

# SENATE BILL No. 467

May 5, 2005, Introduced by Senators GEORGE, SWITALSKI, CHERRY, OLSHOVE, JACOBS, HAMMERSTROM, GILBERT, CROSEY, PATTERSON, PRUSI, BRATER, BARCIA, SCHAUER and STAMAS and referred to the Committee on Health Policy.

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:**

1           Sec. 16221. The department may investigate activities related  
2 to the practice of a health profession by a licensee, a registrant,  
3 or an applicant for licensure or registration. The department may  
4 hold hearings, administer oaths, and order relevant testimony to be  
5 taken and shall report its findings to the appropriate disciplinary  
6 subcommittee. The disciplinary subcommittee shall proceed under

1 section 16226 if it finds that 1 or more of the following grounds  
2 exist:

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

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

11 (i) Incompetence.

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

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

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

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

24 (vi) Lack of good moral character.

25 (vii) Conviction of a criminal offense under sections 520b to  
26 520g of the Michigan penal code, 1931 PA 328, MCL 750.520b to  
27 750.520g. A certified copy of the court record is conclusive

1 evidence of the conviction.

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

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

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

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

20 (xii) Conviction of a violation of section 430 of the Michigan  
21 penal code, 1931 PA 328, MCL 750.430. A certified copy of the court  
22 record is conclusive evidence of the conviction.

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

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

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

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

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

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

9           (i) False or misleading advertising.

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

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

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

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

20           (ii) Betrayal of a professional confidence.

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

23           (iv) Either of the following:

24           (A) A requirement by a licensee other than a physician that an  
25 individual purchase or secure a drug, device, treatment, procedure,  
26 or service from another person, place, facility, or business in  
27 which the licensee has a financial interest.

1 (B) A referral by a physician for a designated health service  
2 that violates section 1877 of part D of title XVIII of the social  
3 security act, 42 USC 1395nn, or a regulation promulgated under that  
4 section. Section 1877 of part D of title XVIII of the social  
5 security act, 42 USC 1395nn, and the regulations promulgated under  
6 that section, as they exist on June 3, 2002, are incorporated by  
7 reference for purposes of this subparagraph. A disciplinary  
8 subcommittee shall apply section 1877 of part D of title XVIII of  
9 the social security act, 42 USC 1395nn, and the regulations  
10 promulgated under that section regardless of the source of payment  
11 for the designated health service referred and rendered. If section  
12 1877 of part D of title XVIII of the social security act, 42 USC  
13 1395nn, or a regulation promulgated under that section is revised  
14 after June 3, 2002, the department shall officially take notice of  
15 the revision. Within 30 days after taking notice of the revision,  
16 the department shall decide whether or not the revision pertains to  
17 referral by physicians for designated health services and continues  
18 to protect the public from inappropriate referrals by physicians.  
19 If the department decides that the revision does both of those  
20 things, the department may promulgate rules to incorporate the  
21 revision by reference. If the department does promulgate rules to  
22 incorporate the revision by reference, the department shall not  
23 make any changes to the revision. As used in this subparagraph,  
24 "designated health service" means that term as defined in section  
25 1877 of part D of title XVIII of the social security act, 42 USC  
26 1395nn, and the regulations promulgated under that section and  
27 "physician" means that term as defined in sections 17001 and 17501.

1           (v) For a physician who makes referrals pursuant to section  
2 1877 of part D of title XVIII of the social security act, 42 USC  
3 1395nn, or a regulation promulgated under that section, refusing to  
4 accept a reasonable proportion of patients eligible for medicaid  
5 and refusing to accept payment from medicaid or medicare as payment  
6 in full for a treatment, procedure, or service for which the  
7 physician refers the individual and in which the physician has a  
8 financial interest. A physician who owns all or part of a facility  
9 in which he or she provides surgical services is not subject to  
10 this subparagraph if a referred surgical procedure he or she  
11 performs in the facility is not reimbursed at a minimum of the  
12 appropriate medicaid or medicare outpatient fee schedule, including  
13 the combined technical and professional components.

14           (f) Beginning June 3, 2003, the department ~~of consumer and~~  
15 ~~industry services~~ shall prepare the first of 3 annual reports on  
16 the effect of this amendatory act on access to care for the  
17 uninsured and medicaid patients. The department shall report on the  
18 number of referrals by licensees of uninsured and medicaid patients  
19 to purchase or secure a drug, device, treatment, procedure, or  
20 service from another person, place, facility, or business in which  
21 the licensee has a financial interest.

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

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

26           (i) Failure to comply with a subpoena issued pursuant to this  
27 part, failure to respond to a complaint issued under this article

1 or article 7, failure to appear at a compliance conference or an  
2 administrative hearing, or failure to report under section 16222 or  
3 16223.

4 (j) Failure to pay an installment of an assessment levied  
5 pursuant to the insurance code of 1956, 1956 PA 218, MCL 500.100 to  
6 500.8302, within 60 days after notice by the appropriate board.

7 (k) A violation of section 17013 or 17513.

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

10 (m) A violation of section 17015 or 17515.

11 (n) A violation of section 17016 or 17516.

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

13 (p) A violation of section 5654 or 5655.

14 (q) A violation of section 16274.

15 (r) A violation of section 17020, ~~or~~ **17020A**, 17520, **OR**  
16 **17520A**.

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

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

20 Sec. 17020. (1) Except as otherwise provided for a test  
21 performed under section 5431 and except as otherwise provided by  
22 law, beginning ~~upon the expiration of 6 months after the effective~~  
23 ~~date of the amendatory act that added this section~~ **SEPTEMBER 15,**  
24 **2000**, a physician or an individual to whom the physician has  
25 delegated authority to perform a selected act, task, or function  
26 under section 16215 shall not order a presymptomatic or predictive  
27 genetic test without first obtaining the written, informed consent

1 of the test subject, pursuant to this section.

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

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

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

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

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

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

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

1           (3) ~~Within 6 months after the effective date of the~~  
2 ~~amendatory act that added this section~~ **BEFORE SEPTEMBER 15, 2000,**  
3 the department of community health, in consultation with the  
4 Michigan board of medicine, the Michigan board of osteopathic  
5 medicine and surgery, at least 1 physician who is board certified  
6 by the American board of medical genetics, and appropriate  
7 professional organizations, shall develop and distribute a model  
8 informed consent form for purposes of this section that  
9 practitioners may adopt. The department of community health shall  
10 include in the model form at least all of the information required  
11 under subsection (2). The department of community health shall  
12 distribute the model form to physicians and other individuals  
13 subject to this section upon request and at no charge. The  
14 department of community health shall review the model form at least  
15 annually for 5 years after the first model form is distributed, and  
16 shall revise the model form if necessary to make the form reflect  
17 the latest developments in medical genetics.

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

22           (5) If a test subject or his or her legally authorized  
23 representative signs a copy of the model informed consent form  
24 developed and distributed under subsection (3), the physician or  
25 individual acting under the delegatory authority of the physician  
26 shall give the test subject a copy of the signed informed consent  
27 form and shall include the original signed informed consent form in

1 the test subject's medical record.

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

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

14 (8) Except as otherwise provided in subsection (9), as used in  
15 this section **AND SECTION 17020A:**

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

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

1 body fluids, unless conducted specifically to determine the  
2 presence, absence, or mutation of a gene or chromosome.

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

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

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

13 **SEC. 17020A. (1) THE FACT THAT A PRESYMPTOMATIC OR PREDICTIVE**  
14 **GENETIC TEST HAS BEEN ORDERED AND CONDUCTED UNDER SECTION 17020 AND**  
15 **THE RESULTS OF THAT TEST ARE PRIVILEGED AND CONFIDENTIAL. EXCEPT AS**  
16 **OTHERWISE PROVIDED BY LAW, A PERSON SHALL NOT DISCLOSE THAT A TEST**  
17 **HAS BEEN ORDERED OR CONDUCTED OR THE RESULTS OF THAT TEST WITHOUT**  
18 **FIRST OBTAINING WRITTEN AUTHORIZATION FROM THE TEST SUBJECT OR HIS**  
19 **OR HER LEGALLY AUTHORIZED REPRESENTATIVE AS PROVIDED UNDER THIS**  
20 **SECTION.**

21 (2) FOR PURPOSES OF SUBSECTION (1), WRITTEN AUTHORIZATION  
22 SHALL BE ON A FORM THAT IS SEPARATE FROM ANY OTHER WRITTEN,  
23 INFORMED CONSENT FORM REQUIRED UNDER SECTION 17020, SHALL IDENTIFY  
24 TO WHOM THE INFORMATION IS TO BE DISCLOSED, AND SHALL INCLUDE THE  
25 FOLLOWING NOTICE:

26 NOTICE OF RIGHTS WITH REGARD TO  
27 GENETIC TESTING AND INFORMATION  
28 MICHIGAN LAW RESTRICTS REQUESTS BY HEALTH INSURERS, NONPROFIT

1 HEALTH CARE CORPORATIONS, HEALTH MAINTENANCE ORGANIZATIONS, AND  
2 EMPLOYERS FOR INDIVIDUALS TO SUBMIT TO GENETIC TESTING, TO DISCLOSE  
3 GENETIC INFORMATION, OR TO DISCLOSE WHETHER GENETIC TESTING HAS  
4 BEEN CONDUCTED OR THE RESULTS OF THAT GENETIC TESTING. INDIVIDUALS  
5 WHO HAVE QUESTIONS ABOUT THEIR RIGHTS MAY SEEK LEGAL ADVICE.

6 (3) FOR PURPOSES OF SUBSECTION (1), A GENERAL CONSENT OR  
7 AUTHORIZATION GIVEN FOR THE RELEASE OF MEDICAL RECORDS OR OTHER  
8 INFORMATION DOES NOT CONSTITUTE WRITTEN AUTHORIZATION FOR  
9 DISCLOSURE UNDER THIS SECTION. A SEPARATE WRITTEN AUTHORIZATION  
10 SHALL BE OBTAINED FOR EACH PERSON TO WHOM THE INFORMATION IS TO BE  
11 DISCLOSED. IF THE TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED  
12 REPRESENTATIVE PROVIDES WRITTEN AUTHORIZATION UNDER THIS SECTION,  
13 THE PERSON SHALL DO EACH OF THE FOLLOWING:

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

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

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

20 RESTRICTIONS ON FURTHER DISCLOSURE OF  
21 GENETIC TESTING AND INFORMATION  
22 THIS INFORMATION IS PRIVILEGED AND CONFIDENTIAL. THIS INFORMATION  
23 IS BEING PROVIDED TO YOU IN ACCORDANCE WITH MICHIGAN LAW AND SHALL  
24 NOT BE FURTHER DISCLOSED WITHOUT A SEPARATE WRITTEN AUTHORIZATION  
25 FROM THE TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED  
26 REPRESENTATIVE. A GENERAL CONSENT OR AUTHORIZATION FOR THE RELEASE

1 OF MEDICAL RECORDS OR OTHER INFORMATION IS NOT SUFFICIENT TO  
2 AUTHORIZE THE DISCLOSURE OF GENETIC TESTING AND INFORMATION.

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

15 Sec. 17520. (1) Except as otherwise provided for a test  
16 performed under section 5431 and except as otherwise provided by  
17 law, beginning ~~upon the expiration of 6 months after the effective~~  
18 ~~date of the amendatory act that added this section~~ **SEPTEMBER 15,**  
19 **2000,** a physician or an individual to whom the physician has  
20 delegated authority to perform a selected act, task, or function  
21 under section 16215 shall not order a presymptomatic or predictive  
22 genetic test without first obtaining the written, informed consent  
23 of the test subject, pursuant to this section.

24 (2) For purposes of subsection (1), written, informed consent  
25 consists of a signed writing executed by the test subject or the  
26 legally authorized representative of the test subject that confirms  
27 that the physician or the individual acting under the delegatory

1 authority of the physician has explained, and the test subject or  
2 the legally authorized representative of the test subject  
3 understands, at a minimum, all of the following:

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

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

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

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

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

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

23 (3) ~~Within 6 months after the effective date of the~~  
24 ~~amendatory act that added this section~~ **BEFORE SEPTEMBER 15, 2000,**  
25 the department of community health, in consultation with the  
26 Michigan board of medicine, the Michigan board of osteopathic  
27 medicine and surgery, at least 1 physician who is board certified

1 by the American board of medical genetics, and appropriate  
2 professional organizations, shall develop and distribute a model  
3 informed consent form for purposes of this section that  
4 practitioners may adopt. The department of community health shall  
5 include in the model form at least all of the information required  
6 under subsection (2). The department of community health shall  
7 distribute the model form to physicians and other individuals  
8 subject to this section upon request and at no charge. The  
9 department of community health shall review the model form at least  
10 annually for 5 years after the first model form is distributed, and  
11 shall revise the model form if necessary to make the form reflect  
12 the latest developments in medical genetics.

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

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

24 (6) If a test subject or his or her legally authorized  
25 representative signs a copy of the model informed consent form  
26 developed and distributed under subsection (3), the test subject is  
27 barred from subsequently bringing a civil action for damages

1 against the physician, or an individual to whom the physician  
2 delegated the authority to perform a selected act, task, or  
3 function under section 16215, who ordered the presymptomatic or  
4 predictive genetic test, based on failure to obtain informed  
5 consent for the presymptomatic or predictive genetic test.

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

9 (8) Except as otherwise provided in subsection (9), as used in  
10 this section **AND SECTION 17520A:**

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

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

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

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

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

8 **SEC. 17520A. (1) THE FACT THAT A PRESYMPTOMATIC OR PREDICTIVE**  
9 **GENETIC TEST HAS BEEN ORDERED AND CONDUCTED UNDER SECTION 17520 AND**  
10 **THE RESULTS OF THAT TEST ARE PRIVILEGED AND CONFIDENTIAL. EXCEPT AS**  
11 **OTHERWISE PROVIDED BY LAW, A PERSON SHALL NOT DISCLOSE THAT A TEST**  
12 **HAS BEEN ORDERED OR CONDUCTED OR THE RESULTS OF THAT TEST WITHOUT**  
13 **FIRST OBTAINING WRITTEN AUTHORIZATION FROM THE TEST SUBJECT OR HIS**  
14 **OR HER LEGALLY AUTHORIZED REPRESENTATIVE AS PROVIDED UNDER THIS**  
15 **SECTION.**

16 (2) FOR PURPOSES OF SUBSECTION (1), WRITTEN AUTHORIZATION  
17 SHALL BE ON A FORM THAT IS SEPARATE FROM ANY OTHER WRITTEN,  
18 INFORMED CONSENT FORM REQUIRED UNDER SECTION 17520, SHALL IDENTIFY  
19 TO WHOM THE INFORMATION IS TO BE DISCLOSED, AND SHALL INCLUDE THE  
20 FOLLOWING NOTICE:

21 **NOTICE OF RIGHTS WITH REGARD TO**  
22 **GENETIC TESTING AND INFORMATION**  
23 **MICHIGAN LAW RESTRICTS REQUESTS BY HEALTH INSURERS, NONPROFIT**  
24 **HEALTH CARE CORPORATIONS, HEALTH MAINTENANCE ORGANIZATIONS, AND**  
25 **EMPLOYERS FOR INDIVIDUALS TO SUBMIT TO GENETIC TESTING, TO DISCLOSE**  
26 **GENETIC INFORMATION, OR TO DISCLOSE WHETHER GENETIC TESTING HAS**  
27 **BEEN CONDUCTED OR THE RESULTS OF THAT GENETIC TESTING. INDIVIDUALS**

1 WHO HAVE QUESTIONS ABOUT THEIR RIGHTS MAY SEEK LEGAL ADVICE.

2 (3) FOR PURPOSES OF SUBSECTION (1), A GENERAL CONSENT OR  
3 AUTHORIZATION GIVEN FOR THE RELEASE OF MEDICAL RECORDS OR OTHER  
4 INFORMATION DOES NOT CONSTITUTE WRITTEN AUTHORIZATION FOR  
5 DISCLOSURE UNDER THIS SECTION. A SEPARATE WRITTEN AUTHORIZATION  
6 SHALL BE OBTAINED FOR EACH PERSON TO WHOM THE INFORMATION IS TO BE  
7 DISCLOSED. IF THE TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED  
8 REPRESENTATIVE PROVIDES WRITTEN AUTHORIZATION UNDER THIS SECTION,  
9 THE PERSON SHALL DO EACH OF THE FOLLOWING:

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

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

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

16 RESTRICTIONS ON FURTHER DISCLOSURE OF

17 GENETIC TESTING AND INFORMATION

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

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

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

10 SEC. 20170A. (1) ALL REPORTS, RECORDS, AND DATA PERTAINING TO  
11 GENETIC TESTING OR OTHER GENETIC INFORMATION ARE PRIVILEGED AND  
12 CONFIDENTIAL. EXCEPT AS OTHERWISE PROVIDED BY LAW, A HEALTH  
13 FACILITY OR AGENCY SHALL NOT DISCLOSE TO ANYONE, OTHER THAN THE  
14 PHYSICIAN OR THE INDIVIDUAL TO WHOM THE PHYSICIAN DELEGATED  
15 AUTHORITY UNDER SECTION 16215, THE TEST RESULTS OF A PRESYMPTOMATIC  
16 OR PREDICTIVE GENETIC TEST OR THE FACT THAT SUCH A TEST WAS ORDERED  
17 WITHOUT FIRST OBTAINING WRITTEN AUTHORIZATION FROM THE TEST SUBJECT  
18 OR HIS OR HER LEGALLY AUTHORIZED REPRESENTATIVE AS REQUIRED UNDER  
19 SECTION 17020A OR 17520A.

20 (2) IF THE TEST SUBJECT OR THE LEGALLY AUTHORIZED  
21 REPRESENTATIVE AGREES TO THE DISCLOSURE OF INFORMATION RELATING TO  
22 HIS OR HER GENETICS OR THE PRESYMPTOMATIC OR PREDICTIVE GENETIC  
23 TESTING, OR BOTH, TO SOMEONE OTHER THAN THE PHYSICIAN OR THE  
24 INDIVIDUAL TO WHOM THE PHYSICIAN DELEGATED THE AUTHORITY TO ORDER  
25 SUCH TESTING, HE OR SHE SHALL PROVIDE THE HEALTH FACILITY OR AGENCY  
26 WITH THE REQUISITE WRITTEN AUTHORIZATION.

27 (3) IF THE TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED

1 REPRESENTATIVE PROVIDES WRITTEN AUTHORIZATION FOR DISCLOSURE UNDER  
2 THIS SECTION, THE HEALTH FACILITY OR AGENCY SHALL DO EACH OF THE  
3 FOLLOWING:

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

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

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

10 RESTRICTIONS ON FURTHER DISCLOSURE OF  
11 GENETIC TESTING AND INFORMATION

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

19 (4) IF A TEST SUBJECT CONSENTS TO THE PERFORMANCE OF A GENETIC  
20 TEST FOR THE SOLE PURPOSE OF ASSISTING IN THE RECOVERY OR  
21 IDENTIFICATION OF HUMAN REMAINS FROM A DISASTER OR ASSISTING IN THE  
22 IDENTIFICATION OF LIVING OR DECEASED MISSING PERSONS BY MATCHING  
23 DNA PROFILES IN THE EVENT OF AN EMERGENCY OR DISASTER, THOSE  
24 RESULTS AS WELL AS THE DNA PROFILES SHALL ONLY BE DISCLOSED AND  
25 USED FOR THOSE IDENTIFICATION PURPOSES, ARE NOT PUBLIC RECORDS, ARE  
26 NOT SUBJECT TO COURT SUBPOENA, AND ARE NOT DISCOVERABLE IN A LEGAL  
27 PROCEEDING. CONSENT PROVIDED FOR TESTING AND DNA PROFILING UNDER

1 THIS SUBSECTION IS NOT CONSENT FOR SECONDARY RESEARCH UTILIZING  
2 THOSE RESULTS OR DNA PROFILES OR ANY OTHER USE EXCEPT FOR THE  
3 IDENTIFICATION OF LIVING OR DECEASED MISSING PERSONS.

4 (5) EXCEPT AS OTHERWISE PROVIDED IN SUBSECTION (6), AS USED IN  
5 THIS SECTION:

6 (A) "GENETIC INFORMATION" MEANS INFORMATION ABOUT A GENE, GENE  
7 PRODUCT, OR INHERITED CHARACTERISTIC WHICH INFORMATION IS DERIVED  
8 FROM A GENETIC TEST.

9 (B) "GENETIC TEST" MEANS THE ANALYSIS OF HUMAN DNA, RNA,  
10 CHROMOSOMES, AND THOSE PROTEINS AND METABOLITES USED TO DETECT  
11 HERITABLE OR SOMATIC DISEASE-RELATED GENOTYPES OR KARYOTYPES FOR  
12 CLINICAL PURPOSES. A GENETIC TEST MUST BE GENERALLY ACCEPTED IN THE  
13 SCIENTIFIC AND MEDICAL COMMUNITIES AS BEING SPECIFICALLY  
14 DETERMINATIVE FOR THE PRESENCE, ABSENCE, OR MUTATION OF A GENE OR  
15 CHROMOSOME IN ORDER TO QUALIFY UNDER THIS DEFINITION. GENETIC TEST  
16 DOES NOT INCLUDE A ROUTINE PHYSICAL EXAMINATION OR A ROUTINE  
17 ANALYSIS, INCLUDING, BUT NOT LIMITED TO, A CHEMICAL ANALYSIS, OF  
18 BODY FLUIDS, UNLESS CONDUCTED SPECIFICALLY TO DETERMINE THE  
19 PRESENCE, ABSENCE, OR MUTATION OF A GENE OR CHROMOSOME.

20 (C) "PREDICTIVE GENETIC TEST" MEANS A GENETIC TEST PERFORMED  
21 FOR THE PURPOSE OF PREDICTING THE FUTURE PROBABILITY THAT THE TEST  
22 SUBJECT WILL DEVELOP A GENETICALLY RELATED DISEASE OR DISABILITY.

23 (D) "PRESYMPTOMATIC GENETIC TEST" MEANS A GENETIC TEST  
24 PERFORMED BEFORE THE ONSET OF CLINICAL SYMPTOMS OR INDICATIONS OF  
25 DISEASE.

26 (6) FOR PURPOSES OF SUBSECTION (5) (B), THE TERM "GENETIC TEST"  
27 DOES NOT INCLUDE A PROCEDURE PERFORMED AS A COMPONENT OF BIOMEDICAL

1 RESEARCH THAT IS CONDUCTED PURSUANT TO FEDERAL COMMON RULE UNDER 21  
2 CFR PARTS 50 AND 56 AND 45 CFR PART 46.