

# THE MASSACHUSETTS GENETIC BILL OF RIGHTS SECTION-BY-SECTION

## SECTION 1

### AMENDS CHAPTER 111 SECTION 70G

#### CREATES AN EXPRESSED RIGHT TO PRIVACY

##### ABOUT THIS CLAUSE:

*Massachusetts is one of forty-three states which don't have an expressed Right to Privacy in its State Constitution. Privacy rights exist only within a specific grant of authority under Massachusetts and Federal law. HIPPA does not currently apply because administrative rules with respect to consent were changed since the original law was passed in the late 1990's. The Genetic Information Non-Discrimination Act passed in 2008, but is limited in scope to policing only Health Insurance and Employment law. This clause expressly creates an individual right to privacy with respect to genetic material and genetic information.*

#### ESTABLISHES GENETIC INFORMATION AS PERSONAL PROPERTY

##### ABOUT THIS CLAUSE:

*Under Current Massachusetts law, ownership of genetic material and information is not currently addressed. The statutes are silent on how inheritance, divisibility, transferability, and other elements of control are to be exercised. This clause recognizes that genetic information and genetic material are real property, and state that an individual may assert dominion over their own genetic material and information.*

#### AMENDS DEFINITIONS OF "GENETIC INFORMATION" AND "GENETIC TEST" AND "WRITTEN CONSENT"

##### ABOUT THIS CLAUSE:

*Biobankers must tell individuals contributing genetic material that their individual genetic material has a monetary value. In addition, patients also must be informed as to the exact nature of a genetic test, its diagnostic consequences and level of certainty that the test serves as a predictor of a genetic conditions onset.*

#### REQUIRES UPHOLDING OF CLIA STANDARDS

##### ABOUT THIS CLAUSE:

*CLIA, the Clinical Laboratories Improvements Amendments are minimal standards for lab facilities handling genetic material. Currently, facilities which handle genetic material which in the creation of a good or service materially rely on an individual's genetic information or material are not covered under CLIA. Without extending CLIA guidelines to these vendors, genetic material can be potentially licensed, sold, or transferred to a third party who may use this information to engage in genetic profiling. This clause puts all entities on equal footing.*

#### ADDRESSES RIGHTS FOR STORING OF REMAINING GENETIC MATERIAL

##### ABOUT THIS CLAUSE:

*Under current Massachusetts law, specific obligations with respect to control and oversight of a genetic material are not addressed. This section seeks to clarify the obligations of the parties to one another and creates sanctions for entities which habitually fail to comply with a basic level of oversight and control.*

#### STRIKES LANGUAGE EXCLUDING RESEARCH INFORMATION FROM PROTECTIONS UNDER DEFINITION OF "GENETIC INFORMATION."

##### ABOUT THIS CLAUSE:

*Extends protections and safeguards to Genetic Information and Genetic Material are extended to testing which is the product of academic and scientific research*

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## STRIKES LANGUAGE EXCLUDING ORGANIZATIONS CONDUCTING PHARMACO-ECONOMIC STUDIES FROM REQUIRING WRITTEN CONSENT

### ABOUT THIS CLAUSE:

*Extends protections and safeguards to Genetic Information and Genetic Material are extended to testing which is the product of comparative effectiveness research.*

## ADDS LANGUAGE THAT HEALTH CARE FACILITIES CANNOT DENY SERVICES SOLELY BASED ON A GENETIC MARKER.

### ABOUT THIS CLAUSE:

*No medical treator or facility may base a decision to treat, not treat or withdraw treatment of a natural person in the Commonwealth of Massachusetts upon the discovery of a genetic marker or a genetic predisposition based upon one's own genetic information or material.*

## STRENGTHENS LANGUAGE AROUND VIOLATIONS AND ESTABLISHES DOLLAR AMOUNT FOR DAMAGES

### ABOUT THIS CLAUSE:

*Individuals adversely affected by unlawful breaches of one's genetic information and genetic material are granted the right to seek relief under section 2 of Chapter 93A.*

## SECTIONS 2 & 3

## REMOVES EXEMPTION FOR LIFE, LONG-TERM CARE AND DISABILITY INSURANCE

### ABOUT THIS SECTION:

*Currently, Genetic Information and Genetic Material are available to Auto, Life, Disability and Long-Term Care insurers for use in underwriting these financial device as part of their business operations as part of the 1999 Gramm Leach Bliley Financial Modernization act.*

*Historically, the Federal Government and individual states has recognized some the sale of a good or service as a public accommodation and reserved the right to police certain financial arrangements when market forces have had the effect of disenfranchising a segment of the population. We believe the state has a public policy interest in affirming the right of all individual to bargain and contract. Ensuring that these arrangements are available to all consumers residing within the Commonwealth of Massachusetts is a public good. This section would prohibit insurers from using genetic information and material as a reason for denying an individual access to coverage.*

*Effectively, these insurance products would be deemed a public accommodation under state law and would be issued on a basis similar to that which existed prior to when Massachusetts enacted heath insurance under the Romney healthcare reforms. As such, these insurance products [ life, disability, long-term care insurance policy] would be subject to a guaranteed issue scheme. Rate-setting for these products would still be exclusively the domain of the insurance companies themselves.*

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## SECTION 4

### STATES THAT AUTO INSURERS CANNOT USE GENETIC INFORMATION IN ESTABLISHING POLICIES AND RATES

#### **ABOUT THIS SECTION:**

*We believe it foreseeable that auto insurers in the Commonwealth would use Genetic Information and Genetic Material as part of routine business operations would charge differential rates in underwriting given the discovery of a genetic marker when a genetic marker increase perceived or actual risk for a policyholder. This genetic information, genetic material and personal health information is currently available to them for use as part of their business operations as part of the 1999 Gramm Leach Bliley Financial Modernization act. As such we believe that without definitive curbs to stop conduct it is inevitable that auto insurers would differentially price coverage for a person who has a marker for epilepsy or cardiac problems. For example, they might be asked to pay higher rates based solely on the presence of a genetic marker, but without having experienced actual onset of a medical episode. In doing so, they will argue they are undertaking a higher level of risk and should be financially rewarded. We believe that Auto Insurance constitutes a public accommodation under the law.*

## SECTION 5

### ADDS "GENETIC INFORMATION" TO LAW AROUND SECURITY BREACHES

#### **ABOUT THIS SECTION:**

*This section expands an existing list of materials and communications which are deemed to be privileged; and places breaches of one's genetic information and material on par under Massachusetts law with similar kinds of breaches of privileged and confidential materials and communications. Under this provision the existing schedule for sanctions would apply to instances where the misuse or misappropriation of one's genetic information or material has occurred.*

## SECTION 6

### STATES THAT GENETIC INFORMATION CANNOT BE USED IN DETERMINING CREDIT WORTHINESS

#### **ABOUT THIS SECTION:**

*The Gramm-Leach-Bliley Financial Modernization act of 1999 grants financial institution access to an individual's genetic information, genetic material and personal health information. This section says that while it may be lawful to possess this information, these financial institutions shall not use this information in conveying a financial instrument or accessing an applicant's creditworthiness.*

## SECTION 7

### ADDS GENETIC INFORMATION TO GENETIC MARKER PROTECTION UNDER THE MA CIVIL RIGHTS ACT

#### **ABOUT THIS SECTION:**

*This provision extends to people with an identifiable genetic marker legal protections under the Massachusetts Civil Rights Act. No current provisions exist to recognize people with a genetic marker as a class of persons under this act.*

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## SECTION 8

**MAKES IT UNLAWFUL TO EXCLUDE A PERSON WITH A GENETIC MARKER OR HANDICAP FROM A PUBLIC PLACE (INCLUDING HOSPITALS AND MEDICAL OFFICES). THE FEDERAL REHABILITATION ACT OF 1973<sup>4</sup> PROHIBITS DISCRIMINATION ON THE BASIS OF DISABILITY IN ANY AGENCY OR PROGRAM THAT RECEIVES FEDERAL FUNDING, INCLUDING HOSPITALS, MEDICAL OR DENTAL OFFICES & EDUCATIONAL INSTITUTIONS**

### **ABOUT THIS SECTION:**

*This element recognizes that Federal Civil Rights protections routinely extended to other class of persons must also be extended to individuals with a genetic marker or genetic predisposition. Failure to do would create a situation tantamount to differential treatment under color of law in accessing certain governmental services and public accommodations.*

## SECTION 9

**DEFINES BONA-FIDE CLINICAL TRIAL, MARKETING PURPOSE, AND GENETIC PROFILING, MAKES IT UNLAWFUL TO ENGAGE IN GENETIC PROFILING FOR MARKETING PURPOSES AND ESTABLISHES FINES FOR VIOLATIONS**

### **ABOUT THIS SECTION:**

*Existing Massachusetts law does not preclude the acts commonly known as “genetic profiling.” Federal laws like HIPPA, the Health Information Privacy and Portability Act and GINA, the Genetic Information Non-Discrimination Act both do not extend individual protections to one’s genetic material and information. The completion of the mapping of the Human Genome project postdates HIPPA’s enactment, and GINA is limited in scope as it only applies to Health Insurance coverage and Employment law.*

*This section makes it unlawful to engage in the practice known as “genetic profiling” for marketing purposes. Genetic profiling is the process by which disaggregated genetic information or genetic material is re-attached to an individuals’ genetic profile for the purpose of marketing a good, service or product.*

*Further clarifies existing terms and definitions for “bona-fide clinical trial, marketing purpose, and data trafficking” as they apply to genetic information and genetic material under Massachusetts law and delineates sanctions for breaches as appropriate.*

## SECTION 10

**STATES THAT MASSHEALTH CANNOT DETERMINE COVERAGE AND BENEFITS SOLELY ON THE BASIS OF A GENETIC MARKER OR CONDITION**

### **ABOUT THIS SECTION:**

*This section is a direct response to current activities in Arizona, where individuals on the state’s Medicaid program, have been denied access to organ transfusion services because they are poor and happen to need a transplant. The Forum believes that medical decision-making best occurs when decisions are made by doctors and patients. As such, this section states that an individual with a genetic marker or condition in and of itself should not be used as the sole basis for denying a patient on MassHealth access to transplant services.*

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## SECTION 11

**SPECIFICALLY DESCRIBES “GENETIC INFORMATION” AS NOT PART OF PUBLIC RECORDS- SIMILAR TO THE TREATMENT OF MEDICAL RECORDS**

### **ABOUT THIS SECTION:**

*Currently, Massachusetts law treats genetic information and genetic material differently than other personal health information. Increasingly, therapeutic products and therapies coming to market will rely on genetic testing as a significant component of a regular medical regime, and as such; the lines between personal health information and genetic information and materials are increasing blurred and intertwined. We believe that the same protections under the law which apply to the handling, transfer and maintenance of health records should be extended to genetic information and genetic material is materially similar to other information in one’s health record.*

## SECTION 12

**ADDS GENETIC INFORMATION TO BE INCLUDED UNDER THE DEFINITIONS OF PERSONAL DATA IN STATUTE DEALING WITH THE FAIR ADMINISTRATION OF PERSONAL DATA BY PUBLIC ENTITIES- AND THE FAIR ADMINISTRATION OF SAID INFORMATION. THE STATUTE INCLUDES PROCEDURES (WHICH WILL NOW INCLUDE GENETIC INFORMATION) TO BE FOLLOWED IN THE EVENT THAT SECURITY IS BREACHED**

### **ABOUT THIS SECTION:**

*The Obama Administration has earmarked Billions dollars as part of the 2009 Stimulus package for the digitizing of Health Records. With so much information now being stored digitally, it is critical that genetic information be stored in a way that creates confidants among consumers of healthcare services. Part of a regime which does this must also include reasonable sanctions and protocols in the case of a breach on behalf of not only private sector actors, but also government entities. As such, this section extends existing rules to governmental entities handling genetic material and genetic information.*

## SECTION 13

**EXCLUDES GENETIC TEST RESULTS OR INFORMATION FROM BEING SHARED IN MEDICAL OR PSYCHIATRIC EMERGENCIES BY PUBLIC ENTITIES WHERE THE INDIVIDUAL IS UNABLE TO PROVIDE CONSENT. ALSO PROHIBITED IS SHARING GENETIC TESTS OR GENETIC INFORMATION WITH THE BUREAU OF SPECIAL INVESTIGATIONS FOR PURPOSES OF FRAUD DETECTION AND CONTROL**

### **ABOUT THIS SECTION:**

*This language attempts to recognize the importance of maintaining a pathway to innovation and inquiry for researchers, academics and others working around the life sciences by carving a narrow evidentiary privilege. It also recognizes the inherent conflicts that arise out of efforts to balance progress and prosperity with personal liberty.*

*This is especially important in light of recent activities. In August of 2010, the University of California at Berkeley encouraged, as a freshman community event all incoming students to make a DNA sample available to researchers as part of an effort to chart intake among freshman and their consumption of alcohol and green leafy vegetables in a latitudinal study. The major impact of this inquiry as it was initially proposed; however was to create a “Genetic Facebook.” It is evitable, we believe, that such a database, (should one eventually come to exist) would be extremely attractive as a potential evidentiary tool which law enforcement agencies would hope to access.*

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*As such, Genetic Information and Genetic Material could eventually be subpoenaed as part of a civil or criminal proceeding. This reality absolutely would have a chilling effect on academic research and scientific inquiry. In order to assure that scientific inquiry and academic research continue unabated, it is absolutely essential that researchers be able to assure members of the public that their samples will be safeguarded. This exception would only apply narrowly to genetic information directly presented to medical, academic and scientific researchers in furtherance of their research. It would not preclude law enforcement from availing themselves of genetic information and material discovered as part of a civil or criminal investigation outside of the realm of academic, scientific and medical research.*

## SECTION 14

### ADDS THE DEFINITION OF GENETIC INFORMATION TO THE LAW REGULATING TRADE & CERTAIN BUSINESSES

#### **ABOUT THIS SECTION:**

*Language in this section recognizes that under HIPPA, the further away one is from the initial point of contact with medical treators, the more likely it is that one's genetic material will be treated as a commodity and less like privileged material. We believe that one's genetic material and genetic testing are an increasingly important part of the treatment regime. Patients as consumers of medical services often have little control over the third-party vendors who are retained by their healthcare providers. These vendors however, are the source of a significant percentage of the breaches confronting patients. Going forward we must recognize that Genetic Information is a "tool of the medical trade" and responsibility for its proper use must be treated no differently than the care required to properly maintain other essential medical tools and equipment. Parties exercising these agreements should be responsible in the event of a breach of one's genetic information or material. Providers failing to comply with an adequate duty to care may be accessed professional sanctions by their respective licensing body. Affected parties may seek relief under section 2 of Chapter 93A*

## SECTION 15

### ADDS "GENETIC INFORMATION" TO THE LAW ESTABLISHING THE DUTY TO REPORT KNOWN SECURITY BREACHES OR UNAUTHORIZED USE OF PERSONAL INFORMATION AND LAYS OUT PENALTIES FOR SUCH UNAUTHORIZED USE

#### **ABOUT THIS SECTION:**

*Creates a duty to inform should an individual's genetic information or material be compromised. Issues guidelines for institutions, and medical providers to alert their patients of a breach of one's genetic material in a timely manner, should affected parties not be alerted in a timely manner additional sanctions may be imposed.*

## SECTION 16

### ADDS "GENETIC INFORMATION" TO THE CRIMINAL STATUTES PUNISHING THOSE WHO COMMIT IDENTITY FRAUD

#### **ABOUT THIS SECTION:**

*Inserts into the current Massachusetts Identity Theft law language which establishes one's individual genetic information as unique and intrinsic to one's self and places one's genetic profile on an equal footing with other unique individual identifiers like one's Social Security Number. This section also establishes sanctions for misuse and misappropriation of this material under the color of Massachusetts law.*

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## SECTION 17

### CREATES PROTECTIONS FOR PEOPLE WITH GENETIC MARKERS IN ACCESSING PROGRAM BENEFITS UNDER THE MASSACHUSETTS WORKERS COMPENSATION PROGRAM

#### **ABOUT THIS SECTION:**

*It is the intention of the parties to ensure that individuals filing worker's compensation claims be judged fairly on the merits of such claims and not risk challenges based on assertions that their genetic information constitutes a pre-existing condition. As Federal and MA state law are silent on whether protections from genetic discrimination apply to individuals seeking relief under the worker's compensation program, this section seeks to clarify that such protections do extend to employees seeking such relief. We believe that protecting individual from the specter of Genetic Discrimination is prudent as a matter of public policy and best serves all the people of this Commonwealth.*

## SECTION 18

### SEVERABILITY CLAUSE

#### **ABOUT THIS SECTION:**

*Adds language stating that: "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."*