SENATE JUDICIARY COMMITTEE
Senator Thomas Umberg, Chair
2023-2024 Regular Session

SB 625 (Nguyen)
Version: April 24, 2023
Hearing Date: April 25, 2023
Fiscal: Yes
Urgency: No
CK

SUBJECT

Newborn screening: genetic diseases: blood samples collected

DIGEST

This bill makes changes to the California Newborn Screening Program, including requiring the California Department of Public Health to permit parents or legal guardians to withhold consent to the storage, retention, and use of the newborn's blood sample for medical research.

EXECUTIVE SUMMARY

The California Newborn Screening Program (CNSP) screens all babies born in California for various serious, but treatable, genetic disorders. At the outset, the program tested for only one disorder, phenylketonuria (PKU). However, the program has expanded to cover over 80 different disorders. Currently, the only valid basis for objecting to the test is if the testing conflicts with the parents' religious beliefs or practices.

Concerns have arisen about parental consent and notice regarding blood specimen collection, retention, and use. This bill makes a number of changes to the program. It requires the California Department of Public Health (CDPH) to permit the parent or legal guardian to withhold consent to allow for the storage and confidential use of the blood sample of the child for research purposes. The parent or legal guardian shall be offered the opportunity to withhold their consent in writing before or at the time the blood sample of the minor is taken. It empowers the parent or legal guardian of the child, and the child, as provided, to request CDPH destroy the blood sample, or not use it for research purposes, or both. The bill prohibits the specimen from being released to any person or entity for law enforcement purposes.

This bill is sponsored by the California Health Coalition Advocacy. It is supported by various civil liberties organizations, including the Electronic Frontier Foundation and A

Voice for Choice Advocacy. It is opposed by the California Hospital Association and the California Children's Hospital Association. The bill passed out of the Senate Health Committee on a 7 to 1 vote.

PROPOSED CHANGES TO THE LAW

Existing law:

1) Requires CDPH to establish a genetic disease unit to coordinate all CDPH programs in the area of genetic disease that will promote a statewide program of information, testing, and counseling services; and, have the responsibility of designating tests and regulations to be used in executing the California Newborn Screening Program (CNSP). (Health & Saf. Code § 125000.)

2) Requires CDPH to include in the CNSP screening for phenylketonuria, fatty acid oxidation, amino acid, organic acid disorders, congenital adrenal hyperplasia, severe combined immunodeficiency (SCID), adrenoleukodystrophy (ALD), and any other disease that is detectable in blood samples as soon as practicable, but no later than two years after the disease is adopted by the federal Recommended Uniform Screening Panel (RUSP) or state law is amended, whichever is later. (Health & Saf. Code §§ 125000, 12501.)

3) Requires CDPH to evaluate and prepare recommendations on the implementation of tests for the detection of hereditary and congenital diseases, including, but not limited to, biotinidase deficiency and cystic fibrosis. Requires CDPH to also evaluate and prepare recommendations on the availability and effectiveness of preventative follow-up interventions, including the use of specialized medically necessary dietary products. (Health & Saf. Code § 125000.)

4) Requires birth attendants to provide pregnant women, prior to the estimated delivery date, with a copy of CDPH's informational material entitled "Important Information for Parents." Requires perinatal licensed health facilities to provide the same to women admitted for delivery if she has not already received it and to translate or read the material in a language she understands if she cannot read it. (17 C.C.R. §§ 6504, 6504.2.)

5) Authorizes the parent or guardian of a newborn child to opt out of the CNSP if they object to a test on the ground that the test conflicts with their religious beliefs or practices. Requires parents or guardians who opt out to sign a refusal form approved by CDPH and provided by the physician or birth attendant. Requires the form to be translated or read in a language understood by the parent or guardian if they cannot read the form. (Health & Saf. Code § 125000; 17 C.C.R. § 6501.2.)

6) Requires perinatal health facilities to collect the CNSP blood spot specimen when a newborn is between 12 and 48 hours old, with certain exceptions, and send such specimen to a CNSP laboratory on the same or next business day. For infants not born in a perinatal licensed health facility, but admitted to such a facility, the facility is required to obtain a specimen within 48 hours of admission and send it to a CNSP laboratory on the same or next business day. For infants neither born nor admitted to a perinatal licensed health facility after birth, the out-of-hospital provider is required to collect the CNSP specimen when a newborn is between 12 and 48 hours old, unless a religious objection is executed, and sent to a CNSP laboratory on the same or next business day. (17 C.C.R. § 6505.)

7) Requires county registrars of births to provide a copy of the informational material described above to each person registering the birth of a newborn that occurred outside of a perinatal health facility when the newborn was not admitted to such a facility within the first 30 days of age. Requires the county registrar of birth to notify the local health officer and CDPH of this birth, and requires the local health department to make every reasonable effort to obtain CNSP specimens. Permits local health departments, with permission from CDPH, to terminate efforts to obtain the CNSP specimen after 30 days. (17 C.C.R. §§ 6505, 6507.1.)

8) Requires CDPH to provide the following forms for the administration of the CNSP: the California Newborn Screening Test Request Form (CDPH-4409) and the Notification of Registration of Birth Which Occurred Out of a Licensed Health Facility (CDPH-4460). (17 C.C.R. § 6501.5.)

9) Requires CNSP results to be available to individuals over 18 years of age or the individual's parent or guardian. Requires results to be held as a confidential medical record, except for data compiled without reference to the identity of any individual and for research purposes, provided that the research has first been reviewed and approved by an institutional review board, as specified. Requires any disclosure of information to preserve the anonymity of the persons tested unless the person has given written consent to disclose the information. (Health & Saf. Code § 124980; 17 C.C.R. § 6502.1.)

10) Requires CDPH 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 the CNSP. (Health & Saf. Code § 125000.)

This bill:

1) Requires CDPH to permit the parent or legal guardian to withhold consent to allow for the storage and confidential use of the blood sample of the minor for

research purposes by CDPH or their approved researchers. The parent or legal guardian shall be offered the opportunity to withhold their consent in writing before or at the time the blood sample of the minor is taken.

2) Prohibits a residual newborn screening specimen from being released to any person or entity for law enforcement purposes or to establish a database for forensic identification.

3) Grants a parent or legal guardian of a minor, or the minor once an adult, the right to request CDPH to destroy the blood sample of the minor collected as a newborn, or not use it for research purposes, or both, and CDPH shall comply with that request. If the person makes the request by email and provides their email address, the department shall send an email acknowledging that the department received the request. If the request is in writing, CDPH shall send a written acknowledgment that the department received the request.

4) An individual who is at least 18 years of age may request the department to destroy, not use for research purposes, or both, their blood sample that was collected, and the department shall do so. If the individual makes the request by email and provides their email address, the department shall send an email acknowledging that the department received the request. If the individual makes the request in writing, the department shall send a written acknowledgment that the department received the request.

5) Requires CDPH to prepare and provide an informational brochure regarding newborn child blood samples collected pursuant to this program that includes:

    a) a brief, plain-language explanation of, and the purpose for, the newborn child screening test and the storage, retention, and use of newborn child blood samples collected pursuant to this article, including that the samples may be shared with third parties for research purposes;
    b) a description of the benefits of both early newborn child screening and the associated research undertaken regarding preventable heritable or congenital disorders;
    c) a description of the California Biobank Program, specifically as it pertains to the Genetic Disease Screening Program, and subsequent storage, retention, and use of the newborn child's blood sample for medical research;
    d) the parent or legal guardian's right to refuse the test based on their religious beliefs;
    e) the parent or legal guardian's right to withhold consent for their minor child's blood sample to be stored and used for research purposes.
    f) the parent or legal guardian's right to request that their minor child's blood sample be destroyed, not used for research purposes, or both, if the

parent or legal guardian has not initially withheld consent to the sample being stored and used for research purposes at the time the sample is taken, and the information necessary to make that request; and

g) the right of an individual who is at least 18 years of age to request that their blood sample be destroyed, not used for research purposes, or both, and the information necessary to make that request.

6) Provides that the above informational brochure be confined to a single, double-sided page and presented in a separate document from the standard informational acceptance, consent, or refusal form required in Section 125004.

7) Requires CDPH to prepare a separate standard informational acceptance, consent, and refusal form that includes all of the following:
   a) a brief, plain-language explanation of, and the purpose for, the newborn child screening test and retention of newborn child blood samples collected pursuant to this article, including that the samples may be shared with third parties for research purposes;
   b) an explanation of the parent's or legal guardian's right to request that their minor child's blood sample be destroyed or not used for research purposes, or both, if the parent or legal guardian has not initially withheld consent to the sample being stored and used for research purposes at the time the sample is taken, and the information necessary to make that request;
   c) a space for the parent or legal guardian of the newborn child to provide a signed and dated written acknowledgment of receipt of the informational brochure regarding the storage, retention, and use of the newborn child's blood sample for medical research;
   d) a space for the parent or legal guardian of the newborn child to withhold consent for the use of the newborn blood sample for research purposes, but still allow for the storage of the sample;
   e) a space for the parent or legal guardian of the newborn child to withhold consent for the storage and use of the newborn blood sample for research purposes; and
   f) a space for the parent or legal guardian of the newborn child to refuse the newborn screening test on their newborn or infant for religious reasons.

8) Requires the standard form to be confined to a single page and presented in a separate document from the informational brochure required in Section 125003. A copy shall be maintained by the birth attendant or the perinatal licensed health facility in the medical record of the mother of the newborn child. In the event that emergency circumstances make it impossible to obtain the signed standard form, a note shall be placed in the medical record of the mother documenting the emergency or reason why the form could not be obtained, and the newborn child shall be administered the genetic screening test and the newborn child blood

sample shall be stored and retained for medical research pursuant to Section 125000.

9) Defines "informational acceptance, consent, and refusal form" or "standard form" to mean the form described above.

10) Requires the informational brochure and the standard form to be distributed as follows:
    a) a birth attendant engaged in providing perinatal care shall provide a pregnant woman, at least four weeks prior to the estimated date of delivery, with a copy of the informational brochure and a copy of the standard form provided by CDPH;
    b) if the informational brochure or standard form has not been so provided, a perinatal licensed health facility shall provide each pregnant woman admitted for delivery with a copy of the informational brochure and a copy of the standard form; and
    c) the local registrar of births and deaths shall provide a copy of the informational brochure and a copy of the standard 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 after birth. The local registrar of births and deaths shall notify the local health officer and the department of each of these registrations.

11) Defines "birth attendant" as a person licensed or certified by the state to provide maternity care and to deliver pregnant women or to practice medicine. "Perinatal licensed health facility" means a health facility licensed by the state and approved to provide perinatal, delivery, newborn intensive care, newborn nursery, or pediatric services.

COMMENTS

1. Screening newborns for potential genetic disorders

The California Newborn Screening (NBS) Program is a public health program that screens all babies for many serious but treatable genetic disorders. Newborn screening began in California in 1966 and has grown to include screening for 80 different disorders, both genetic (passed down in families) and congenital (present at birth). The purpose of the program is to detect these disorders early so they can be treated from shortly after birth.

Medical professional take a blood sample from each newborn baby within the first few days of birth and carry out the screening. Currently parents can object to the screening only on religious grounds. However, all parents are authorized to thereafter contact

the program to have the blood specimen destroyed after screening.

Attendant regulations require that pregnant persons are given a copy of the informational material, entitled "Important Information for Parents," provided by CDPH. The brochure lays out what the program is, why it is carried out, and how it is done. It also lays out what happens with the blood specimen after the testing:

> **What Happens to My Baby's Blood Spots After the Newborn Screening Test is Done?** California, like many other states, stores newborn screening bloodspot cards. The bloodspot cards may be used for tests to improve the screening program or to develop tests for new disorders. The bloodspots may also be used for studies about diseases in women and children. The stored bloodspot cards do not have information, such as names or addresses, that can be used to identify you or your baby. The program follows all federal and state privacy and research laws. If you want the bloodspot card destroyed after the newborn screening test is done, that is your right.
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> To learn more about the storage and use of leftover blood spots, or to find out how to get your baby's bloodspot card destroyed, visit: https://www.cdph.ca.gov/Programs/CFH/DGDS/Pages/NBS/IIP.aspx

California law requires the NBS program to use or provide newborn screening specimens for department-approved studies of diseases in women and children, such as research related to identifying and preventing disease. This could be to study birth defects, chronic disease, exposure to toxins or infections.

2. Providing disclosures and notice of rights

This bill seeks to further increase parental and individual control around the program. According to the author:

> Through great strides made in medical technology and science, humans can literally see the genetic building blocks that make them who they are and, in some instances, can use that information for genealogical or medical histories for families. But with great power and technology, some guardrails should be established, especially about who can access the genetic information and data. Parents and guardians should be fully informed about the process of collecting, analyzing and storing genetic information collected from newborn infants. There is no denying the importance of the work by the Department of Public Health and this screening program but Californians should have a choice in how their information is used and accessed.

This bill statutorily requires creation and dissemination of an information brochure that educates parents about the newborn screening program, the benefits of the program, and the parents' rights with regard to the program. This includes not only the right to refuse the test for religious reasons and the right to ask for the destruction of the specimen collected, but also the right to withhold consent to allow for the storage and confidential use of the blood sample for research purposes by CDPH. The bill establishes this right and specifically requires that the parent be offered the opportunity to withhold consent in writing before or at the time the blood sample of the baby is taken.

The bill also requires a standard form to be created. The form must again inform parents about the program and what is done with the blood samples, and include a description of the parents' rights. The form must also have spaces for the parent to provide a written acknowledgment of receipt of the informational brochure; for the parent to withhold consent for the use and/or storage of the specimen; and to refuse the screening test for religious reasons.

The bill also imposes a strong protection for specimens collected. It explicitly prohibits releasing a residual newborn screening specimen to any person or entity for law enforcement purposes or to establish a database for forensic identification.

The law in part is driven by articles sounding the alarm as to potential privacy intrusions into the biobanks holding these specimens. One began:

> It's a little-known fact: California stores newborn blood spot (NBS) samples from every child born in the state. Parents don't have to consent, so many don't even know.
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> DNA from the samples may be used for potentially life-saving research, but in light of the Golden State Killer case and evolving DNA technology, there are new questions about what else the DNA is being used for and why the state does not ask for consent before indefinitely storing a child's DNA.[1]

The Electronic Frontier Foundation writes in support:

> Newborn screening is standard in California and across the country and is considered one of the most successful public health programs. The increasing use of the database for law enforcement investigations, however, threatens to undermine the trust everyone can place in this

[1] Julie Watts, *CA Still Storing Newborn DNA Without Consent. Golden State Killer Case Raising New Concerns* (Dec. 7, 2020) CBS Sacramento, https://www.cbsnews.com/sacramento/news/newborn-dna-california-consent-gsk-killer/ [as of Apr. 21, 2023].

> important database. S.B. 625 would ensure that the state places commonsense privacy guardrails on this information, including blocking its use from law enforcement and setting reasonable data maintenance and consent rules around the
> information.
>
> California takes pride in leading the country on protecting privacy, enshrining the right to privacy in the state constitution by ballot initiative in 1972. Yet California parents are not informed about the blood samples taken from every infant and stored indefinitely in the state's database.2 No one is asked for their consent to participate in medical research that may use that database. No one is asked if it is alright when researchers work to map the genomes from these samples. No one can ask for them to be destroyed. S.B. 625 would establish rules to give people this kind of control over these samples—collected for the best of intentions, but increasingly reappropriated for uses that are far outside the original intent.

California Health Coalition Advocacy, the sponsor of the bill, writes that the bill is "needed to provide important information about newborn screening to parents and guardians and protect the genetic privacy of children born in California."

Writing in opposition, the California Hospital Association asserts:

> Current law requires health care providers to give all pregnant patients a one-page handout from CDPH that explains the newborn screening program. The handout informs patients about how to opt out of having their baby's blood spot tested for religious reasons and how to have their baby's blood spot destroyed after testing so it is not used for research.
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> As currently written, SB 625 would require every Californian giving birth (500,000 per year) to fill out a form with three choices (whether or not to test/store/use blood for research) and four different signature lines (acknowledgement of receipt, test, store, research). The bill would create a huge administrative challenge for moms, obstetricians, hospitals, and CDPH to obtain, store, and transmit these 500,000 forms and, most importantly, match them to the correct baby and blood spot card. It is inevitable that mistakes will be made (by the mother, doctor, hospital, or CDPH), and some babies will fall through the cracks and not get tested — with potentially devastating consequences.

Stanford Hospital writes in opposition:

> California enjoys a robust newborn screening program that allows for early detection of numerous rare and serious conditions. With this

information in hand, pediatricians and others are in a position to promptly treat these conditions before more serious health issues arise. Additionally, the research use of these samples and related data is essential to develop better diagnostic tests for congenital and heritable diseases as well as illnesses from environmental exposure.

Stanford and others in the hospital community are concerned the bill could compromise California's newborn screening program by making it an opt-in, as opposed to the current opt-out option. Additionally, by requiring the new interim step of obtaining written consent, further administrative time and resources will be needed for proper documentation.

SUPPORT

California Health Coalition Advocacy (sponsor)
A Voice for Choice Advocacy
ACLU California Action
American Nurses Association - California
California Health Coalition Advocacy
Central Coast Health Coalition
Educate. Advocate.
Electronic Frontier Foundation
National Association of Pediatric Nurse Practitioners (NAPNAP)
Physicians & Patients Reclaiming Medicine

OPPOSITION

California Children's Hospital Association
California Hospital Association
Children's Specialty Care Coalition
Children's Hospital of Orange County
Lucile Packard Children's Hospital – Stanford Children's Health
Stanford Health Care

RELATED LEGISLATION

Pending Legislation: SB 570 (Becker, 2023) prevents CDPH from prohibiting a laboratory, as specified, from offering all noninvasive prenatal tests, as ordered by a prenatal care provider, or otherwise limit the number of tests that the laboratory may provide to a pregnant person who has an order from a prenatal care provider. SB 570 is currently in the Senate Appropriations Committee.

Prior Legislation:

SB 41 (Umberg, Ch. 596, Stats. 2021) established the Genetic Information Privacy Act, providing additional protections for genetic data by regulating the collection, use, maintenance, and disclosure of such data.

AB 556 (Maienschein, Ch. 170, Stats. 2021) established a private cause of action for damages against a person who misuses sperm, ova, or embryos in violation of Section 367g of the Penal Code. AB 556 provides for damages for a prevailing plaintiff, including actual or statutory damages.

AB 170 (Gatto, 2015) was substantially similar to this bill. AB 170 died in Senate Health.

PRIOR VOTES:

Senate Health Committee (Ayes 7, Noes 1) Do pass as amended.
Senate Health Committee (Ayes 11, Noes 0) Reconsideration granted.
Senate Health Committee (Ayes 6, Noes 1) Failed passage in Committee.

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