

**HOUSE SUBSTITUTE FOR
SENATE BILL NO. 593**

A bill to amend 1978 PA 368, entitled "Public health code," 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:

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

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

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

9 (i) Incompetence.

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

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

15 (iv) Declaration of mental incompetence by a court of compe-
16 tent jurisdiction.

17 (v) Conviction of a misdemeanor punishable by imprisonment
18 for a maximum term of 2 years; a misdemeanor involving the ille-
19 gal delivery, possession, or use of a controlled substance; or a
20 felony. A certified copy of the court record is conclusive evi-
21 dence of the conviction.

22 (vi) Lack of good moral character.

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

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

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

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

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

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

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

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

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

26 (iv) Obtaining, possessing, or attempting to obtain or
27 possess a controlled substance as defined in section 7104 or a

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1 drug as defined in section 7105 without lawful authority; or
2 selling, prescribing, giving away, or administering drugs for
3 other than lawful diagnostic or therapeutic purposes.

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

6 (i) False or misleading advertising.

7 (ii) Dividing fees for referral of patients or accepting
8 kickbacks on medical or surgical services, appliances, or medica-
9 tions purchased by or in behalf of patients.

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

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

14 (i) Misrepresentation to a consumer or patient or in obtain-
15 ing or attempting to obtain third party reimbursement in the
16 course of professional practice.

17 (ii) Betrayal of a professional confidence.

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

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

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

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

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1 (h) Failure to comply with a subpoena issued pursuant to
2 this part, failure to respond to a complaint issued under this
3 article or article 7, failure to appear at a compliance confer-
4 ence or an administrative hearing, or failure to report under
5 section 16222 or 16223.

6 (i) Failure to pay an installment of an assessment levied
7 pursuant to ~~section 2504 of~~ the insurance code of 1956, 1956 PA
8 218, MCL ~~500.2504~~ 500.100 TO 500.8302, within 60 days after
9 notice by the appropriate board.

10 (j) A violation of section 17013 or 17513.

11 (k) Failure to meet 1 or more of the requirements for licen-
12 sure or registration under section 16174.

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

14 (m) A violation of section 17016 or 17516.

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

16 (o) A violation of section 5654 or 5655.

17 (p) A violation of section 16274.

18 (Q) A VIOLATION OF SECTION 17020 OR 17520.

19 Sec. 16226. (1) After finding the existence of 1 or more of
20 the grounds for disciplinary subcommittee action listed in sec-
21 tion 16221, a disciplinary subcommittee shall impose 1 or more of
22 the following sanctions for each violation:

23

24 Violations of Section 16221

Sanctions

25 Subdivision (a), (b)(ii), Probation, limitation, denial,
26 (b)(iv), (b)(vi), or suspension, revocation,

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1 (b)(vii) restitution, community service,
2 or fine.
3 Subdivision (b)(viii) Revocation or denial.
4 Subdivision (b)(i), Limitation, suspension,
5 (b)(iii), (b)(v), revocation, denial,
6 (b)(ix), probation, restitution,
7 (b)(x), or (b)(xi) community service, or fine.
8 Subdivision (c)(i) Denial, revocation, suspension,
9 probation, limitation, commu-
10 nity service, or fine.
11 Subdivision (c)(ii) Denial, suspension, revocation,
12 restitution, community service,
13 or fine.
14 Subdivision (c)(iii) Probation, denial, suspension,
15 revocation, restitution, commu-
16 nity service, or fine.
17 Subdivision (c)(iv) Fine, probation, denial,
18 or (d)(iii) suspension, revocation, commu-
19 nity service,
20 or restitution.
21 Subdivision (d)(i) Reprimand, fine, probation,
22 or (d)(ii) community service, denial,
23 or restitution.
24 Subdivision (e)(i) Reprimand, fine, probation,
25 limitation, suspension, commu-
26 nity service, denial, or
27 restitution.

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1 Subdivision (e)(ii)

Reprimand, probation,

2 or (h)

suspension, restitution, commu-
nity service, denial, or fine.

4 Subdivision (e)(iii)

Reprimand, fine, probation,

5 or (e)(iv)

suspension, revocation, limita-
tion, community service,
denial, or restitution.

8 Subdivision (f)

Reprimand or fine.

9 Subdivision (g)

Reprimand, probation, denial,
suspension, revocation, limita-
tion, restitution, community
service, or fine.

10

11

12

13 Subdivision (i)

Suspension or fine.

14 Subdivision (j), ~~or~~

15 (o), OR (Q)

Reprimand or fine.

16 Subdivision (k)

Reprimand, denial, or
limitation.

17

18 Subdivision (l) or (n)

Denial, revocation, restitution,
probation, suspension, limita-
tion, reprimand, or fine.

19

20

21 Subdivision (m)

Revocation or denial.

22 Subdivision (p)

Revocation.

23

(2) Determination of sanctions for violations under this

24

section shall be made by a disciplinary subcommittee. If, during

25

judicial review, the court of appeals determines that a final

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decision or order of a disciplinary subcommittee prejudices

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substantial rights of the petitioner for 1 or more of the grounds

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1 listed in section 106 of the administrative procedures act of
2 1969, 1969 PA 306, MCL 24.306, and holds that the final decision
3 or order is unlawful and is to be set aside, the court shall
4 state on the record the reasons for the holding and may remand
5 the case to the disciplinary subcommittee for further
6 consideration.

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

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

17 SEC. 17020. (1) EXCEPT AS OTHERWISE PROVIDED FOR A TEST
18 PERFORMED UNDER SECTION 5431 AND EXCEPT AS OTHERWISE PROVIDED BY
19 LAW, BEGINNING UPON THE EXPIRATION OF 6 MONTHS AFTER THE EFFEC-
20 TIVE DATE OF THE AMENDATORY ACT THAT ADDED THIS SECTION, A PHYSI-
21 CIAN OR AN INDIVIDUAL TO WHOM THE PHYSICIAN HAS DELEGATED AUTHOR-
22 ITY TO PERFORM A SELECTED ACT, TASK, OR FUNCTION UNDER SECTION
23 16215 SHALL NOT ORDER A PRESYMPTOMATIC OR PREDICTIVE GENETIC TEST
24 WITHOUT FIRST OBTAINING THE WRITTEN, INFORMED CONSENT OF THE TEST
25 SUBJECT, PURSUANT TO THIS SECTION.

26 (2) FOR PURPOSES OF SUBSECTION (1), WRITTEN, INFORMED
27 CONSENT CONSISTS OF A SIGNED WRITING EXECUTED BY THE TEST SUBJECT

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1 OR THE LEGALLY AUTHORIZED REPRESENTATIVE OF THE TEST SUBJECT THAT
2 CONFIRMS THAT THE PHYSICIAN OR THE INDIVIDUAL ACTING UNDER THE
3 DELEGATORY AUTHORITY OF THE PHYSICIAN HAS EXPLAINED, AND THE TEST
4 SUBJECT OR THE LEGALLY AUTHORIZED REPRESENTATIVE OF THE TEST
5 SUBJECT UNDERSTANDS, AT A MINIMUM, ALL OF THE FOLLOWING:

6 (A) THE NATURE AND PURPOSE OF THE PRESYMPTOMATIC OR PREDIC-
7 TIVE GENETIC TEST.

8 (B) THE EFFECTIVENESS AND LIMITATIONS OF THE PRESYMPTOMATIC
9 OR PREDICTIVE GENETIC TEST.

10 (C) THE IMPLICATIONS OF TAKING THE PRESYMPTOMATIC OR PREDIC-
11 TIVE GENETIC TEST, INCLUDING, BUT NOT LIMITED TO, THE MEDICAL
12 RISKS AND BENEFITS.

13 (D) THE FUTURE USES OF THE SAMPLE TAKEN FROM THE TEST
14 SUBJECT IN ORDER TO CONDUCT THE PRESYMPTOMATIC OR PREDICTIVE
15 GENETIC TEST AND THE INFORMATION OBTAINED FROM THE PRESYMPTOMATIC
16 OR PREDICTIVE GENETIC TEST.

17 (E) THE MEANING OF THE PRESYMPTOMATIC OR PREDICTIVE GENETIC
18 TEST RESULTS AND THE PROCEDURE FOR PROVIDING NOTICE OF THE
19 RESULTS TO THE TEST SUBJECT.

20 (F) WHO WILL HAVE ACCESS TO THE SAMPLE TAKEN FROM THE TEST
21 SUBJECT IN ORDER TO CONDUCT THE PRESYMPTOMATIC OR PREDICTIVE
22 GENETIC TEST AND THE INFORMATION OBTAINED FROM THE PRESYMPTOMATIC
23 OR PREDICTIVE GENETIC TEST, AND THE TEST SUBJECT'S RIGHT TO CON-
24 FIDENTIAL TREATMENT OF THE SAMPLE AND THE INFORMATION.

25 (3) WITHIN 6 MONTHS AFTER THE EFFECTIVE DATE OF THE AMENDA-
26 TORY ACT THAT ADDED THIS SECTION, THE DEPARTMENT OF COMMUNITY
27 HEALTH, IN CONSULTATION WITH THE MICHIGAN BOARD OF MEDICINE, THE

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1 MICHIGAN BOARD OF OSTEOPATHIC MEDICINE AND SURGERY, AT LEAST 1
2 PHYSICIAN WHO IS BOARD CERTIFIED BY THE AMERICAN BOARD OF MEDICAL
3 GENETICS, AND APPROPRIATE PROFESSIONAL ORGANIZATIONS, SHALL
4 DEVELOP AND DISTRIBUTE A MODEL INFORMED CONSENT FORM FOR PURPOSES
5 OF THIS SECTION THAT PRACTITIONERS MAY ADOPT. THE DEPARTMENT OF
6 COMMUNITY HEALTH SHALL INCLUDE IN THE MODEL FORM AT LEAST ALL OF
7 THE INFORMATION REQUIRED UNDER SUBSECTION (2). THE DEPARTMENT OF
8 COMMUNITY HEALTH SHALL DISTRIBUTE THE MODEL FORM TO PHYSICIANS
9 AND OTHER INDIVIDUALS SUBJECT TO THIS SECTION UPON REQUEST AND AT
10 NO CHARGE. THE DEPARTMENT OF COMMUNITY HEALTH SHALL REVIEW THE
11 MODEL FORM AT LEAST ANNUALLY FOR 5 YEARS AFTER THE FIRST MODEL
12 FORM IS DISTRIBUTED, AND SHALL REVISE THE MODEL FORM IF NECESSARY
13 TO MAKE THE FORM REFLECT THE LATEST DEVELOPMENTS IN MEDICAL
14 GENETICS.

15 (4) THE DEPARTMENT OF COMMUNITY HEALTH, IN CONSULTATION WITH
16 THE ENTITIES DESCRIBED IN SUBSECTION (3), MAY ALSO DEVELOP AND
17 DISTRIBUTE A PAMPHLET THAT PROVIDES FURTHER EXPLANATION OF THE
18 INFORMATION INCLUDED IN THE MODEL INFORMED CONSENT FORM.

19 (5) IF A TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED REP-
20 REPRESENTATIVE SIGNS A COPY OF THE MODEL INFORMED CONSENT FORM
21 DEVELOPED AND DISTRIBUTED UNDER SUBSECTION (3), THE PHYSICIAN OR
22 INDIVIDUAL ACTING UNDER THE DELEGATORY AUTHORITY OF THE PHYSICIAN
23 SHALL GIVE THE TEST SUBJECT A COPY OF THE SIGNED INFORMED CONSENT
24 FORM AND SHALL INCLUDE THE ORIGINAL SIGNED INFORMED CONSENT FORM
25 IN THE TEST SUBJECT'S MEDICAL RECORD.

26 (6) IF A TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED
27 REPRESENTATIVE SIGNS A COPY OF THE MODEL INFORMED CONSENT FORM

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1 DEVELOPED AND DISTRIBUTED UNDER SUBSECTION (3), THE TEST SUBJECT
2 IS BARRED FROM SUBSEQUENTLY BRINGING A CIVIL ACTION FOR DAMAGES
3 AGAINST THE PHYSICIAN, OR AN INDIVIDUAL TO WHOM THE PHYSICIAN
4 DELEGATED THE AUTHORITY TO PERFORM A SELECTED ACT, TASK, OR FUNC-
5 TION UNDER SECTION 16215, WHO ORDERED THE PRESYMPTOMATIC OR PRE-
6 DICTIVE GENETIC TEST, BASED ON FAILURE TO OBTAIN INFORMED CONSENT
7 FOR THE PRESYMPTOMATIC OR PREDICTIVE GENETIC TEST.

8 (7) A PHYSICIAN'S DUTY TO INFORM A PATIENT UNDER THIS SEC-
9 TION DOES NOT REQUIRE DISCLOSURE OF INFORMATION BEYOND WHAT A
10 REASONABLY WELL-QUALIFIED PHYSICIAN LICENSED UNDER THIS ARTICLE
11 WOULD KNOW.

12 (8) EXCEPT AS OTHERWISE PROVIDED IN SUBSECTION (9), AS USED
13 IN THIS SECTION:

14 (A) "GENETIC INFORMATION" MEANS INFORMATION ABOUT A GENE,
15 GENE PRODUCT, OR INHERITED CHARACTERISTIC WHICH INFORMATION IS
16 DERIVED FROM A GENETIC TEST.

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

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1 (C) "PREDICTIVE GENETIC TEST" MEANS A GENETIC TEST PERFORMED
2 FOR THE PURPOSE OF PREDICTING THE FUTURE PROBABILITY THAT THE
3 TEST SUBJECT WILL DEVELOP A GENETICALLY RELATED DISEASE OR
4 DISABILITY.

5 (D) "PRESYMPTOMATIC GENETIC TEST" MEANS A GENETIC TEST PER-
6 FORMED BEFORE THE ONSET OF CLINICAL SYMPTOMS OR INDICATIONS OF
7 DISEASE.

8 (9) FOR PURPOSES OF SUBSECTION (8)(B), THE TERM "GENETIC
9 TEST" DOES NOT INCLUDE A PROCEDURE PERFORMED AS A COMPONENT OF
10 BIOMEDICAL RESEARCH THAT IS CONDUCTED PURSUANT TO FEDERAL COMMON
11 RULE UNDER 21 C.F.R. PARTS 50 AND 56 AND 45 C.F.R. PART 46.

12 SEC. 17520. (1) EXCEPT AS OTHERWISE PROVIDED FOR A TEST
13 PERFORMED UNDER SECTION 5431 AND EXCEPT AS OTHERWISE PROVIDED BY
14 LAW, BEGINNING UPON THE EXPIRATION OF 6 MONTHS AFTER THE EFFEC-
15 TIVE DATE OF THE AMENDATORY ACT THAT ADDED THIS SECTION, A PHYSI-
16 CIAN OR AN INDIVIDUAL TO WHOM THE PHYSICIAN HAS DELEGATED AUTHOR-
17 ITY TO PERFORM A SELECTED ACT, TASK, OR FUNCTION UNDER SECTION
18 16215 SHALL NOT ORDER A PRESYMPTOMATIC OR PREDICTIVE GENETIC TEST
19 WITHOUT FIRST OBTAINING THE WRITTEN, INFORMED CONSENT OF THE TEST
20 SUBJECT, PURSUANT TO THIS SECTION.

21 (2) FOR PURPOSES OF SUBSECTION (1), WRITTEN, INFORMED CON-
22 SENT CONSISTS OF A SIGNED WRITING EXECUTED BY THE TEST SUBJECT OR
23 THE LEGALLY AUTHORIZED REPRESENTATIVE OF THE TEST SUBJECT THAT
24 CONFIRMS THAT THE PHYSICIAN OR THE INDIVIDUAL ACTING UNDER THE
25 DELEGATORY AUTHORITY OF THE PHYSICIAN HAS EXPLAINED, AND THE TEST
26 SUBJECT OR THE LEGALLY AUTHORIZED REPRESENTATIVE OF THE TEST
27 SUBJECT UNDERSTANDS, AT A MINIMUM, ALL OF THE FOLLOWING:

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1 (A) THE NATURE AND PURPOSE OF THE PRESYMPTOMATIC OR
2 PREDICTIVE GENETIC TEST.

3 (B) THE EFFECTIVENESS AND LIMITATIONS OF THE PRESYMPTOMATIC
4 OR PREDICTIVE GENETIC TEST.

5 (C) THE IMPLICATIONS OF TAKING THE PRESYMPTOMATIC OR PREDIC-
6 TIVE GENETIC TEST, INCLUDING, BUT NOT LIMITED TO, THE MEDICAL
7 RISKS AND BENEFITS.

8 (D) THE FUTURE USES OF THE SAMPLE TAKEN FROM THE TEST
9 SUBJECT IN ORDER TO CONDUCT THE PRESYMPTOMATIC OR PREDICTIVE
10 GENETIC TEST AND THE INFORMATION OBTAINED FROM THE PRESYMPTOMATIC
11 OR PREDICTIVE GENETIC TEST.

12 (E) THE MEANING OF THE PRESYMPTOMATIC OR PREDICTIVE GENETIC
13 TEST RESULTS AND THE PROCEDURE FOR PROVIDING NOTICE OF THE
14 RESULTS TO THE TEST SUBJECT.

15 (F) WHO WILL HAVE ACCESS TO THE SAMPLE TAKEN FROM THE TEST
16 SUBJECT IN ORDER TO CONDUCT THE PRESYMPTOMATIC OR PREDICTIVE
17 GENETIC TEST AND THE INFORMATION OBTAINED FROM THE PRESYMPTOMATIC
18 OR PREDICTIVE GENETIC TEST, AND THE TEST SUBJECT'S RIGHT TO CON-
19 FIDENTIAL TREATMENT OF THE SAMPLE AND THE INFORMATION.

20 (3) WITHIN 6 MONTHS AFTER THE EFFECTIVE DATE OF THE AMENDA-
21 TORY ACT THAT ADDED THIS SECTION, THE DEPARTMENT OF COMMUNITY
22 HEALTH, IN CONSULTATION WITH THE MICHIGAN BOARD OF MEDICINE, THE
23 MICHIGAN BOARD OF OSTEOPATHIC MEDICINE AND SURGERY, AT LEAST 1
24 PHYSICIAN WHO IS BOARD CERTIFIED BY THE AMERICAN BOARD OF MEDICAL
25 GENETICS, AND APPROPRIATE PROFESSIONAL ORGANIZATIONS, SHALL
26 DEVELOP AND DISTRIBUTE A MODEL INFORMED CONSENT FORM FOR PURPOSES
27 OF THIS SECTION THAT PRACTITIONERS MAY ADOPT. THE DEPARTMENT OF

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1 COMMUNITY HEALTH SHALL INCLUDE IN THE MODEL FORM AT LEAST ALL OF
2 THE INFORMATION REQUIRED UNDER SUBSECTION (2). THE DEPARTMENT OF
3 COMMUNITY HEALTH SHALL DISTRIBUTE THE MODEL FORM TO PHYSICIANS
4 AND OTHER INDIVIDUALS SUBJECT TO THIS SECTION UPON REQUEST AND AT
5 NO CHARGE. THE DEPARTMENT OF COMMUNITY HEALTH SHALL REVIEW THE
6 MODEL FORM AT LEAST ANNUALLY FOR 5 YEARS AFTER THE FIRST MODEL
7 FORM IS DISTRIBUTED, AND SHALL REVISE THE MODEL FORM IF NECESSARY
8 TO MAKE THE FORM REFLECT THE LATEST DEVELOPMENTS IN MEDICAL
9 GENETICS.

10 (4) THE DEPARTMENT OF COMMUNITY HEALTH, IN CONSULTATION WITH
11 THE ENTITIES DESCRIBED IN SUBSECTION (3), MAY ALSO DEVELOP AND
12 DISTRIBUTE A PAMPHLET THAT PROVIDES FURTHER EXPLANATION OF THE
13 INFORMATION INCLUDED IN THE MODEL INFORMED CONSENT FORM.

14 (5) IF A TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED REP-
15 RESENTATIVE SIGNS A COPY OF THE MODEL INFORMED CONSENT FORM
16 DEVELOPED AND DISTRIBUTED UNDER SUBSECTION (3), THE PHYSICIAN OR
17 INDIVIDUAL ACTING UNDER THE DELEGATORY AUTHORITY OF THE PHYSICIAN
18 SHALL GIVE THE TEST SUBJECT A COPY OF THE SIGNED INFORMED CONSENT
19 FORM AND SHALL INCLUDE THE ORIGINAL SIGNED INFORMED CONSENT FORM
20 IN THE TEST SUBJECT'S MEDICAL RECORD.

21 (6) IF A TEST SUBJECT OR HIS OR HER LEGALLY AUTHORIZED REP-
22 RESENTATIVE SIGNS A COPY OF THE MODEL INFORMED CONSENT FORM
23 DEVELOPED AND DISTRIBUTED UNDER SUBSECTION (3), THE TEST SUBJECT
24 IS BARRED FROM SUBSEQUENTLY BRINGING A CIVIL ACTION FOR DAMAGES
25 AGAINST THE PHYSICIAN, OR AN INDIVIDUAL TO WHOM THE PHYSICIAN
26 DELEGATED THE AUTHORITY TO PERFORM A SELECTED ACT, TASK, OR
27 FUNCTION UNDER SECTION 16215, WHO ORDERED THE PRESYMPTOMATIC OR

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1 PREDICTIVE GENETIC TEST, BASED ON FAILURE TO OBTAIN INFORMED
2 CONSENT FOR THE PRESYMPTOMATIC OR PREDICTIVE GENETIC TEST.

3 (7) A PHYSICIAN'S DUTY TO INFORM A PATIENT UNDER THIS SEC-
4 TION DOES NOT REQUIRE DISCLOSURE OF INFORMATION BEYOND WHAT A
5 REASONABLY WELL-QUALIFIED PHYSICIAN LICENSED UNDER THIS ARTICLE
6 WOULD KNOW.

7 (8) EXCEPT AS OTHERWISE PROVIDED IN SUBSECTION (9), AS USED
8 IN THIS SECTION:

9 (A) "GENETIC INFORMATION" MEANS INFORMATION ABOUT A GENE,
10 GENE PRODUCT, OR INHERITED CHARACTERISTIC WHICH INFORMATION IS
11 DERIVED FROM A GENETIC TEST.

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

23 (C) "PREDICTIVE GENETIC TEST" MEANS A GENETIC TEST PERFORMED
24 FOR THE PURPOSE OF PREDICTING THE FUTURE PROBABILITY THAT THE
25 TEST SUBJECT WILL DEVELOP A GENETICALLY RELATED DISEASE OR
26 DISABILITY.

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16

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
5 TEST" DOES NOT INCLUDE A PROCEDURE PERFORMED AS A COMPONENT OF
6 BIOMEDICAL RESEARCH THAT IS CONDUCTED PURSUANT TO FEDERAL COMMON
7 RULE UNDER 21 C.F.R. PARTS 50 AND 56 AND 45 C.F.R. PART 46.