

Date of Hearing: March 17, 2015

ASSEMBLY COMMITTEE ON PRIVACY AND CONSUMER PROTECTION

Gatto, Chair

AB 170 (Gatto) – As Amended March 11, 2015 **As Proposed to be Amended**

SUBJECT: Newborn screening: genetic diseases: blood samples collected

SUMMARY: Requires the Department of Public Health (DPH) to prepare and provide informational materials about the California Newborn Screening Program (CNSP) to a parent or guardian of a newborn prior to a newborn screening test, and requires DPH to obtain written informed consent from a parent or legal guardian before storing, retaining and using a newborn's blood sample for medical research. Specifically, **this bill:**

1) Requires DPH to:

- a) Obtain the informed consent of the parent or guardian of a newborn child before storing, retaining or using a newborn child's blood sample for medical research and defines "informed consent" for purposes of the CNSP as "a written authorization signed and dated by a parent or legal guardian of a newborn child";
- b) Destroy, or not use for research purposes, the blood sample of a minor, upon request of the minor's parent or legal guardian;
- c) Destroy, or not use for research purposes, the blood sample of an individual who is at least 18 years of age, upon request of the individual;
- d) Prepare and provide informational materials on the CNSP that explain to parents and guardians of newborn children the following:
 - i. The storage, retention and use of the blood sample;
 - ii. The parent or guardian's right to request that a blood sample be destroyed or not used for research purposes; and
 - iii. The right of an individual at least 18 years of age to request that his or her blood sample be destroyed or not used for research purposes.
- e) Prepare and provide a standard informed consent form for the CNSP that sets forth clearly and in detail the following:
 - i. The purpose of the newborn child screening test and retention of newborn blood samples;
 - ii. The benefits of the screening and the research undertaken regarding heritable and congenital disorders;
 - iii. A space for the parent or legal guardian to acknowledge receipt of informational materials about the newborn child screening test;
 - iv. A space for the parent or legal guardian to indicate his or her consent to the storage, retention, and use of the newborn's blood sample for medical research;

- v. A space for the parent to legal guardian to indicate his or her request for information about the right to refuse a newborn child screening test on the ground that the test conflicts with his or her religious beliefs or practices; and
 - vi. A space for the parent or legal guardian to sign and date the form.
- 2) Requires that a parent or guardian of a newborn child must receive the CNSP informational materials and informed consent form prior to the newborn screening test.
 - 3) Requires every birth attendant engaged in perinatal care to provide the DPH informational materials and standard informed consent form to a pregnant woman.
 - 4) Requires every perinatal licensed health facility to provide the DPH informational materials and standard informed consent form to each pregnant woman admitted for delivery prior to the collection of the blood sample, if the consent form was not already provided during perinatal care.
 - 5) Requires every local registrar of births to provide the DPH informational materials and standard informed consent form to each person registering the birth of a newborn that occurred outside of a perinatal licensed health facility when the newborn was not admitted to a perinatal licensed health facility within the first 30 days of age.
 - 6) Requires a copy of the standard informed consent form to be maintained with the newborn child's medical records.
 - 7) Specifies that DPH may not store, retain, or use for medical research a newborn child's blood sample collected and used for the newborn screening test, unless the parent or guardian of the newborn child indicates his or her consent on a completed informed consent form.
 - 8) Makes other clarifying or nonsubstantive changes.

EXISTING LAW:

- 1) Requires DPH to establish a genetic disease unit to coordinate all DPH programs in the area of genetic disease that promotes a statewide program of information, testing, and counseling services, designates tests and regulations to be used in executing this program, and designates tests and regulations used in executing the CNSP. (Health and Safety Code (HSC) Section 124977 *et seq.*)
- 2) Requires DPH to fully inform a parent or guardian of a minor of the purposes of testing for hereditary disorders prior to performing any genetic testing. (HSC 124980)
- 3) Specifies that no test may be performed on any minor over the objection of the minor's parent or guardian and requires DPH to give a parent or guardian of a minor a reasonable opportunity to object. (HSC 124980)
- 4) Gives the parent or guardian of the newborn child a specific option to object to the newborn screening test on the ground that the test conflicts with his or her religious beliefs or

practices. (HSC 125000)

- 5) Requires DPH to provide genetic screening and follow-up services, allows DPH to provide laboratory testing facilities or work with qualified outside labs to conduct testing, requires DPH to charge a fee for newborn screening and follow-up services, and requires the amount of the fee to be periodically adjusted in order to meet the costs of CNSP. (HSC 124977 and 125000)
- 6) Prohibits, under the State Confidentiality of Medical Information Act (CMIA), providers of health care, health care service plans, or contractors, as defined, from sharing medical information without the patient's written authorization, subject to exceptions, including among others, certain research. (Civil (Civ.) Code Section 56 *et seq.*)
- 7) Protects, under the federal Health Insurance Portability and Accountability Act (HIPAA), the privacy of patients' health information and generally provides that a covered entity, as defined (health plan, health care provider, and health care clearing house), may not use or disclose "protected," i.e., individually identifiable, health information except as specified or as authorized by the patient in writing. (45 Code of Federal Regulations Section 160 *et seq.*)
- 8) Prohibits, under the Unruh Civil Rights Act and the Fair Employment and Housing Act (FEHA), discrimination on the basis of genetic information. (Civ. Code 51 and Government Code Section 12920 *et seq.*)
- 9) Prohibits, under the federal Genetic Information and Nondiscrimination Act (GINA), discrimination in group health plan coverage and employment based on genetic information. (Public Law 110-233)
- 10) Requires separate written consent for the release of certain types of sensitive medical information, including: HIV status and test results, the donation of human egg cells for research purposes, and genetic test results for life or disability insurance applications. (HSC 120975-121125; HSC 125350 *et seq.*; and Insurance Code (IC) Section 10140.1)
- 11) Establishes various penalties concerning the disclosure of genetic test results, when the genetic test is requested by an insurer for purposes of life or disability insurance. (IC 10149.1)

FISCAL EFFECT: Unknown

COMMENTS:

- 1) Purpose of this bill. This bill is intended to ensure that parents receive information about the CNSP and protect children's genetic privacy by requiring DPH to obtain written informed consent from parents and guardians before keeping and using children's genetic data for medical research. This measure will be heard as proposed to be amended, based upon mocked-up amendments provided by the author. This measure is author-sponsored.
- 2) Author's statement. According to the author's office, "AB 170 is necessary because, regardless of current regulations, the majority of parents are not aware that their child's newborn blood sample is being retained by the state and may potentially be used in research.

A report from the Council for Responsible Genetics cites numerous studies that indicate the vast majority of surveyed parents would prefer an informed consent process instead of the current opt-out afforded to them. Most interestingly, a study by Beth Tarini found that “[i]f parental permission was obtained, most parents reported that they would either be ‘very willing’ (38%) or ‘somewhat willing’ (37.4%) to permit use of their children’s newborn screening samples for future research studies . . . If parental permission was not obtained, substantially fewer parents reported that they would either be ‘very willing’ (11.3%) or ‘somewhat willing’ (16.9%) to permit use of the [CNSP] sample for research. Moreover, over half of parents (55.7%) would be ‘very unwilling’ to permit the use of their child’s newborn screening sample for research purposes.”

- 3) CNSP. According to DPH, the CNSP is recognized nationally as an essential preventive health program. All states in the nation and the District of Columbia have established newborn screening programs. In California, the test is administered to virtually every newborn before the baby leaves the hospital by taking a few drops of blood from the baby’s heel and placing the blood spots on a special filter paper that is then sent to a state-approved laboratory for testing.

If identified early, many genetic disorders can be treated before they cause serious health problems. According to DPH, approximately 500,000 newborns are screened each year for over 80 genetic and congenital disorders, and about 875 children are identified with a genetic disorder each year in California. Parents can get the test results from the baby’s doctor or clinic, which takes about two weeks. If the baby needs more tests, parents will get a letter or a phone call a few days after discharge from the hospital. Positive test results are immediately telephoned to a follow-up coordinator at one of the Newborn Screening Area Service Centers throughout the state. The coordinator contacts the newborn’s physician to arrange for repeat testing. If repeat testing determines that the baby has a disorder, the coordinator will supply the latest clinical information on diagnosis and treatment and assist with referrals to special care clinics. Medi-Cal, health plans, and most private insurance providers pay for the test.

- 4) The California Biobank. According to DPH, blood samples collected from newborns under the CNSP are maintained in the California Biobank which contains the combined biospecimen and data resources of two DPH screening and monitoring programs, the California Genetic Disease Screening Program (GDSP) and the California Birth Defects Monitoring Program. GDSP administers the CNSP and the Prenatal Screening Program. The California Biobank is required to make specimens and related data available to researchers for the following approved purposes:
 - a) Identify risk factors for children’s and women’s diseases;
 - b) Develop and evaluate screening tests;
 - c) Develop and evaluate screening strategies; and,
 - d) Develop and evaluate treatments.

The California Biobank houses more than 16 million newborn blood samples. According to DPH, since the CNSP began in 1980, the GDSP has banked leftover blood spots from screened newborns in freezer storage, but only those banked since 1982 are readily available. The specimens are physically labeled with a unique number and stored without any

identifying information. Researchers may receive both specimens and the data related to specimens. GDSP's 16 million newborn specimens represent "an entire generation of Californians" according to DPH.

- 5) Current privacy and consumer protections for genetic data. Currently, federal and state laws offer various protections for genetic information. For example, HIPAA and CMIA generally require a patient's written consent before disclosure of medical information. In 2008, the federal government enacted GINA to prohibit discrimination in group health plan coverage and employment based on genetic information. In California, the Unruh Civil Rights Act and FEHA prohibit discrimination on the basis of genetic information.

Current law governing the CNSP requires DPH to fully inform a parent or guardian of the purposes of the newborn screening test and offer a reasonable opportunity to opt-out of the test for religious reasons.

This bill would expand the current privacy protections in place for CNSP by creating an opt-in consent requirement – not for the test itself – but for the future storage, retention and use of a newborn's blood sample for medical research. In addition to requiring opt-in consent for medical research uses, the bill also strengthens current privacy law by specifically requiring informational materials about the CNSP program to be provided *prior* to newborn testing, and by requiring DPH to create and use a standard informed consent form that contains spaces for a parent or guardian to:

- a) Acknowledge receipt of informational materials;
 - b) Opt in to medical research uses of the blood sample taken; and,
 - c) Request more information about opting out of the newborn screening test itself.
- 6) Privacy and genetic data. As noted by the United States Department of Health and Human Services (DHHS) in a 2009 progress report, genetic information raises unique ethical and legal issues that other types of medical information may not. According to that report: "A particular concern is that whole-genome scans will provide a unique DNA identifier that could potentially be linked with data obtained or stored in other contexts, which has implications for consent and privacy." (A Progress Report and Future Directions of the Secretary's Advisory Committee on Genetics, Health, and Society, *The Integration of Genetic Technologies Into Health Care and Public Health*, January 2009, p. 8.)

While the benefits of having large databanks of genetic data for medical research are undisputed, the author contends that the unknown potential future uses of genetic data create the need for revisiting current law privacy protections for genetic data. In fact, in October 2012, the Presidential Commission for the Study of Bioethical Issues, an advisory panel of the nation's leaders in medicine, science, ethics, religion, law, and engineering, released a report that recommends adopting new policies to help ensure privacy and security as the field of genomics advances and urged federal and state governments to ensure a consistent floor of privacy protections covering whole genome sequencing data regardless of how that genetic information was obtained. (Privacy and Progress in Whole Genome Sequencing, *Presidential Commission for the Study of Bioethical Issues*, Oct. 11, 2012)

By way of precedent, California law already requires a separate written consent for other types of sensitive medical information, including:

- a) Genetic test results for a life or disability insurance application;
 - b) HIV status and test results, except for diagnosis, care, and treatment; and,
 - c) Donation of human egg cells for research purposes.
- 7) Arguments in support. The American Federation of State, County and Municipal Employees (AFSCME) states in support of the bill, “AFSCME supports AB 170 because we believe that a person must have the right to decide how their blood samples are being used.”
- 8) Arguments in opposition. According to the California Hospital Association, “This bill changes the current system of testing newborns for preventable heritable and congenital disorders which has worked very well in California for over 30 years. Currently, hospitals provide new mothers with written information developed by the California Department of Public Health about newborn testing. Mothers then have the ability to decline the testing if they wish. Very few mothers decline testing their babies for these disorders. The net result of this bill would be to decrease the number of newborns tested for these devastating disorders which can be prevented or ameliorated if detected.”
- 9) Prior Legislation. AB 1559 (Pan), Chapter 565, Statutes of 2014, expanded DPH statewide screening of newborns to include screening for adrenoleukodystrophy (ALD) as soon the federal Recommended Uniform Screening Panel approved the addition of ALD.

SB 222 (Padilla) of 2014 would have enacted the Genetic Information Privacy Act, which would have required an individual’s written authorization prior to the collection of genetic information for testing, analysis, retention or disclosure. SB 222 was held in the Senate Appropriations Committee.

SB 1267 (Padilla) of 2012 would have required an individual’s written authorization prior to the collection of genetic information for testing, analysis, retention or disclosure. The bill would have required destruction of the genetic information upon completion of the purpose authorization was obtained. SB 1267 was held in the Senate Appropriations Committee.

SB 1731 (Block), Chapter 336, Statutes of 2012, established the Newborn Critical Congenital Heart Disease (CCHD) Screening Program and required hospitals, beginning July 1, 2013, to offer a pulse oximetry test for the identification of CCHD to parents of newborns prior to discharge.

AB 395 (Pan), Chapter 461, Statutes of 2011, expanded statewide screening of newborns to include screening for severe combined immunodeficiency.

SB 1103 (Committee on Budget and Fiscal Review), Chapter 228, Statutes of 2004, expanded statewide screening of newborns to include tandem mass spectrometry screening for fatty acid oxidation, amino acid, organic acid disorders, and congenital adrenal hyperplasia.

AB 442 (Committee on Budget), Chapter 1161, Statutes of 2002, required hospitals to collect

fees associated with any tests conducted under CNSP.

SB 537 (Greene), Chapter 1011, Statutes of 1998, required DPH to establish a program to provide extended newborn genetic screening services for persons who elect to have, and pay for, the additional screening.

10) Double-referral. This bill has been double-referred to the Assembly Health Committee, where it will be heard if passed by this Committee.

REGISTERED SUPPORT / OPPOSITION:

Support

American Federation of State, County and Municipal Employees (AFSCME)

Opposition (Prior Version)

California Hospital Association (CHA)

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