Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Chapter 111 Section 70G of the General Laws, as appearing in the 2010 official edition, is hereby struck and replaced with the following:

The Commonwealth recognizes that genetic information is a unique product of an individual's body, the unauthorized use of which interferes with both privacy rights and property interests of that individual. It is hereby declared that it shall be a goal of the Commonwealth to declare genetic information the exclusive property of the individual from whom the information is obtained. It is a further goal of the Commonwealth to maintain an individual's privacy by prohibiting the disclosure of said genetic information without the informed written consent of the person to whom the information pertains.

(a) For purposes of this section, the following words shall have the following meanings:

"Confidential research information", any results of a genetic test maintained pursuant to pharmacological or clinical research protocols which are subject to and conducted in accordance with the review and approval of an Institutional Review Board established pursuant to the provisions of 45 CFR 46 and 21 CFR 50 and 56 which protects the confidentiality of the individual who is the subject of the genetic test either by encryption, encoding or other means consistent with the requirements of said federal regulations, or where the identity of the individual is unknown or protected from disclosure by encrypting or encoding, or by other means consistent with the requirements of said federal regulations.

"Genetic information", any written or recorded individually identifiable result of a genetic test as defined by this section or explanation of such a result about a gene, gene product or inherited characteristic derived from the individual or a family member of the individual. For purposes of this section, the term genetic information shall not include any information about an identifiable person that is taken:

(1) as a biopsy, autopsy, or clinical specimen solely for the purpose of conducting an immediate clinical or diagnostic test that is not a test of DNA, RNA, mitochondrial DNA, chromosomes or proteins;

(2) as a blood sample solely for blood banking;

(3) as a newborn screening pursuant to section 110A;

(4) as information pertaining to the abuse of drugs or alcohol which is derived from tests given for the exclusive purpose of determining the abuse of drugs or alcohol.

"Genetic test", a test of human DNA, RNA, mitochondrial DNA, chromosomes or proteins for the purpose of identifying genes, inherited, genetic mutations or acquired

genetic abnormalities, or the presence or absence of inherited or acquired characteristics in genetic material. Genetic tests shall include those taken in the course of a physical medical exam or a family history analysis. For the purposes of this section, the term genetic test shall not include tests given for drugs, alcohol, cholesterol, or HIV.

"Informed written consent", a written consent form for the requested release of a person's genetic information, or the release of genetic information, or for the release of medical records containing such information. Such written consent form shall state the purpose for which the information is being requested and shall be distinguished from written consent for the release of any other medical information.

"Insurance Institution", any corporation, association, partnership, reciprocal exchange, inter-insurer, insurance support organization as defined in chapter 175I, Lloyds insurer, so-called, fraternal benefit society or other person engaged in the business of insurance, including health maintenance organizations, medical service plans and hospital service plans, preferred provider arrangements and savings bank life insurance, as defined in chapters 175, 176, 176A, 176B, 176C, 176G, 176I, and 178A.

"Person", any natural person, corporation, association, partnership or other legal entity.

"Prior written consent", a written consent form signed by the person who is the subject of the test or, if that person lacks capacity to consent, signed by the person authorized to consent for such person which form shall not be a general waiver or consent for genetic testing or a general authorization for the release of medical records or medical information, which may be revoked or amended at any time, and which shall include:—

(1) a statement of the purpose of the test;

(2) a statement that prior to signing the consent form, the consenting person discussed with the medical practitioner ordering the test the reliability of positive or negative test results and the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease;

(3) a statement that the consenting person was informed about the availability and importance of genetic counseling and provided with written information identifying a genetic counselor or medical geneticist from whom the consenting person might obtain such counseling;

(4) a general description of each specific disease or condition tested for; and

(5) the person or persons to whom the test results may be disclosed;

(b) Genetic material shall be considered real property subject to one's individual control and dominion in accord with generally held precepts of property law in the Commonwealth. Individuals may make arrangement for appropriate storage, and maintenance of genetic information and genetic material in keeping with the intent for

which such information and material may be stored for some future use as appropriate, as determined by the property holder. In accordance with generally held precepts of property law in the Commonwealth, any decedent may specifically authorize in writing for their surviving spouse or other family member to use their genetic information or material as expressed under the terms and conditions of their last will and testament. In the case where an entity collects genetic material or genetic information with the possible future intent of resale, licensing, or transfer of this material for collateral gain, the individual who provided the genetic material or information must be made aware and compensated at a fair market value. Prior to entering into a contract to share one's personal health information, genetic material or genetic information, a person must be made aware both orally and in writing that their donation is a commodity and is of some material value.

(c) Hospital, dispensary, laboratory, hospital-affiliated registry, physician, insurance institution, insurance support organization, or insurance representative, and commercial genetic testing company, agency, or association reports and records pertaining to any genetic information are the exclusive property rights of the person sampled or analyzed, shall not be public records, and the contents thereof shall not be divulged by any person having charge of or access to the same without informed written consent, except upon proper judicial order or to a person whose official duties, in the opinion of the commissioner, entitle receipt of the information contained therein, or as confidential research information for use in epidemiological or clinical research conducted for the purpose of generating scientific knowledge about genes or learning about the genetic basis of disease or for developing pharmaceutical and other treatments of disease.

The person sampled or analyzed shall be offered several options for storing any of their remaining genetic material, donating said genetic material to another individual, discarding, or donating for research. Disclosure of options for the storage of remaining genetic material must be made at the time of attaining written consent for testing or use of genetic information. Any entity handling and maintaining genetic information or genetic material are to follow the documented guidelines for the disposal of Genetic Information as documented in the Centers for Medicaid and Medicare Services Clinical Laboratory Improvement Amendments (CLIA guidelines) or a similar subsequent regulation. Where subsequent regulations are silent on questions of law addressed in the CLIA guidelines, the CLIA guidelines shall be legally controlling.

A laboratory receiving a request to conduct a genetic test from a facility, as defined in section 70E, or a physician or health care provider may conduct the requested test only when the request is accompanied by a signed statement of the medical practitioner ordering the test warranting that the appropriate prior written consent has been obtained from the patient except where the test is conducted as confidential research information for use in epidemiological or clinical research conducted for the purpose of generating scientific knowledge about genes or learning about the genetic basis of disease or for developing pharmaceutical and other treatments of disease. The signed request authorizes the laboratory to perform the test and disclose the results to the medical practitioner.

(d) No facility, as defined in section 70E, and no physician or health care provider shall: (1) test any person for genetic information without first obtaining the prior written consent; (2) disclose the results of a genetic test to any person other than the subject thereof without first obtaining the informed written consent except where the results disclosed will be used only as is confidential research information for use in epidemiological or clinical research conducted for the purpose of generating scientific knowledge about genes or learning about the genetic basis of disease or for developing pharmaceutical and other treatments of disease; or identify the person being tested to any other person without first obtaining informed written consent or upon proper judicial order; (3) deny services to an individual solely on the basis of a genetic marker or condition to which an individual's genetic information indicates he or she is predisposed.

(e) A laboratory receiving a request to conduct a genetic test from a facility, as defined in section 70E, or a physician or health care provider or any entity which enters into a contract with a third party for analysis of genetic information, genetic material or personal health information, shall be responsible for safeguarding the confidentiality of said materials and data which results thereof.

(f) Whoever violates any provisions of this section shall be deemed to have violated section 2 of chapter 93A. Any person whose rights under this section have been violated, interfered with, or attempted to be interfered with may institute and prosecute in his own name and on his own behalf, or the attorney general, acting on behalf of the Commonwealth, may institute a civil action for injunctive and other equitable relief. In addition to the actual damages suffered by the person, a person violating this section shall be liable for damages in the amount of $5,000 or, if the violation resulted in profit or monetary gain to the violator, $100,000.

(g) This section shall not apply to a law enforcement official in the execution of his official duties; to a hospital, laboratory or physician carrying out tests upon proper judicial order; or to law enforcement or health care personnel, or any other person, in the execution of their official duties pursuant to chapter 22E.

SECTION 2. Chapter 175 Section 108I is hereby amended by striking in subsection (c) the following language:

"If the applicant chooses to submit genetic information, then the insurer is authorized to use that information to set the terms of a policy provided that such information is reliable information relating to the insured's mortality or morbidity, based on sound actuarial principles, or actual or reasonably anticipated experience."

SECTION 3. Chapter 175 Section 120E is hereby amended by striking in subsection (c) the following language:

"If the applicant chooses to submit genetic information, then the insurer is authorized to use that information to set the terms of a policy provided that such information is reliable

information relating to the insured's mortality or morbidity, based on sound actuarial principles, or actual or reasonably anticipated experience."

SECTION 4. Chapter 175 the General Laws is hereby amended by adding the following section:

Section 113X. For the purposes of this section the following words shall have the following meanings:—

"Genetic information", a written recorded individually identifiable result of a genetic test as defined in this section or explanation of such a result.

"Genetic test", a test of human DNA, RNA, mitochondrial DNA, chromosomes or proteins for the purpose of identifying the genes or genetic abnormalities, or the presence or absence of inherited or acquired characteristics in genetic material. For the purpose of this section, the term genetic test shall not include tests given for the exclusive purposes of determining the abuse of drugs or alcohol.

No company, and no officer or agent thereof, and no insurance broker, shall cancel, refuse to issue or renew, or in any way make or permit any distinction or discrimination in the amount of payment of premiums or rates charged, in the length of coverage, or in any other of the terms and conditions as authorized pursuant to section 113. Any violation of this section shall constitute an unfair method of competition or unfair or deceptive act or practice in violation of chapters 93A and 176D. The commissioner may promulgate rules and regulations pursuant to this section.

SECTION 5. Chapter 93H Section 1 of the General Laws is hereby amended by inserting after the words "general public" under the definition of "personal information", the following:

(d) Genetic information as defined by Chapter 111 Section 70G(a).

SECTION 6. Chapter 151B Section 4 of the General Laws is hereby amended by adding after the word "age" in section 14, the word "genetic information."

SECTION 7. Chapter 265 Section 39 of the General Laws is hereby amended by adding after the word "sexual orientation" in section (a), the word "genetic information."

SECTION 8. Chapter 272 Section 98 of the General Laws is hereby amended by adding after the word "sexual orientation" the words "genetic marker or handicap."

SECTION 9. Chapter 118G is hereby amended by inserting after section 33 the following section:--

Section 34.-(a) As used in this section the following words shall, unless the context clearly requires otherwise, have the following meanings:--

"Bona- fide clinical trial", any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and health outcome, has received approval from an appropriate Institutional Review Board, and has been registered at ClinicalTrials.gov prior to

———"Marketing purpose", means any activity by a company making or selling prescribed products, or such company's agent, intended to influence purchasing choices of its products, including but not limited to:

(1) advertising, publicizing, promoting or sharing information about a product;

(2) identifying individuals to receive a message promoting use of a particular product, including but not limited to an advertisement, brochure, or contact by a sales representative;

(3) planning the substance of a sales representative visit or communication or the substance of an advertisement or other promotional message or document;

(4) evaluating or compensating sales representatives;

(5) identifying individuals to receive any form of gift, product sample, consultancy, or any other item, service, compensation or employment of value;

"Genetic profiling," any effort to attach an individual's demographic information to their genetic information or genetic material <u>for marketing purposes.</u>

(b) No person shall license, use, sell, or transfer for any marketing purpose, prescribed product information related to a regulated transaction that was the result of genetic profiling. A record of a regulated transaction containing genetic information may be transferred to another entity, including to another branch or subsidiary of the same firm, only if it carries satisfactory assurance that the recipient will safeguard the records from being disclosed or used in the commonwealth for marketing purposes.

(c) Nothing in this section shall prohibit the collection use, transfer, or sale of prescribed product information for marketing purposes if:-- (i) the data is aggregated; (ii) the data does not contain identifying information; and (iii) the data cannot be used, directly or indirectly, to obtain identifying information.

(d) Nothing in this section shall prohibit the collection, use, transfer, or sale of prescribed product information for non- marketing purposes, including, but not limited to, patient care, patient care management, utilization review, health care research, bona fide clinical trials, product safety studies, transfer of information to the patient or patient's authorized representative, and as required by law.

(e) Nothing in this section shall be interpreted to regulate conduct that takes place wholly outside of the commonwealth.

(g) Whoever violates any provision of this section shall be liable for damages in the amount of $5,000, or if the violation resulted in profit or monetary gain to the violator, $100,000.

(h) A violation of this section shall also constitute an unfair or deceptive act or practice in the conduct of trade in violation of Section 2 of Chapter 93A. Any person whose rights under this section have been violated may institute and prosecute in his own name and on his own behalf, or the attorney general, acting on behalf of the commonwealth, may institute a civil action for injunctive and other equitable relief.

i) If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

SECTION 10. Chapter 111E Section 9E is hereby amended by adding a section (17):

(17). Eligibility for and the medical benefits provided by MassHealth shall not be determined solely on the basis of a genetic marker or condition.

SECTION 11. Chapter 4, Section 7, clause 26 (c) is herby amended by inserting after the word, "information," the following, "including genetic information."

SECTION 12. Chapter 66A Section 1 is herby amended by inserting after the words, "Personal data, any information concerning an individual," the following, "including genetic information as defined in Chapter 111, Section 70G."

SECTION 13. Chapter 66A Section 2 (c) is herby amended after the words, "medical or psychiatric data" by inserting the following, "excluding a genetic test or genetic information."

SECTION 14. Chapter 93 Section 50 is herby amended by adding the following definition, "genetic information- any written or recorded individually identifiable result of a genetic test as defined by Chapter 111, Section 70G."

SECTION 15. Chapter 93H Section 3 is herby amended by adding each time the words, "personal information," appear the following, "including a person's genetic information."

SECTION 16. Chapter 266 Section 37E is herby amended by inserting after the words, "social security number" the following words, "genetic information" as defined by Chapter 111 Section 70G.

SECTION 17. Chapter 152 is herby amended by adding a new section, "Section 14b." and inserting the following:

Section 14b. For the purposes of this section the following words shall have the following meanings:—

"Genetic information", a written recorded individually identifiable result of a genetic test as defined in this section or explanation of such a result.

"Genetic test", a test of human DNA, RNA, mitochondrial DNA, chromosomes or proteins for the purpose of identifying the genes or genetic abnormalities, or the presence or absence of inherited or acquired characteristics in genetic material. For the purpose of this section, the term genetic test shall not include tests given for the exclusive purposes of determining the abuse of drugs or alcohol.

No company, and no officer or agent thereof, and no insurance broker, shall cancel, refuse to issue or renew, or in any way make or permit any distinction or discrimination in the amount of payment of premiums or rates charged, in the length of coverage, or in any other of the terms and conditions of any individual policy of workers compensation insurance, authorized pursuant to Chapter 152, based on genetic information as defined in this section. No company, officer or agent thereof, and, no insurance broker shall require genetic tests or genetic information as defined in this section, as a condition of the issuance or renewal of any such individual or group policy of workers compensation authorized pursuant to Chapter 152. Any violation of this section shall constitute an unfair method of competition or unfair or deceptive act or practice in violation of chapters 93A and 176D. The commissioner may promulgate rules and regulations pursuant to this section.

SECTION 18. If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.