SUBSTITUTE FOR

SENATE BILL NO. 467

A bill to amend 1978 PA 368, entitled

"Public health code,"

by amending sections 16221, 17020, and 17520 (MCL 333.16221, 333.17020, and 333.17520), section 16221 as amended by 2004 PA 214 and sections 17020 and 17520 as added by 2000 PA 29, and by adding sections 17020a, 17520a, and 20170a.

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 that 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 520b to 520g of the Michigan penal code, 1931 PA 328, MCL 750.520b to 750.520g. 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.

(*xii*) Conviction of a violation of section 430 of the Michigan penal code, 1931 PA 328, MCL 750.430. 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*) Either of the following:

(A) A requirement by a licensee other than a physician that an individual 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.

(B) A referral by a physician for a designated health service that violates section 1877 of part D of title XVIII of the social security act, 42 USC 1395nn, or a regulation promulgated under that section. Section 1877 of part D of title XVIII of the social security act, 42 USC 1395nn, and the regulations promulgated under that section, as they exist on June 3, 2002, are incorporated by reference for purposes of this subparagraph. A disciplinary subcommittee shall apply section 1877 of part D of title XVIII of the social security act, 42 USC 1395nn, and the regulations promulgated under that section regardless of the source of payment for the designated health service referred and rendered. If section 1877 of part D of title XVIII of the social security act, 42 USC 1395nn, or a regulation promulgated under that section is revised after June 3, 2002, the department shall officially take notice of the revision. Within 30 days after taking notice of the revision, the department shall decide whether or not the revision pertains to referral by physicians for designated health services and continues to protect the public from inappropriate referrals by physicians. If the department decides that the revision does both of those things, the department may promulgate rules to incorporate the revision by reference. If the department does promulgate rules to incorporate the revision by reference, the department shall not make any changes to the revision. As used in this subparagraph, "designated health service" means that term as defined in section 1877 of part D of title XVIII of the social security act, 42 USC

1395nn, and the regulations promulgated under that section and "physician" means that term as defined in sections 17001 and 17501.

(*v*) For a physician who makes referrals pursuant to section 1877 of part D of title XVIII of the social security act, 42 USC 1395nn, or a regulation promulgated under that section, refusing to accept a reasonable proportion of patients eligible for medicaid and refusing to accept payment from medicaid or medicare as payment in full for a treatment, procedure, or service for which the physician refers the individual and in which the physician has a financial interest. A physician who owns all or part of a facility in which he or she provides surgical services is not subject to this subparagraph if a referred surgical procedure he or she performs in the facility is not reimbursed at a minimum of the appropriate medicaid or medicare outpatient fee schedule, including the combined technical and professional components.

(f) Beginning June 3, 2003, the department ~~of consumer and industry services~~ shall prepare the first of 3 annual reports on the effect of this amendatory act on access to care for the uninsured and medicaid patients. The department shall report on the number of referrals by licensees of uninsured and medicaid patients 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.

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

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

(i) 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.

(j) 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.

(k) A violation of section 17013 or 17513.

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

(m) A violation of section 17015 or 17515.

(n) A violation of section 17016 or 17516.

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

(p) A violation of section 5654 or 5655.

(q) A violation of section 16274.

(r) A violation of section 17020**,** ~~or~~ **17020A,** 17520**, OR 17520A**.

(s) A violation of the medical records access act**, 2004 PA 47, MCL 333.26261 TO 333.26271**.

(t) A violation of section 17764(2).

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~~ **SEPTEMBER 15, 2000**, 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~~ **BEFORE SEPTEMBER 15, 2000**, 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 **AND SECTION 17020A:**

(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.~~ **CFR** parts 50 and 56 and 45 ~~C.F.R.~~ **CFR** part 46.

SEC. 17020A. (1) THE FACT THAT A PRESYMPTOMATIC OR PREDICTIVE GENETIC TEST HAS BEEN ORDERED AND CONDUCTED UNDER SECTION 17020 AND THE RESULTS OF THAT TEST ARE PRIVILEGED AND CONFIDENTIAL. EXCEPT AS OTHERWISE PROVIDED BY LAW, A PERSON SHALL NOT DISCLOSE THAT A TEST HAS BEEN ORDERED OR CONDUCTED OR THE RESULTS OF THAT TEST FOR PURPOSES OTHER THAN TREATMENT, PAYMENT,

OR HEALTH CARE OPERATIONS AS PROVIDED UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996, PUBLIC LAW 104-191, AND REGULATIONS PROMULGATED UNDER THAT ACT, 45 CFR PARTS 160 AND 164, WITHOUT FIRST OBTAINING WRITTEN AUTHORIZATION FROM THE TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED REPRESENTATIVE AS PROVIDED UNDER THIS SECTION.

(2) FOR PURPOSES OF SUBSECTION (1), WRITTEN AUTHORIZATION SHALL BE ON A FORM THAT IDENTIFIES TO WHOM THE INFORMATION IS TO BE DISCLOSED AND INCLUDES THE FOLLOWING NOTICE:

NOTICE OF RIGHTS WITH REGARD TO GENETIC TESTING AND INFORMATION

MICHIGAN LAW RESTRICTS REQUESTS BY HEALTH INSURERS, NONPROFIT HEALTH CARE CORPORATIONS, HEALTH MAINTENANCE ORGANIZATIONS, AND EMPLOYERS FOR INDIVIDUALS TO SUBMIT TO GENETIC TESTING, TO DISCLOSE GENETIC INFORMATION, OR TO DISCLOSE WHETHER GENETIC TESTING HAS BEEN CONDUCTED OR THE RESULTS OF THAT GENETIC TESTING. INDIVIDUALS WHO HAVE QUESTIONS ABOUT THEIR RIGHTS MAY SEEK LEGAL ADVICE.

(3) FOR PURPOSES OF SUBSECTION (1), A GENERAL CONSENT OR AUTHORIZATION GIVEN FOR THE RELEASE OF MEDICAL RECORDS OR OTHER MEDICAL INFORMATION DOES NOT CONSTITUTE WRITTEN AUTHORIZATION FOR DISCLOSURE UNDER THIS SECTION. THE INFORMED CONSENT FORM REQUIRED UNDER SECTION 17020 FOR THE PERFORMANCE OF GENETIC TESTING SHALL SATISFY THE WRITTEN AUTHORIZATION REQUIREMENTS FOR DISCLOSURE UNDER THIS SECTION IF THAT INFORMED CONSENT FORM IDENTIFIES TO WHOM THE GENETIC INFORMATION IS BEING PROVIDED, INCLUDES THE

NOTICE DESCRIBED UNDER SUBSECTION (2), AND REQUIRES A SEPARATE SIGNATURE FOR DISCLOSURE THAN THE SIGNATURE REQUIRED FOR THE PERFORMANCE OF THE GENETIC TESTING. IF THE TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED REPRESENTATIVE PROVIDES WRITTEN AUTHORIZATION UNDER THIS SECTION, THE PERSON SHALL DO EACH OF THE FOLLOWING:

(A) PROVIDE THE TEST SUBJECT WITH A COPY OF THE SIGNED WRITTEN AUTHORIZATION.

(B) MAINTAIN THE ORIGINAL SIGNED WRITTEN AUTHORIZATION IN THE TEST SUBJECT'S MEDICAL RECORD.

(C) PROVIDE THE TEST SUBJECT AND THE PERSON TO WHOM THE INFORMATION IS BEING DISCLOSED WITH THE FOLLOWING NOTICE:

RESTRICTIONS ON FURTHER DISCLOSURE OF GENETIC TESTING AND INFORMATION

THIS INFORMATION IS PRIVILEGED AND CONFIDENTIAL. THIS INFORMATION IS BEING PROVIDED TO YOU IN ACCORDANCE WITH MICHIGAN LAW AND SHALL NOT BE FURTHER DISCLOSED WITHOUT A SEPARATE WRITTEN AUTHORIZATION FROM THE TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED REPRESENTATIVE. A GENERAL CONSENT OR AUTHORIZATION FOR THE RELEASE OF MEDICAL RECORDS OR OTHER INFORMATION IS NOT SUFFICIENT TO AUTHORIZE THE DISCLOSURE OF GENETIC TESTING AND INFORMATION.

(4) IF A TEST SUBJECT CONSENTS TO THE PERFORMANCE OF A GENETIC TEST FOR THE SOLE PURPOSE OF ASSISTING IN THE RECOVERY OR IDENTIFICATION OF HUMAN REMAINS FROM A DISASTER OR ASSISTING IN

THE IDENTIFICATION OF LIVING OR DECEASED MISSING PERSONS BY MATCHING FORENSIC DNA PROFILES IN THE EVENT OF AN EMERGENCY OR DISASTER, THOSE RESULTS AS WELL AS THE DNA PROFILES SHALL ONLY BE DISCLOSED AND USED FOR THOSE IDENTIFICATION PURPOSES, ARE NOT PUBLIC RECORDS, ARE NOT SUBJECT TO COURT SUBPOENA, AND ARE NOT DISCOVERABLE IN A LEGAL PROCEEDING. CONSENT PROVIDED FOR TESTING AND DNA PROFILING UNDER THIS SUBSECTION IS NOT CONSENT FOR SECONDARY RESEARCH UTILIZING THOSE RESULTS OR DNA PROFILES OR ANY OTHER USE EXCEPT FOR THE IDENTIFICATION OF LIVING OR DECEASED MISSING PERSONS.

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~~ **SEPTEMBER 15, 2000**, 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~~ **BEFORE SEPTEMBER 15, 2000**, 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 **AND SECTION 17520A**:

(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.~~ **CFR** parts 50 and 56 and 45 ~~C.F.R.~~ **CFR** part 46.

SEC. 17520A. (1) THE FACT THAT A PRESYMPTOMATIC OR PREDICTIVE GENETIC TEST HAS BEEN ORDERED AND CONDUCTED UNDER SECTION 17520 AND THE RESULTS OF THAT TEST ARE PRIVILEGED AND CONFIDENTIAL. EXCEPT AS OTHERWISE PROVIDED BY LAW, A PERSON SHALL NOT DISCLOSE THAT A TEST HAS BEEN ORDERED OR CONDUCTED OR THE RESULTS OF THAT TEST FOR PURPOSES OTHER THAN TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS AS PROVIDED UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996, PUBLIC LAW 104-191, AND REGULATIONS PROMULGATED UNDER THAT ACT, 45 CFR PARTS 160 AND 164, WITHOUT FIRST OBTAINING WRITTEN AUTHORIZATION FROM THE TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED REPRESENTATIVE AS PROVIDED UNDER THIS SECTION.

(2) FOR PURPOSES OF SUBSECTION (1), WRITTEN AUTHORIZATION SHALL BE ON A FORM THAT IDENTIFIES TO WHOM THE INFORMATION IS TO BE DISCLOSED AND INCLUDES THE FOLLOWING NOTICE:

NOTICE OF RIGHTS WITH REGARD TO
GENETIC TESTING AND INFORMATION

MICHIGAN LAW RESTRICTS REQUESTS BY HEALTH INSURERS, NONPROFIT HEALTH CARE CORPORATIONS, HEALTH MAINTENANCE ORGANIZATIONS, AND

EMPLOYERS FOR INDIVIDUALS TO SUBMIT TO GENETIC TESTING, TO DISCLOSE GENETIC INFORMATION, OR TO DISCLOSE WHETHER GENETIC TESTING HAS BEEN CONDUCTED OR THE RESULTS OF THAT GENETIC TESTING. INDIVIDUALS WHO HAVE QUESTIONS ABOUT THEIR RIGHTS MAY SEEK LEGAL ADVICE.

(3) FOR PURPOSES OF SUBSECTION (1), A GENERAL CONSENT OR AUTHORIZATION GIVEN FOR THE RELEASE OF MEDICAL RECORDS OR OTHER MEDICAL INFORMATION DOES NOT CONSTITUTE WRITTEN AUTHORIZATION FOR DISCLOSURE UNDER THIS SECTION. THE INFORMED CONSENT FORM REQUIRED UNDER SECTION 17020 FOR THE PERFORMANCE OF GENETIC TESTING SHALL SATISFY THE WRITTEN AUTHORIZATION REQUIREMENTS FOR DISCLOSURE UNDER THIS SECTION IF THAT INFORMED CONSENT FORM IDENTIFIES TO WHOM THE GENETIC INFORMATION IS BEING PROVIDED, INCLUDES THE NOTICE DESCRIBED UNDER SUBSECTION (2), AND REQUIRES A SEPARATE SIGNATURE FOR DISCLOSURE THAN THE SIGNATURE REQUIRED FOR THE PERFORMANCE OF THE GENETIC TESTING. IF THE TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED REPRESENTATIVE PROVIDES WRITTEN AUTHORIZATION UNDER THIS SECTION, THE PERSON SHALL DO EACH OF THE FOLLOWING:

(A) PROVIDE THE TEST SUBJECT WITH A COPY OF THE SIGNED WRITTEN AUTHORIZATION.

(B) MAINTAIN THE ORIGINAL SIGNED WRITTEN AUTHORIZATION IN THE TEST SUBJECT'S MEDICAL RECORD.

(C) PROVIDE THE TEST SUBJECT AND THE PERSON TO WHOM THE INFORMATION IS BEING DISCLOSED WITH THE FOLLOWING NOTICE:

RESTRICTIONS ON FURTHER DISCLOSURE OF

GENETIC TESTING AND INFORMATION

THIS INFORMATION IS PRIVILEGED AND CONFIDENTIAL. THIS INFORMATION IS BEING PROVIDED TO YOU IN ACCORDANCE WITH MICHIGAN LAW AND SHALL NOT BE FURTHER DISCLOSED WITHOUT A SEPARATE WRITTEN AUTHORIZATION FROM THE TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED REPRESENTATIVE. A GENERAL CONSENT OR AUTHORIZATION FOR THE RELEASE OF MEDICAL RECORDS OR OTHER INFORMATION IS NOT SUFFICIENT TO AUTHORIZE THE DISCLOSURE OF GENETIC TESTING AND INFORMATION.

(4) IF A TEST SUBJECT CONSENTS TO THE PERFORMANCE OF A GENETIC TEST FOR THE SOLE PURPOSE OF ASSISTING IN THE RECOVERY OR IDENTIFICATION OF HUMAN REMAINS FROM A DISASTER OR ASSISTING IN THE IDENTIFICATION OF LIVING OR DECEASED MISSING PERSONS BY MATCHING DNA PROFILES IN THE EVENT OF AN EMERGENCY OR DISASTER, THOSE RESULTS AS WELL AS THE DNA PROFILES SHALL ONLY BE DISCLOSED AND USED FOR THOSE IDENTIFICATION PURPOSES, ARE NOT PUBLIC RECORDS, ARE NOT SUBJECT TO COURT SUBPOENA, AND ARE NOT DISCOVERABLE IN A LEGAL PROCEEDING. CONSENT PROVIDED FOR TESTING AND DNA PROFILING UNDER THIS SUBSECTION IS NOT CONSENT FOR SECONDARY RESEARCH UTILIZING THOSE RESULTS OR DNA PROFILES OR ANY OTHER USE EXCEPT FOR THE IDENTIFICATION OF LIVING OR DECEASED MISSING PERSONS.

SEC. 20170A. (1) ALL REPORTS, RECORDS, AND DATA PERTAINING TO GENETIC TESTING OR OTHER GENETIC INFORMATION ARE PRIVILEGED AND CONFIDENTIAL. EXCEPT AS OTHERWISE PROVIDED BY LAW, A HEALTH FACILITY OR AGENCY SHALL NOT DISCLOSE THE TEST RESULTS OF A

PRESYMPTOMATIC OR PREDICTIVE GENETIC TEST OR THE FACT THAT SUCH A TEST WAS ORDERED FOR PURPOSES OTHER THAN TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS AS PROVIDED UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996, PUBLIC LAW 104-191, AND REGULATIONS PROMULGATED UNDER THAT ACT, 45 CFR PARTS 160 AND 164, WITHOUT FIRST OBTAINING WRITTEN AUTHORIZATION FROM THE TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED REPRESENTATIVE AS REQUIRED UNDER SECTION 17020A OR 17520A.

(2) IF THE TEST SUBJECT OR THE LEGALLY AUTHORIZED REPRESENTATIVE AGREES TO THE DISCLOSURE OF INFORMATION RELATING TO HIS OR HER GENETICS OR THE PRESYMPTOMATIC OR PREDICTIVE GENETIC TESTING, OR BOTH, HE OR SHE SHALL PROVIDE THE HEALTH FACILITY OR AGENCY WITH THE REQUISITE WRITTEN AUTHORIZATION.

(3) IF THE TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED REPRESENTATIVE PROVIDES WRITTEN AUTHORIZATION FOR DISCLOSURE UNDER THIS SECTION, THE HEALTH FACILITY OR AGENCY SHALL DO EACH OF THE FOLLOWING:

(A) PROVIDE THE TEST SUBJECT WITH A COPY OF THE SIGNED WRITTEN AUTHORIZATION.

(B) MAINTAIN THE ORIGINAL SIGNED WRITTEN AUTHORIZATION IN THE TEST SUBJECT'S MEDICAL RECORD.

(C) PROVIDE THE TEST SUBJECT AND THE PERSON TO WHOM THE INFORMATION IS BEING DISCLOSED WITH THE FOLLOWING NOTICE:

RESTRICTIONS ON FURTHER DISCLOSURE OF GENETIC TESTING AND INFORMATION

THIS INFORMATION IS PRIVILEGED AND CONFIDENTIAL. THIS INFORMATION

IS BEING PROVIDED TO YOU IN ACCORDANCE WITH MICHIGAN LAW AND SHALL NOT BE FURTHER DISCLOSED WITHOUT A SEPARATE WRITTEN AUTHORIZATION FROM THE TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED REPRESENTATIVE. A GENERAL CONSENT OR AUTHORIZATION FOR THE RELEASE OF MEDICAL RECORDS OR OTHER INFORMATION IS NOT SUFFICIENT TO AUTHORIZE THE DISCLOSURE OF GENETIC TESTING AND INFORMATION.

(4) IF A TEST SUBJECT CONSENTS TO THE PERFORMANCE OF A GENETIC TEST FOR THE SOLE PURPOSE OF ASSISTING IN THE RECOVERY OR IDENTIFICATION OF HUMAN REMAINS FROM A DISASTER OR ASSISTING IN THE IDENTIFICATION OF LIVING OR DECEASED MISSING PERSONS BY MATCHING DNA PROFILES IN THE EVENT OF AN EMERGENCY OR DISASTER, THOSE RESULTS AS WELL AS THE DNA PROFILES SHALL ONLY BE DISCLOSED AND USED FOR THOSE IDENTIFICATION PURPOSES, ARE NOT PUBLIC RECORDS, ARE NOT SUBJECT TO COURT SUBPOENA, AND ARE NOT DISCOVERABLE IN A LEGAL PROCEEDING. CONSENT PROVIDED FOR TESTING AND DNA PROFILING UNDER THIS SUBSECTION IS NOT CONSENT FOR SECONDARY RESEARCH UTILIZING THOSE RESULTS OR DNA PROFILES OR ANY OTHER USE EXCEPT FOR THE IDENTIFICATION OF LIVING OR DECEASED MISSING PERSONS.

(5) EXCEPT AS OTHERWISE PROVIDED IN SUBSECTION (6), 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.

(6) FOR PURPOSES OF SUBSECTION (5)(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 CFR PARTS 50 AND 56 AND 45 CFR PART 46.