAD or from a Massachusetts court.

3. Prohibition of Discrimination on the Basis of Genetic Information in the Issue of Health Insurance

The Act provides that no health insurer, hospital service corporation, medical service corporation, HMO or preferred provider arrangement may make any distinction or discrimination in the terms and conditions of health benefit plan coverage offered to any individual or group "based on genetic information", and no such company may require genetic tests or information as a condition of the issuance or renewal of any such coverage. For the purpose of these sections, "genetic information" is defined as the results of a genetic test or the explanation of such results. Family history is not included in the definition.

4. Protection Against Unfair Discrimination on the Basis of Genetic Information in the Issuance of Disability, Long Term Care and Life Insurance

The Act does not prohibit an issuer of disability, long term care or life insurance from making any distinction or discrimination on the basis of genetic information. Rather, such insurers may not "practice unfair discrimination because of the results of a genetic test or the provision of genetic information." "Unfair discrimination" is defined as

cancellation, refusal to issue or renew, charging any increased rate, restricting the length of coverage or in any way practicing discrimination based on genetic information unless such action is taken pursuant to reliable information relating to the insured's mortality or

morbidity, based on sound actuarial principles or actual or reasonably anticipated claims experience.

For the purposes of the regulation of disability, long-term care and life insurance, a "genetic test" excludes

tests given for drugs, alcohol, cholesterol or HIV; any test for the purpose of diagnosing or detecting an existing disease process; any test performed due to the presence of symptoms, signs or other manifestations of a disease, illness or impairment or other disease process; or any test that is taken as a biopsy, autopsy or clinical specimen solely for the purpose of an immediate clinical or diagnostic test that is not a test of DNA, RNA, mitochondrial DNA, chromosomes or proteins.

A broader range of tests is excluded from the category of genetic tests to enable insurers to have access to clinical testing information that they have historically requested and used in underwriting decisions while providing new rules with respect to tests which are more narrowly defined as genetic tests.

An insurer may not require an applicant for insurance to undergo a genetic test as a condition of insurance. However, the insurer may ask the applicant whether the applicant has had a genetic test. The applicant must be informed by the insurer that he is not required to answer the question, but if he fails to do so, such failure may result in an increased rate or denial of coverage. If an applicant discloses genetic test results that provide reliable information with respect to an individual's mortality or morbidity, an insurer may use that information to set the terms of the policy.

The Commissioner of the Massachusetts Division of Insurance has the authority to determine whether the use of genetic information by disability, long term care and life insurers constitutes "unfair discrimination" and, after a hearing, may enjoin such practices and impose penalties. If a determination of unfair discrimination is made, the Commissioner is further required, in consultation with the Department of Public Health, to hold a public hearing and may determine that the genetic test which is the subject of the hearing provides no reliable information related to the insured's mortality or morbidity so that its use by an insurer constitutes unfair discrimination. The Commissioner is directed to review the list of tests which have been determined to be unreliable at least annually.

The provisions with respect to disability, long term care and life insurance will sunset as of December 31, 2005. In the interim, a special study commission will evaluate the use of genetic information by insurers and whether changes in the law are necessary to protect the privacy of genetic information furnished by insurance applicants. The members of the commission will include a representative of the Massachusetts Medical Society.

The Future

The confidentiality protections afforded by the Act are an important initial step in protecting genetic privacy in Massachusetts. It will be important that such protections be extended to broader categories of genetic information as knowledge about the genetic basis of disease expands.

New protections for all personally identifiable health information are contained in the final federal regulations published on December 28, 2000 under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In addition, a bill designated "An Act Relative to Protecting the Privacy of Medical Records" has been filed for consideration by the Massachusetts legislature. This bill would provide a higher level of protection for the confidentiality of all medical information under Massachusetts law. As a general principle, because genetic information is often contained in general medical information about an individual as an integral part of a medical record, affording a greater protection for all medical information will be the most effective protection of genetic information.

The Medical Society will continue to assist its members to become informed about new laws affecting the privacy of health information and how to comply with their obligations under these laws.

1. This article has been prepared by the Massachusetts Medical Society Office of the General Counsel and the law firm of Choate, Hall & Stewart (Boston, Massachusetts) solely as an educational and informational resource for Massachusetts Medical Society members and others who may be interested in the subject matter.

2. The information contained in this article (including its Attachments) should not be construed as legal advice or legal opinions on specific facts.

3. Individuals seeking legal advice should consult with an attorney.

KEY DEFINITIONS IN CHAPTER 254 OF THE ACTS OF 2000
(AN ACT RELATIVE TO INSURANCE AND GENETIC TESTING
AND PRIVACY PROTECTION)

1. Definitions for Purposes of the Confidentiality Provisions

Genetic Test: a test of human DNA, RNA, mitochondrial DNA, chromosomes or proteins for the purpose of identifying

- genes
- inherited or acquired genetic abnormalities
- presence or absence of inherited or acquired characteristics in genetic material

Excluded:

- tests given for drugs, alcohol, cholesterol, HIV
- any test for diagnosing or detecting an existing disease, illness, impairment or disorder

Genetic Information: Any written or recorded individually identifiable

- result of a genetic test (as defined above)
- explanation of the result of a genetic test

Excluded (what is not genetic information): any information taken as

- a biopsy, autopsy or clinical specimen solely for the purpose of conducting an immediate clinical or diagnostic test that is not a test of DNA, RNA, mitochondrial DNA, chromosomes or proteins
- a blood sample solely for blood banking
- a newborn screening pursuant to Section 110A of c. 111
- confidential research information for use in epidemiological and clinical research conducted for the purposes of
 - generating scientific knowledge about genes
 - learning about genes
 - learning about the genetic basis of disease
 - developing pharmaceutical and other treatments of disease
- information pertaining to the abuse of drugs or alcohol which is derived from tests given for the exclusive purpose of determining the abuse of drugs or alcohol

Confidential Research Information: any results of a genetic test (as defined above) maintained pursuant to a pharmacological or clinical research protocol

subject to review by an Institutional Review Board (IRB) under federal law which protects the confidentiality of the individual who is the subject of the information either by encryption, encoding or other means consistent with the requirements of federal regulations; or

where the identity of the individual is unknown or protected from disclosure by encrypting, encoding or other means consistent with federal regulations

2. Definitions for Purposes of Provisions Prohibiting Discrimination in Employment

Genetic Test: a test of human DNA, RNA, mitochondrial DNA, chromosomes or proteins for the purpose of identifying

- genes
- genetic abnormalities
- presence or absence of inherited or acquired characteristics in genetic material

Excluded:

- tests given for the exclusive purpose of determining the abuse of drugs or alcohol

Genetic Information: Any written or recorded individually identifiable

- result of a genetic test (as defined above)
- explanation of the result of a genetic test
- **family history pertaining to the presence, absence, variation, alteration or modification of a human gene or genes**

Excluded (what is not genetic information):

- information pertaining to the abuse of drugs or alcohol which is derived from tests given for the exclusive purpose of determining the abuse of drugs or alcohol

3. Definitions for Purposes of Provisions Prohibiting Discrimination in Health Insurance

Genetic Test: a test of human DNA, RNA, mitochondrial DNA, chromosomes or proteins for the purpose of identifying

- genes
- genetic abnormalities
- presence or absence of inherited or acquired characteristics in genetic material

Excluded:

- tests given for the exclusive purpose of determining the abuse of drugs or alcohol

Genetic Information:

Any written or recorded individually identifiable

- result of a genetic test
- explanation of the result of a genetic test

4. **Definitions for Purposes of Provisions Prohibiting Unfair Discrimination in Disability, Long Term Care and Life Insurance**

Genetic Test:

a test of human DNA, RNA, mitochondrial DNA, chromosomes or proteins for the purpose of identifying

- genes
- inherited or acquired genetic abnormalities
- presence of absence of inherited or acquired characteristics in genetic material associated with a predisposition to disease, illness, impairment or other disease process

Excluded:

- tests given for drugs, alcohol, cholesterol, HIV
- any test for diagnosing or detecting an existing disease process
- any test performed because of the presence of symptoms, signs or other manifestations of a disease, illness or impairment or other disease process
- any test that is taken as a biopsy, autopsy or clinical specimen solely for the purpose of conducting an immediate clinical or diagnostic test that is not a test of DNA, RNA, mitochondrial DNA, chromosomes or proteins

Genetic Information:

Any written or recorded individually identifiable

- result of a genetic test
- explanation of the result of a genetic test

Excluded: (what is not genetic information)

- information pertaining to the abuse of drugs or alcohol which is derived from tests given for the exclusive purpose of determining the abuse of drugs or alcohol

SAMPLE

Attachment 2

This is a special consent form for genetic testing. Please read it carefully. If you do not understand something in this consent form or in the information you have received about the genetic test described below, please ask for additional information before you sign this form.

**CONSENT TO GENETIC TESTING AND DISCLOSURE OF TEST
RESULTS TO PHYSICIAN**

1. I hereby give my consent to my physician _____ (the "Physician") to arrange for the performance of the following test (the "Test") for me:

Name of Test

2. I understand that the purpose of the Test is:
3. I understand that the Test may disclose that I have or that I am at risk of acquiring the following disease(s) or condition(s):
4. Prior to signing this Consent Form, my Physician discussed with me the reliability of a positive or negative result from the Test and the level of certainty that a positive result is a predictor of the disease or condition being tested for.
5. My Physician has discussed with me the importance and availability of genetic counseling and that I may seek genetic counseling about the Test and the test result(s). I have received written information from my Physician identifying one or more genetic counselors from whom I may obtain such counseling.
6. I authorize the results of the Test to be disclosed to my Physician for the purpose of providing medical care to me.

Date _____

Name of Patient (print)

Signature of Patient

Signature of Patient's Authorized
Representative*

* Representative may sign only if patient is not capable of giving informed consent.

This is a special form by which you are authorizing the disclosure of genetic information about yourself. Please read it carefully. If you do not understand something in this consent form or if you have a question about the disclosure of genetic information, please ask for additional information before you sign this form.

CONSENT FOR THE DISCLOSURE OF GENETIC INFORMATION

1. I hereby give my consent to my physician _____ (the "Physician") to disclose the results of the following genetic test (the "Test") that has been or will be performed for me:

Name of Test

The results of the Test contain genetic information (the "Genetic Information"). The purpose of this consent form is solely to authorize disclosure of this Genetic Information and not to authorize the disclosure of any other medical information about me.

2. I consent to the disclosure of the Genetic Information **only** to the following individual(s) or organization(s) and **not** to any other person or organization.

Name of individual or organization: _____

Address: _____

Other contact information (optional): _____

3. I authorize the disclosure of the Genetic Information to the individual(s) or organization(s) named above for the following purpose(s):

4. I acknowledge that I have signed a separate informed consent form by which I have given my consent to the performance of the Test.

Date _____

Name of Patient (print)

Signature of Patient

Signature of Patient's Authorized Representative*

* Representative may sign only if patient is not capable of giving informed consent.