

PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

333.17520 Genetic test; informed consent.

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.

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