Act No. 29
Public Acts of 2000
Approved by the Governor
March 14, 2000
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March 15, 2000
EFFECTIVE DATE: March 15, 2000

STATE OF MICHIGAN
90TH LEGISLATURE
REGULAR SESSION OF 2000

Introduced by Senators Goschka, Schwarz, Hammerstrom, Johnson, Gougeon, Shugars, Sikkema and McCotter

ENROLLED SENATE BILL No. 593

AN ACT to amend 1978 PA 368, entitled "An act to protect and promote the public health; to codify, revise, consolidate, classify, and add to the laws relating to public health; to provide for the prevention and control of diseases and disabilities; to provide for the classification, administration, regulation, financing, and maintenance of personal, environmental, and other health services and activities; to create or continue, and prescribe the powers and duties of, departments, boards, commissions, councils, committees, task forces, and other agencies; to prescribe the powers and duties of governmental entities and officials; to regulate occupations, facilities, and agencies affecting the public health; to regulate health maintenance organizations and certain third party administrators and insurers; to provide for the imposition of a regulatory fee; to promote the efficient and economical delivery of health care services, to provide for the appropriate utilization of health care facilities and services, and to provide for the closure of hospitals or consolidation of hospitals or services; to provide for the collection and use of data and information; to provide for the transfer of property; to provide certain immunity from liability; to regulate and prohibit the sale and offering for sale of drug paraphernalia under certain circumstances; to provide for the implementation of federal law; to provide for penalties and remedies; to provide for sanctions for violations of this act and local ordinances; to repeal certain acts and parts of acts; to repeal certain parts of this act; and to repeal certain parts of this act on specific dates," by amending sections 16221 and 16226 (MCL 333.16221 and 333.16226), section 16221 as amended by 1998 PA 227 and section 16226 as amended by 1998 PA 109, and by adding sections 17020 and 17520.

The People of the State of Michigan enact:

Sec. 16221. The department may investigate activities related to the practice of a health profession by a licensee, a registrant, or an applicant for licensure or registration. The department may hold hearings, administer oaths, and order relevant testimony to be taken and shall report its findings to the appropriate disciplinary subcommittee. The disciplinary subcommittee shall proceed under section 16226 if it finds that 1 or more of the following grounds exist:

(a) A violation of general duty, consisting of negligence or failure to exercise due care, including negligent delegation to or supervision of employees or other individuals, whether or not injury results, or any conduct, practice, or condition which impairs, or may impair, the ability to safely and skillfully practice the health profession.

(b) Personal disqualifications, consisting of 1 or more of the following:

(*i*) Incompetence.

(*ii*) Subject to sections 16165 to 16170a, substance abuse as defined in section 6107.

(*iii*) Mental or physical inability reasonably related to and adversely affecting the licensee's ability to practice in a safe and competent manner.

(*iv*) Declaration of mental incompetence by a court of competent jurisdiction.

(*v*) Conviction of a misdemeanor punishable by imprisonment for a maximum term of 2 years; a misdemeanor involving the illegal delivery, possession, or use of a controlled substance; or a felony. A certified copy of the court record is conclusive evidence of the conviction.

(*vi*) Lack of good moral character.

(*vii*) Conviction of a criminal offense under sections 520a to 520*l* of the Michigan penal code, 1931 PA 328, MCL 750.520a to 750.520*l*. A certified copy of the court record is conclusive evidence of the conviction.

(*viii*) Conviction of a violation of section 492a of the Michigan penal code, 1931 PA 328, MCL 750.492a. A certified copy of the court record is conclusive evidence of the conviction.

(*ix*) Conviction of a misdemeanor or felony involving fraud in obtaining or attempting to obtain fees related to the practice of a health profession. A certified copy of the court record is conclusive evidence of the conviction.

(*x*) Final adverse administrative action by a licensure, registration, disciplinary, or certification board involving the holder of, or an applicant for, a license or registration regulated by another state or a territory of the United States, by the United States military, by the federal government, or by another country. A certified copy of the record of the board is conclusive evidence of the final action.

(*xi*) Conviction of a misdemeanor that is reasonably related to or that adversely affects the licensee's ability to practice in a safe and competent manner. A certified copy of the court record is conclusive evidence of the conviction.

(c) Prohibited acts, consisting of 1 or more of the following:

(*i*) Fraud or deceit in obtaining or renewing a license or registration.

(*ii*) Permitting the license or registration to be used by an unauthorized person.

(*iii*) Practice outside the scope of a license.

(*iv*) Obtaining, possessing, or attempting to obtain or possess a controlled substance as defined in section 7104 or a drug as defined in section 7105 without lawful authority; or selling, prescribing, giving away, or administering drugs for other than lawful diagnostic or therapeutic purposes.

(d) Unethical business practices, consisting of 1 or more of the following:

(*i*) False or misleading advertising.

(*ii*) Dividing fees for referral of patients or accepting kickbacks on medical or surgical services, appliances, or medications purchased by or in behalf of patients.

(*iii*) Fraud or deceit in obtaining or attempting to obtain third party reimbursement.

(e) Unprofessional conduct, consisting of 1 or more of the following:

(*i*) Misrepresentation to a consumer or patient or in obtaining or attempting to obtain third party reimbursement in the course of professional practice.

(*ii*) Betrayal of a professional confidence.

(*iii*) Promotion for personal gain of an unnecessary drug, device, treatment, procedure, or service.

(*iv*) Directing or requiring an individual to purchase or secure a drug, device, treatment, procedure, or service from another person, place, facility, or business in which the licensee has a financial interest.

(f) Failure to report a change of name or mailing address within 30 days after the change occurs.

(g) A violation, or aiding or abetting in a violation, of this article or of a rule promulgated under this article.

(h) Failure to comply with a subpoena issued pursuant to this part, failure to respond to a complaint issued under this article or article 7, failure to appear at a compliance conference or an administrative hearing, or failure to report under section 16222 or 16223.

(i) Failure to pay an installment of an assessment levied pursuant to the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302, within 60 days after notice by the appropriate board.

(j) A violation of section 17013 or 17513.

(k) Failure to meet 1 or more of the requirements for licensure or registration under section 16174.

(*l*) A violation of section 17015 or 17515.

(m) A violation of section 17016 or 17516.

(n) Failure to comply with section 9206(3).

(o) A violation of section 5654 or 5655.

(p) A violation of section 16274.

(q) A violation of section 17020 or 17520.

Sec. 16226. (1) After finding the existence of 1 or more of the grounds for disciplinary subcommittee action listed in section 16221, a disciplinary subcommittee shall impose 1 or more of the following sanctions for each violation:

Violations of Section 16221	Sanctions
Subdivision (a), (b)(*ii*), (b)(*iv*), (b)(*vi*), or (b)(*vii*)	Probation, limitation, denial, suspension, revocation, restitution, community service, or fine.
Subdivision (b)(*viii*)	Revocation or denial.
Subdivision (b)(*i*), (b)(*iii*), (b)(*v*), (b)(*ix*), (b)(*x*), or (b)(*xi*)	Limitation, suspension, revocation, denial, probation, restitution, community service, or fine.
Subdivision (c)(*i*)	Denial, revocation, suspension, probation, limitation, community service, or fine.
Subdivision (c)(*ii*)	Denial, suspension, revocation, restitution, community service, or fine.
Subdivision (c)(*iii*)	Probation, denial, suspension, revocation, restitution, community service, or fine.
Subdivision (c)(*iv*) or (d)(*iii*)	Fine, probation, denial, suspension, revocation, community service, or restitution.
Subdivision (d)(*i*) or (d)(*ii*)	Reprimand, fine, probation, community service, denial, or restitution.
Subdivision (e)(*i*)	Reprimand, fine, probation, limitation, suspension, community service, denial, or restitution.
Subdivision (e)(*ii*) or (h)	Reprimand, probation, suspension, restitution, community service, denial, or fine.
Subdivision (e)(*iii*) or (e)(*iv*)	Reprimand, fine, probation, suspension, revocation, limitation, community service, denial, or restitution.
Subdivision (f)	Reprimand or fine.
Subdivision (g)	Reprimand, probation, denial, suspension, revocation, limitation, restitution, community service, or fine.
Subdivision (i)	Suspension or fine.
Subdivision (j), (o), or (q)	Reprimand or fine.
Subdivision (k)	Reprimand, denial, or limitation.
Subdivision (*l*) or (n)	Denial, revocation, restitution, probation, suspension, limitation, reprimand, or fine.
Subdivision (m)	Revocation or denial.
Subdivision (p)	Revocation.

(2) Determination of sanctions for violations under this section shall be made by a disciplinary subcommittee. If, during judicial review, the court of appeals determines that a final decision or order of a disciplinary subcommittee prejudices substantial rights of the petitioner for 1 or more of the grounds listed in section 106 of the administrative procedures act of 1969, 1969 PA 306, MCL 24.306, and holds that the final decision or order is unlawful and is to be set aside, the court shall state on the record the reasons for the holding and may remand the case to the disciplinary subcommittee for further consideration.

(3) A disciplinary subcommittee may impose a fine of up to, but not exceeding, $250,000.00 for a violation of section 16221(a) or (b).

(4) A disciplinary subcommittee may require a licensee or registrant or an applicant for licensure or registration who has violated this article or article 7 or a rule promulgated under this article or article 7 to satisfactorily complete an educational program, a training program, or a treatment program, a mental, physical, or professional competence examination, or a combination of those programs and examinations.

Sec. 17020. (1) Except as otherwise provided for a test performed under section 5431 and except as otherwise provided by law, beginning upon the expiration of 6 months after the effective date of the amendatory act that added this section, a physician or an individual to whom the physician has delegated authority to perform a selected act, task, or function under section 16215 shall not order a presymptomatic or predictive genetic test without first obtaining the written, informed consent of the test subject, pursuant to this section.

(2) For purposes of subsection (1), written, informed consent consists of a signed writing executed by the test subject or the legally authorized representative of the test subject that confirms that the physician or the individual acting under the delegatory authority of the physician has explained, and the test subject or the legally authorized representative of the test subject understands, at a minimum, all of the following:

(a) The nature and purpose of the presymptomatic or predictive genetic test.

(b) The effectiveness and limitations of the presymptomatic or predictive genetic test.

(c) The implications of taking the presymptomatic or predictive genetic test, including, but not limited to, the medical risks and benefits.

(d) The future uses of the sample taken from the test subject in order to conduct the presymptomatic or predictive genetic test and the information obtained from the presymptomatic or predictive genetic test.

(e) The meaning of the presymptomatic or predictive genetic test results and the procedure for providing notice of the results to the test subject.

(f) Who will have access to the sample taken from the test subject in order to conduct the presymptomatic or predictive genetic test and the information obtained from the presymptomatic or predictive genetic test, and the test subject's right to confidential treatment of the sample and the information.

(3) Within 6 months after the effective date of the amendatory act that added this section, the department of community health, in consultation with the Michigan board of medicine, the Michigan board of osteopathic medicine and surgery, at least 1 physician who is board certified by the American board of medical genetics, and appropriate professional organizations, shall develop and distribute a model informed consent form for purposes of this section that practitioners may adopt. The department of community health shall include in the model form at least all of the information required under subsection (2). The department of community health shall distribute the model form to physicians and other individuals subject to this section upon request and at no charge. The department of community health shall review the model form at least annually for 5 years after the first model form is distributed, and shall revise the model form if necessary to make the form reflect the latest developments in medical genetics.

(4) The department of community health, in consultation with the entities described in subsection (3), may also develop and distribute a pamphlet that provides further explanation of the information included in the model informed consent form.

(5) If a test subject or his or her legally authorized representative signs a copy of the model informed consent form developed and distributed under subsection (3), the physician or individual acting under the delegatory authority of the physician shall give the test subject a copy of the signed informed consent form and shall include the original signed informed consent form in the test subject's medical record.

(6) If a test subject or his or her legally authorized representative signs a copy of the model informed consent form developed and distributed under subsection (3), the test subject is barred from subsequently bringing a civil action for damages against the physician, or an individual to whom the physician delegated the authority to perform a selected act, task, or function under section 16215, who ordered the presymptomatic or predictive genetic test, based on failure to obtain informed consent for the presymptomatic or predictive genetic test.

(7) A physician's duty to inform a patient under this section does not require disclosure of information beyond what a reasonably well-qualified physician licensed under this article would know.

(8) Except as otherwise provided in subsection (9), as used in this section:

(a) "Genetic information" means information about a gene, gene product, or inherited characteristic which information is derived from a genetic test.

(b) "Genetic test" means the analysis of human DNA, RNA, chromosomes, and those proteins and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. A genetic test must be generally accepted in the scientific and medical communities as being specifically determinative for the presence, absence, or mutation of a gene or chromosome in order to qualify under this definition. Genetic test does not include a routine physical examination or a routine analysis, including, but not limited to, a chemical analysis, of body fluids, unless conducted specifically to determine the presence, absence, or mutation of a gene or chromosome.

(c) "Predictive genetic test" means a genetic test performed for the purpose of predicting the future probability that the test subject will develop a genetically related disease or disability.

(d) "Presymptomatic genetic test" means a genetic test performed before the onset of clinical symptoms or indications of disease.

(9) For purposes of subsection (8)(b), the term "genetic test" does not include a procedure performed as a component of biomedical research that is conducted pursuant to federal common rule under 21 C.F.R. parts 50 and 56 and 45 C.F.R. part 46.

Sec. 17520. (1) Except as otherwise provided for a test performed under section 5431 and except as otherwise provided by law, beginning upon the expiration of 6 months after the effective date of the amendatory act that added this section, a physician or an individual to whom the physician has delegated authority to perform a selected act, task, or function under section 16215 shall not order a presymptomatic or predictive genetic test without first obtaining the written, informed consent of the test subject, pursuant to this section.

(2) For purposes of subsection (1), written, informed consent consists of a signed writing executed by the test subject or the legally authorized representative of the test subject that confirms that the physician or the individual acting under the delegatory authority of the physician has explained, and the test subject or the legally authorized representative of the test subject understands, at a minimum, all of the following:

(a) The nature and purpose of the presymptomatic or predictive genetic test.

(b) The effectiveness and limitations of the presymptomatic or predictive genetic test.

(c) The implications of taking the presymptomatic or predictive genetic test, including, but not limited to, the medical risks and benefits.

(d) The future uses of the sample taken from the test subject in order to conduct the presymptomatic or predictive genetic test and the information obtained from the presymptomatic or predictive genetic test.

(e) The meaning of the presymptomatic or predictive genetic test results and the procedure for providing notice of the results to the test subject.

(f) Who will have access to the sample taken from the test subject in order to conduct the presymptomatic or predictive genetic test and the information obtained from the presymptomatic or predictive genetic test, and the test subject's right to confidential treatment of the sample and the information.

(3) Within 6 months after the effective date of the amendatory act that added this section, the department of community health, in consultation with the Michigan board of medicine, the Michigan board of osteopathic medicine and surgery, at least 1 physician who is board certified by the American board of medical genetics, and appropriate professional organizations, shall develop and distribute a model informed consent form for purposes of this section that practitioners may adopt. The department of community health shall include in the model form at least all of the information required under subsection (2). The department of community health shall distribute the model form to physicians and other individuals subject to this section upon request and at no charge. The department of community health shall review the model form at least annually for 5 years after the first model form is distributed, and shall revise the model form if necessary to make the form reflect the latest developments in medical genetics.

(4) The department of community health, in consultation with the entities described in subsection (3), may also develop and distribute a pamphlet that provides further explanation of the information included in the model informed consent form.

(5) If a test subject or his or her legally authorized representative signs a copy of the model informed consent form developed and distributed under subsection (3), the physician or individual acting under the delegatory authority of the physician shall give the test subject a copy of the signed informed consent form and shall include the original signed informed consent form in the test subject's medical record.

(6) If a test subject or his or her legally authorized representative signs a copy of the model informed consent form developed and distributed under subsection (3), the test subject is barred from subsequently bringing a civil action for damages against the physician, or an individual to whom the physician delegated the authority to perform a selected act, task, or function under section 16215, who ordered the presymptomatic or predictive genetic test, based on failure to obtain informed consent for the presymptomatic or predictive genetic test.

(7) A physician's duty to inform a patient under this section does not require disclosure of information beyond what a reasonably well-qualified physician licensed under this article would know.

(8) Except as otherwise provided in subsection (9), as used in this section:

(a) "Genetic information" means information about a gene, gene product, or inherited characteristic which information is derived from a genetic test.

(b) "Genetic test" means the analysis of human DNA, RNA, chromosomes, and those proteins and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. A genetic test must be generally accepted in the scientific and medical communities as being specifically determinative for the presence, absence, or mutation of a gene or chromosome in order to qualify under this definition. Genetic test does not include a routine physical examination or a routine analysis, including, but not limited to, a chemical analysis, of body fluids, unless conducted specifically to determine the presence, absence, or mutation of a gene or chromosome.

(c) "Predictive genetic test" means a genetic test performed for the purpose of predicting the future probability that the test subject will develop a genetically related disease or disability.

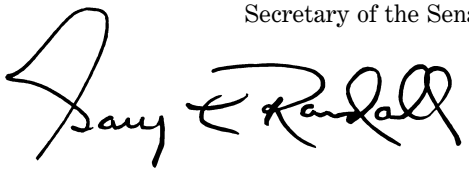
(d) "Presymptomatic genetic test" means a genetic test performed before the onset of clinical symptoms or indications of disease.

(9) For purposes of subsection (8)(b), the term "genetic test" does not include a procedure performed as a component of biomedical research that is conducted pursuant to federal common rule under 21 C.F.R. parts 50 and 56 and 45 C.F.R. part 46.

This act is ordered to take immediate effect.

Carol Morey Viventi

Secretary of the Senate.



Clerk of the House of Representatives.

Approved

Governor.