

APHL Newborn Screening Symposium 2024

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Model language for state regulations regarding NBS specimen and data access by law enforcement and related entities

A Roundtable Conversation

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Objectives

- Describe experiences of states that have allowed law enforcement access to newborn screening specimens and data.
- Discuss issues related to the use of newborn screening specimens and related data by law enforcement and other related entities.
- Identify possible policy options and model language which states may incorporate to prohibit law enforcement access and use of newborn screening specimens and related data.



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Background

- The Newborn Screening Ethical, Legal, Social, and Policy Issues (ELSPI) Subcommittee reviewed existing state statutes regarding law enforcement access to newborn screening resources in developing language to help states clearly prohibit law enforcement access and use of these residual samples and associated data in such investigations.
- In this roundtable session, we will present several possible policy options and their rationale, which attendees can modify to suit their state's needs. Attendees will leave with model language ready for incorporation into state regulation, policy or statute after appropriate review and approval by their policy makers.



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State, federal laws

- Iowa Administrative Code 641.4.2(8)(e): “A residual newborn screening specimen shall not be released to any person or entity for commercial purposes, law enforcement purposes or to establish a database for forensic identification” (Recently amended to apply to the prohibited release of newborn screening information, as well.)
- **Proposed** New Jersey bill A4642: A person shall not 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 Attorney General and Commissioner of Banking and Insurance... The requirements of this section shall not apply to genetic information obtained: ... From a newborn [screening requirements established by State or federal law] for the purposes of detecting disorders or conditions for which newborn screening is explicitly authorized pursuant to the Newborn Screening Program in the Department of Health,... unless the use is authorized by: (a) an order of a court of competent jurisdiction; or (b) with the informed consent of the newborn’s parent or guardian;...
- A state statutory privilege would not apply to the federal government because federal policy can supersede state statutes.



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State laws, continued

- Minnesota: Subd. 5. Newborn screening program operations.

(a) "Newborn screening program operations" means actions, testing, and procedures directly related to the operation of the newborn screening program, limited to the following:

- (1) confirmatory testing;
- (2) laboratory quality control assurance and improvement;
- (3) calibration of equipment;
- (4) evaluating and improving the accuracy of newborn screening tests for conditions approved for screening in MN;
- (5) validation of equipment and screening methods;
- (6) continuity of operations to ensure testing can continue as required by Minnesota law in the event of an emergency;
- (7) follow-up services for the cases of heritable and congenital disorders identified by newborn screening; and
- (8) utilization of blood samples and test results for studies related to newborn screening, including studies used to develop new tests.

(b) No research or public health studies other than those described in paragraph (a) shall be conducted without written consent as described under subdivision 7.

(c) Any sale of bloodspots, test results, or other data collected in the newborn screening program is strictly prohibited.



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Concept of stewardship vs. ownership of specimens and data

- Who “owns” the specimens and related data, and therefore who has the authority to release
- States vary –
 - Michigan BioTrust has “qualified” ownership – holds the specimen in trust
 - Iowa Newborn Screening Program acts as “steward” of the data and specimens but are not the owner.



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Considerations

- Law enforcement generally believes that implied negation within regulatory language is not actual negation of law enforcement access – for this reason, may be better to directly state that law enforcement does not have access, or rDBS is not subject to law enforcement use.
- Access by law enforcement should be the same for spots and for data in regulatory language.
- Protections for specimens that are involved in research may imply that those protections don't apply to other specimens (non-research specimens); language should be the same for both to ensure equal protection of all specimens.
- Even if listing out specific allowed uses, be more explicit and also specify that law enforcement does not/may not use or have access to the specimens and data.
- Which parent may grant permission? This could present a conflict if there is a competing interest between the parents.



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Sample language

- “A residual newborn screening specimen and/or its related data shall not be released to any person or entity for commercial purposes or law enforcement purposes or to establish a database for forensic identification.”



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Breakout group questions: 15 minutes

- What are current practices/policies across states regarding who can access rDBS and related information and to whom can they be released (i.e., does your state have a policy?)
 - If no policy is in place, would a model like this be useful to help develop/guide such policy or regulation in your state?
- Would you propose any revisions to the language?
- What would be the barriers to you implementing such regulation or legislation?
 - Can the subcommittee provide any support in implementing this language?
- What is the frequency of requests from law enforcement agencies?
- What are states' needs around policy development?
- What are states' general concerns around this topic?
- Would it be helpful to hold a national meeting with state NBS representatives and their legal counsels to discuss NBS policy and legal issues?



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Report out and Discussion

Sample language, Option 2

- “Newborn screening dried blood spots are collected solely for the benefit of the health of the individual and the public health, and may not be introduced into evidence or otherwise used in furtherance of a criminal proceeding.”



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Next Steps

- The Ethical, Legal, Social, and Policy Issues (ELSPI) Subcommittee will consider any revisions proposed here and distribute the final version of the model language for states to use after the Symposium.
- The Subcommittee is in early discussions to plan a national meeting focused on NBS policy and legal issues in 2025/2026.



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Thank you!

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