The New Jersey Law Revision Commission is required to “[c]onduct a continuous examination of the general and permanent statutory law of this State and the judicial decisions construing it” and to propose to the Legislature revisions to the statutes to “remedy defects, reconcile conflicting provisions, clarify confusing language and eliminate redundant provisions.” N.J.S. 1:12A-8.

This Report is distributed to advise interested persons of the Commission's tentative recommendations and to notify them of the opportunity to submit comments. Comments should be received by the Commission no later than September 30, 2014.

The Commission will consider these comments before making its final recommendations to the Legislature. The Commission often substantially revises tentative recommendations as a result of the comments it receives. If you approve of the Report, please inform the Commission so that your approval can be considered along with other comments. Please send comments concerning this Report or direct any related inquiries, to:

Vito J. Petitti, Counsel
New Jersey Law Revision Commission
153 Halsey Street, 7th Fl., Box 47016
Newark, New Jersey 07102
973-648-4575
(Fax) 973-648-3123
Email: vjp@njlrc.org
Web site: http://www.njlrc.org
Executive Summary

Advancements in science and technology have made it possible to learn information from the DNA molecule about an individual’s probable medical future.1 “One challenge emphasized by the scientists involved in decoding the human genome is the potential misuse of genetic information, which the new technologies will make available...In the employment context, the potential use of genetic information to make hiring, firing, and other personnel decisions raises the most concern.”2

In July 2010, the Uniform Law Commission (“ULC”) approved and recommended for enactment in all the States the Uniform Protection of Genetic Information in Employment Act (“UPGIEA”). As an alternative to adopting UPGIEA in its entirety, the Commission is considering a recommendation to incorporate into New Jersey’s Genetic Privacy Act3 (“GPA”) those provisions of UPGIEA not yet addressed in New Jersey law.

Background

At the time of this report, 37 states, including New Jersey, have enacted statutes regulating how employers collect, use, retain, or disclose employees’ genetic information.4 Enacted in 1996, New Jersey’s GPA is one of the most comprehensive laws protecting genetic information to be passed in any state.5 In 2008, Congress passed the Genetic Information Nondiscrimination Act (“GINA”) in response to the explosion of advancements in the science of genetics and in recognition of the potential for discrimination based on genetic information.6 The UPGIEA, not yet adopted in any state, attempts to comprehensively regulate “acquisition, use, retention, and disclosure of genetic information in the context of employment” and “allows individuals to control the privacy of their genetic information, preventing the misuse of that information.”7

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1 See N.J.S. 10:5-44, Findings, declarations relative to genetic information.
5 GINA Will Protect You, Just Not from Death: The Genetic Information Nondiscrimination Act and Its Failure to Include Life Insurance Within Its Protections, 34 Seton Hall Legis. J. 93, 102 (2009)
Existing New Jersey Law

New Jersey’s GPA treats genetic information as a person’s private property.8 N.J.S. 10:5-45 of the GPA provides that “[n]o person shall obtain genetic information from an individual, or from an individual’s DNA sample, without first obtaining informed consent from the individual or the individual’s representative.”9 Correspondingly, N.J.S. 10:5-46 contains exceptions to GPA.10 For example, the GPA does not fully apply in criminal investigations or paternity suits.11 N.J.S. 10:5-47 regulates disclosure of genetic information,12 and N.J.S. 10:5-48 governs notice requirements for persons to be tested and the process for obtaining informed consent.13 N.J.S. 10:5-48(b) provides, with certain exceptions, that the “Commissioner of Health and Senior Services, in consultation with the Commissioner of Banking and Insurance, shall promulgate regulations...governing procedures for obtaining informed written consent...” N.J.S. 10:5-48(c) provides, however, that “[t]he provisions of this section shall not apply to newborn screening requirements established by State or federal law.” Finally, N.J.S. 10:5-49 governs penalties for anyone found in violation of the GPA14 and provides for both monetary fines and terms of imprisonment.

Similar to GINA, the federal law in this area, New Jersey’s GPA prohibits employers from discriminating against individuals based on their genetic information.15 Under the GPA, employers cannot discriminate against a prospective or future employee because of her genetic information, because she declines to take a genetic test, or because she fails to “make available the results of a genetic test.”16 New Jersey law also prohibits “unfair discrimination against an individual in the application of the results of a genetic test or genetic information in the issuance, withholding, extension or renewal of a policy of life insurance.”17 If an insurer plans to use genetic test results, it must “notify the individual who is the subject of the genetic test that such a test [will] be required and [must] obtain the individual’s written informed consent for the test prior to the administration of the test.”18 The insurer must also provide the results of the test to a “physician or other health care professional designated by the individual” and the individual can indicate in writing if she wishes “to be informed of the results of the test.”19

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8 GINA Will Protect You, Just Not from Death: The Genetic Information Nondiscrimination Act and Its Failure to Include Life Insurance Within Its Protections, 34 Seton Hall Legis. J. 93, 102 (2009)
9 N.J.S. 10:5-45.
10 N.J.S. 10:5-46.
11 See Id.
12 N.J.S. 10:5-47.
14 N.J.S. 10:5-49.
16 N.J.S. 17B:30-12.
17 GINA Will Protect You, Just Not from Death: The Genetic Information Nondiscrimination Act and Its Failure to Include Life Insurance Within Its Protections, 34 Seton Hall Legis. J. 93, at 103 (2009) (quoting N.J.S. 17B:30-12(f)).
18 Id.
19 Id.
In New Jersey, there is a private right of action for victims of employment discrimination and a plaintiff may initiate suit by filing in Superior Court.\textsuperscript{20}

**Federal Law**

GINA “[p]rohibits use of an individual’s genetic information by employers in employment decisions such as hiring, firing, job assignments, and promotions” and “[p]rohibits employers from requesting, requiring, or purchasing genetic information about an individual employee or family member.”\textsuperscript{21} GINA “[d]oes not subject employers to remedies and procedures that are any different from those in other civil rights laws such as Title VII and the Americans with Disabilities Act.” Furthermore, GINA “[d]oes not prohibit workplace collection of genetic information for toxic monitoring programs, employer-sponsored wellness program, administration of federal and state Family and Medical Leave laws, and in certain cases of inadvertent acquisition of information.” However, in these cases the employer may not use or disclose the information.\textsuperscript{22}

Under GINA, “genetic information” is defined as “information about: a person’s genetic tests; genetic tests of a person’s family members (up to and including fourth-degree relatives); any manifestation of a disease or disorder in a family member; participation of a person or family member in research that includes genetic testing, counseling, or education.” However, “genetic information” does not include information about sex or age.\textsuperscript{23}

A “genetic test” is defined by GINA as “a test that assesses genotypes, mutations, or chromosomal changes.” Examples of protected tests are: tests for BRCA1/BRCA2 (breast cancer) or HNPCC (colon cancer) mutations; classifications of genetic properties of an existing tumor to help determine therapy; tests for Huntington disease mutations; and carrier screening for disorders (e.g. screenings for cystic fibrosis, sickle cell anemia, spinal, muscular atrophy, and the fragile X syndrome). However, GINA does not protect routine tests such as complete blood counts (CBC, or blood panel), cholesterol tests, and liver-function tests or analysis—including DNA analysis—of infectious agents such as bacteria, viruses, and fungi. For example, an HIV test is not covered by GINA.\textsuperscript{24}

GINA does not apply to members of the United States Military, to veterans obtaining health care through the Veteran’s Administration, or to the Indian Health Service.\textsuperscript{25} Nor does GINA include protection from genetic discrimination in life insurance, disability insurance, or long-term-care insurance.\textsuperscript{26} GINA affects—and differs from—current federal anti-discrimination

\textsuperscript{21} Genetic & Public Policy Center, Information on the Genetic Information Nondiscrimination Act (GINA), http://www.dnapolicy.org (last visited 7/3/2014).
\textsuperscript{22} Id.
\textsuperscript{23} Id.
\textsuperscript{24} Id.
\textsuperscript{25} Id.
\textsuperscript{26} Id.
laws. While the Americans with Disabilities Act contains an exception that allows an employer, in special circumstances, to make a decision based on information that would otherwise be protected, GINA does not allow for an exception. Furthermore, under GINA, prohibitions contained in the Employee Retirement Income Security Act (“ERISA”) extend to genetic information. Finally, GINA expands the protections of the Health Insurance Portability and Accountability Act (“HIPAA”) by requiring “that all genetic information be treated as health information under HIPAA, thus making this information subject to HIPAA’s privacy regulations.”

Why the Uniform Law Commission Believes the UPGIEA is Necessary

According to the ULC, there is a need for states to uniformly regulate the disclosure and use of genetic information in the workplace, especially considering that GINA’s employment provisions do not preempt state legislation that provides equal or greater protection to individuals.

The ULC emphasizes that the UPGIEA must be passed to (1) encourage individuals to take genetic tests, (2) to clear up confusion regarding whether GINA preempts existing state laws, and (3) to promote uniformity among states.

The drafters of the UPGIEA explain that, while scientific developments in the field of genetics hold many promises for the future, individuals will be unwilling to take genetic tests unless they are confident that they can control the privacy of their genetic information and that their genetic information will not be used to harm them in the workplace for reasons that are not related to their ability to do the job. It is clear, however, that the New Jersey Legislature has taken this concern seriously. New Jersey’s GPA opens with “A[n] [act] concerning genetic testing and privacy and medical underwriting.” (Emphasis added.) N.J.S. 10:5–48 of the GPA provides that “a person who requires or requests that genetic testing be done or receives records, results or findings of genetic testing shall provide the person tested with notice that the test was performed and that the records, results or findings were received unless otherwise directed by informed consent.”

Regarding preemption of state law, according to the ULC, GINA has created general uncertainty about the enforceability of state genetic statutes in the context of employment.
fact, GINA contains provisions mandating that employers, employment agencies, labor organizations, and joint labor-management committees comply with state or local law in order to acquire genetic information and specifies that “nothing in this title shall be construed to limit the rights or protections of an individual under other Federal or State statute that provides equal or greater protection than is provided under this title.” But “New Jersey law provides comprehensive protection of genetic information. GINA will likely not provide any protection in addition to what the [New Jersey] state law already provides.”

The ULC also asserts that the UPGIEA would address the lack of uniformity among existing state statutes, which has created burdens on employers operating in more than one jurisdiction. It is thus helpful to compare the UPGIEA’s key provisions, as promulgated by the ULC, with those of New Jersey’s GPA.

**Highlights of the UPGIEA**

The Uniform Act is designed to eliminate the preemption problems created by GINA for existing state statutes by incorporating the key definitions and concepts of GINA. It also complements and supplements GINA with provisions that are more protective of employees, following the pattern of many state fair employment laws that supplement Title VII and other federal statutes. As discussed above, because of the GPA’s existing protections, “GINA will likely not provide any protection in addition to what the [New Jersey] state law already provides.”

The Act comprehensively regulates acquisition, use, retention, and disclosure of genetic information in the employment setting, and New Jersey’s GPS contains corresponding protections: N.J.S. 10:5-45 requires informed consent to acquire genetic information; N.J.S. 17:B:30-12 prohibits discriminatory use of genetic information; and N.J.S. 10:5-47 sets conditions for disclosure of genetic information.

The Uniform Act expands coverage beyond that of GINA in two principal ways. First, it closes a gap in GINA by extending coverage to entities that credential or license workers along with employers, unions, employment agencies, and training programs. N.J.S. 10:5-5 of New Jersey’s GPA defines “employer” so as to include “labor organizations,” but is silent as to the other entities mentioned in the UPGIEA. A proposed revision may be found in the Appendix.

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37 Genetic Information Nondiscrimination Act, Pub. L. No. 110-233 (2010), Title 1, Section 209(a)(1)

38 GINA Will Protect You, Just Not from Death: The Genetic Information Nondiscrimination Act and Its Failure to Include Life Insurance Within Its Protections, 34 Seton Hall Legis. J. 93, 102 (2009)


40 See Id.


42 GINA Will Protect You, Just Not from Death: The Genetic Information Nondiscrimination Act and Its Failure to Include Life Insurance Within Its Protections, 34 Seton Hall Legis. J. 93, 102 (2009)
which expands the definitions of “employer” and “person” to include employment agencies, employment entities, labor-management committees, labor-management training or apprentice programs, and credentialing authorities. The language of these definitions is taken from the UPGIEA’s definition section. Second, the UPGIEA includes employers with five or more employees, while giving states an option to extend coverage to smaller employers. This follows the pattern of state fair employment statutes, many of which cover smaller employers than those covered under Title VII. Here, the GPA does not define “employer” in terms of a specific number of employees, but doing so would have the effect of eroding the GPA’s protections.\textsuperscript{43}

The Act protects employees by requiring them to authorize employer acquisition of their genetic information and voluntary genetic testing as part of an employee wellness program or a genetic monitoring program. These authorization requirements are consistent with GINA, but are more specific. The Act sets forth the desirable content for authorization forms to give employers guidance and the assurance that they are following the law. It also allows employees to submit genetic information voluntarily so that it can be used for their protection, for example, in support of a request for reassignment to avoid a workplace substance to which a worker has a genetic susceptibility. N.J.S. 10:5-45, of the GPA, correspondingly requires informed consent to obtain genetic information from an individual or from the individual’s DNA sample. The GPA itself provides no examples of authorization forms, but \textit{N.J.S} 10:5-48 refers to New Jersey’s Administrative Procedure Act, \textit{N.J.S} 52:14B-1 \textit{et seq.}, which governs procedures for obtaining informed written consent. Nor does GPA provide a vehicle for providing voluntary information to be used as the above example describes, but the Commission proposes adding such a provision as an exception to the prohibition in N.J.S. 10:5-45 against acquiring genetic information without informed consent. The proposed new language is taken from Section 6 of the UPGIEA (See Appendix).

The Act supplements GINA with specific provisions on genetic testing, which is treated in GINA as part of the general category of acquisition of genetic information. The Act allows an employer to offer genetic testing only as part of a voluntary employee wellness program or a genetic monitoring program. N.J.S. 10:5-45 already requires informed consent to obtain genetic information from an individual or from the individual’s DNA sample.

The Act recognizes the importance of genetic counseling for employees’ decisions to have a genetic test and in interpreting the results and requires genetic counseling before an employee or family member authorizes a genetic test and when a test predicts a disease or disorder unless the individual waives genetic counseling in writing. Since the Act recognizes that genetic counseling is an emerging profession that is not regulated in many states, it does not impose requirements on who may provide counseling. Therefore, unless there is state law to the contrary, counseling may be provided by physicians, geneticists, and nurse practitioners in addition to trained genetic counselors. The Act also regulates genetic testing by setting standards

\textsuperscript{43} New Mexico is the only state in which a bill enacting the UPGIEA has been introduced. According to the Cisco McSorley Fiscal Impact Report, available at http://www.nmlegis.gov/sessions/13\%20regular/firs/sb0445.pdf (last visited 7/2/2014), the New Mexico Attorney General’s Office articulated its concern regarding “the numerous exceptions outlined in the proposed legislation.” SB 445, which died in committee, had raised the qualifying number of employees from five to 15.
that require reporting the results to the employee, destroying the employee’s biological sample and expunging genetic information produced ancillary to the test. While New Jersey’s GPA offers no provision regarding genetic counseling, N.J.S. 10:5-48 already requires notice to persons receiving genetic testing. A proposed revision to this section requiring the availability of genetic counseling may be found in the Appendix. The new language is taken from Section 10 of the UPGIEA. Also, N.J.S. 10:5-46 requires authorization in order to retain genetic information and N.J.S. 10:5-46 requires prompt destruction of DNA samples.

In order to prevent employment discrimination based on genetic information, the Act follows GINA by prohibiting specific actions based on genetic information, such as failure to hire, discharge, or discrimination in compensation or terms and conditions of employment. It also more comprehensively prohibits any adverse employment action against an employee based on the employee’s genetic information. The Act incorporates GINA’s provisions that make genetic information confidential and limit disclosures of that information. It supplements GINA by allowing employees to direct disclosures to third parties and by giving employees a specific right to inspect and copy genetic information in the employer’s possession and to submit corrected information. Here, N.J.S. 10:5-12, of New Jersey’s GPA, likewise prohibits employment discrimination based on genetic information and, as discussed above, N.J.S. 10:5-13 provides a private right of action for victims of employment discrimination. N.J.S. 10:5-47 sets conditions for disclosure of genetic information, but the GPA has no provision for directing disclosures to third parties. This has been addressed by a proposed revision to N.J.S. 10:5-47, which incorporates language from Section 20(b)(2) of the UPGIEA. N.J.S. 10:5-46 already allows employees to inspect and copy genetic information in the employer’s possession, and to request the correction of erroneous information.

The enforcement and remedies section establishes a state-law private cause of action for violations of the Act. It allows a state to use its fair employment enforcement apparatus and offers the option to exhaust administrative remedies prior to a private lawsuit. In contrast to the provisions of GINA, states may enforce the Act and employees may file a cause of action based on a theory of disparate impact. Remedies are not limited to those authorized for Title VII, therefore federal caps on damages do not apply. Awards of attorney’s fees generally follow federal law, are discretionary, and are authorized only for prevailing employees in order to cover the cost of enforcing the Act. Here, N.J.S. 10:5-49, in addition to providing fines and imprisonment for unlawful disclosure of genetic information, establishes a private right of action, whereby “[a]ny person who discloses an individual’s genetic information in violation [of law] shall be liable to the individual for all actual damages, including damages for economic, bodily, or emotional harm which is proximately caused by the disclosure.”

Commission’s Recommendation

While the Commission is mindful of the ULC’s concerns regarding uniformity, New Jersey’s GPA has been in place since 1996 and is a well-integrated work of legislation that already offers many of UPGIEA’s protections. Nevertheless, the Commission has identified
some areas where existing New Jersey law can be revised in order to bring it more in line with UPGIEA.

Appendix—Proposed Changes to Existing New Jersey Statute

The text of relevant sections of New Jersey’s Genetic Privacy Act, with proposed revisions shown with underlining/strikethrough, is as follows:

10:5-5. Definitions
As used in P.L.1945, c. 169 (C.10:5-1 et seq.), unless a different meaning clearly appears from the context:

a. “Person” includes one or more individuals, partnerships, associations, organizations, labor organizations, employment agencies, employment entities, labor-management committees, labor-management training or apprenticeship programs, credentialing authorities, corporations, legal representatives, trustees, trustees in bankruptcy, receivers, and fiduciaries.

b. “Employment agency” includes any person undertaking to procure employees or opportunities for others to work.

c. “Labor organization” includes any organization which exists and is constituted for the purpose, in whole or in part, of collective bargaining, or of dealing with employers concerning grievances, terms or conditions of employment, or of other mutual aid or protection in connection with employment.

d. “Unlawful employment practice” and “unlawful discrimination” include only those unlawful practices and acts specified in section 11 of P.L.1945, c. 169 (C.10:5-12).

e. “Employer” includes all persons as defined in subsection a. of this section unless otherwise specifically exempt under another section of P.L.1945, c. 169 (C.10:5-1 et seq.), and includes the State, any political or civil subdivision thereof, and all public officers, agencies, boards or bodies.

* * *

nn. “Genetic characteristic” means any inherited gene or chromosome, or alteration thereof, that is scientifically or medically believed to predispose an individual to a disease, disorder or syndrome, or to be associated with a statistically significant increased risk of development of a disease, disorder or syndrome.


oo. “Genetic information” means the information about genes, gene products or inherited characteristics that may derive from an individual or family member.

pp. “Genetic test” means a test for determining the presence or absence of an inherited genetic characteristic in an individual, including tests of nucleic acids such as DNA, RNA and mitochondrial DNA, chromosomes or proteins in order to identify a predisposing genetic characteristic.

qq. “Genetic counseling” includes providing an individual with an assessment of the individual’s genetic risk for an inherited genetic condition by interpreting family medical histories; educating an individual about the inheritance, testing, management, or prevention of a genetic condition using an approach that promotes the individual’s autonomy and self-direction in decisionmaking; helping an individual understand the risks and benefits of testing for a genetic trait to promote informed decisionmaking about whether to undergo genetic testing; communicating and interpreting test results; and providing support, informational resources, and referrals, as appropriate, to help an individual adapt to the medical, psychological, and familial implications of having or being at risk of having a genetic condition.

rr. “Employment entity” means an employer, employment agency, labor organization, labor-management committee, or credentialing authority.

ss. “Labor-management committee” means a person that establishes, offers, or controls apprenticeship or other training or retraining programs. The term includes an agent of the committee.

tt. “Credentialing authority” means a person that provides a license, registration, or credential or certifies competence necessary for an individual to qualify for employment or to participate in an occupation or profession.


VVVV. “Gender identity or expression” means having or being perceived as having a gender related identity or expression whether or not stereotypically associated with a person’s assigned sex at birth.

WWWW. “Civil Union” means a legally recognized union of two eligible individuals established pursuant to R.S.37:1-1 et seq. and P.L.2006, c. 103 (C.37:1-28 et al.).

XXXX. “Premium wages” means additional remuneration for night, weekend or holiday work, or for standby or irregular duty.
“Premium benefit” means an employment benefit, such as seniority, group life insurance, health insurance, disability insurance, sick leave, annual leave, or an educational or pension benefit that is greater than the employment benefit due the employee for an equivalent period of work performed during the regular work schedule of the employee.

10:5-45. Genetic information not to be obtained without prior informed consent; exceptions

No person shall obtain genetic information from an individual, or from an individual’s DNA sample, without first obtaining informed consent from the individual or the individual’s representative according to regulations promulgated by the Commissioner of Health and Senior Services, in consultation with the Commissioner of Banking and Insurance, pursuant to subsection b. of section 9 of P.L.1996, c. 126 (C. 10:5-48).

a. The requirements of this section shall not apply to genetic information obtained:

(1) By a State, county, municipal or federal law enforcement agency for the purposes of establishing the identity of a person in the course of a criminal investigation or prosecution;

(2) To determine paternity in accordance with the provisions of section 11 of P.L.1983, c. 17 (C. 9:17-48);


(4) To determine the identity of deceased individuals;

(5) For anonymous research where the identity of the subject will not be released;

(6) Pursuant to newborn screening requirements established by State or federal law; or

(7) As authorized by federal law for the identification of persons.

(8) When an employee voluntarily submits the genetic information to the employment entity and authorizes the employment entity’s acquisition and use of the information in accordance with 10:5-46; and the employment entity uses the genetic information only for the purposes authorized by the employee.

b. In the case of a policy of life insurance or a disability income insurance contract, informed consent shall be obtained pursuant to the provisions of P.L.1985, c. 179 (C. 17:23A-1 et seq.).
10:5-47. Disclosure of identity

a. Regardless of the manner of receipt or the source of genetic information, including information received from an individual, a person may not disclose or be compelled, by subpoena or any other means, to disclose the identity of an individual upon whom a genetic test has been performed or to disclose genetic information about the individual in a manner that permits identification of the individual, unless:

(1) Disclosure is necessary for the purposes of a criminal or death investigation or a criminal or juvenile proceeding;

(2) Disclosure is necessary to determine paternity in accordance with the provisions of section 11 of P.L.1983, c. 17 (C. 9:17-48);

(3) Disclosure is authorized by order of a court of competent jurisdiction;

(4) Disclosure is made pursuant to the provisions of the “DNA Database and Databank Act of 1994,” P.L.1994, c. 136 (C. 53:1-20.17 et seq.);

(5) Disclosure is authorized by the tested individual or the tested individual’s representative by signing a consent which complies with the requirements of the Department of Health and Senior Services;

(6) Disclosure is for the purpose of furnishing genetic information relating to a decedent for medical diagnosis of blood relatives of the decedent;

(7) Disclosure is for the purpose of identifying bodies;

(8) Disclosure is pursuant to newborn screening requirements established by State or federal law;

(9) Disclosure is authorized by federal law for the identification of persons; or

(10) Disclosure is by an insurer pursuant to the requirements of P.L.1985, c. 179 (C. 17:23A-1 et seq.).

(11) Disclosure is by an employment entity to a person that the employee or, if the genetic information is that of a family member, the family member of the employee has designated in a knowing, voluntary, written, and signed authorization which describes the genetic material to be disclosed, identifies the person to whom the genetic information is to be disclosed, indicates the duration of the authorization, and states that the individual is entitled to a copy of the authorization.

b. The provisions of this section apply to any subsequent disclosure by any person after another person has disclosed genetic information or the identity of an individual upon whom a genetic test has been performed.
10:5-48. Notice to person tested; rules and regulations for obtaining informed consent

a. A person who requires or requests that genetic testing be done or receives records, results or findings of genetic testing shall provide the person tested with notice that the test was performed and that the records, results or findings were received unless otherwise directed by informed consent pursuant to section 6 of P.L.1996, c. 126 (C. 10:5-45). The notice shall state that the information may not be disclosed to any person without the written consent of the person tested, unless disclosure is made pursuant to one of the exceptions provided for in section 8 of P.L.1996, c. 126 (C. 10:5-47).

b. A person who requires or requests that genetic testing be done shall provide genetic counseling about the risks and benefits of a genetic test before the individual authorizes the test unless:

(1) the individual knowingly and voluntarily waives counseling before the authorization in a signed record that contains information about the benefits of genetic counseling, or

(2) the test is part of genetic monitoring required by state or federal law.

bc. The Commissioner of Health and Senior Services, in consultation with the Commissioner of Banking and Insurance, shall promulgate regulations pursuant to the provisions of the “Administrative Procedure Act,” P.L.1968, c. 410 (C. 52:14B-1 et seq.) governing procedures for obtaining informed written consent pursuant to P.L.1996, c. 126, except where the procedures for obtaining informed written consent already are governed by national standards for informed consent as designated by the Commissioner of Health and Senior Services by regulation, which may include, but need not be limited to, guidelines from the Office of Protection for Research Risk, the Food and Drug Administration or other appropriate federal agencies.

d. The provisions of this section shall not apply to newborn screening requirements established by State or federal law.