



APHL Position Statement

Parental Consent for Newborn Screening

A. Statement of Position

The Association of Public Health Laboratories (APHL) supports the position that public health newborn screening (NBS) should be mandated and should not require parental consent.

B. Implementation

1. APHL will present its position to state health agencies and health policy makers as well as other groups such as ASTHO, AMCHP, ACHDNC, ACMG, MOD, Hastings Center, CDC, CLIAC, NCSL, etc. to assure that state NBS programs will be able to continue to operate under allowed refusal (i.e. opt out) rather than mandatory consent (i.e. opt in).
2. APHL will monitor and review proposed federal laws involving consent requirements affecting mandated NBS programs and will convey proposed changes and potential concerns to its members.
3. APHL will provide support through consultation to NBS programs as individual state legislative issues develop, and it will maintain a record of enacted legislation regarding NBS parental consent.
4. APHL will collect and share program educational and refusal materials from all member state NBS programs.

C. Background/Data Supporting Position

The mandatory nature of NBS is justified because state programs have the responsibility to protect citizens that are unable to protect themselves, such

as newborns. To this end, newborn screening is mandated because the need for early diagnosis and treatment of screened conditions is so important that programs put the interest of the child and the ability to protect the child from future disease at the forefront.

The primary purpose of a formal informed consent process prior to undergoing medical tests is to inform the patient (or in the case of minors, the parent or legal guardian) of the relevant benefits and risks associated with collecting the sample for testing, what the test results mean, and the potential for false positive or false negative results. In the case of NBS, the risk associated with the collection of a few drops of blood and the risk of false positive results has been deemed minimal compared to the benefits of early detection of disease. Where no specimen is submitted due to parental refusal, the possibility of not detecting a child with one or more of the screened conditions is estimated to be approximately one in 600 infants nationwide¹

Most states do allow parental refusal for screening, typically on religious grounds, and some states for philosophical or other reasons. If a program allows refusal, parents should understand that they have this option, and be informed of the purpose of newborn screening and the implications of refusing a potentially lifesaving test prior to exercising this choice. Documentation of refusal should include statements that the screening was offered and that the potential implications of refusal were explained. Parental signatures should be obtained to ensure they understand these implications. A copy of the refusal should be maintained in the infant's record,

and a copy should be forwarded to the newborn screening program. Understanding the need for transparency and trust as well as potential concerns around mandated newborn screening programs, several critical program components must be in place in order to support the position that NBS should be mandated and not require parental consent:

- The screening panel only includes conditions that have undergone thorough evidence review and have met established state-specific criteria for inclusion on the state screening panel or have been recommended by the Secretary of Health and Human Services for the uniform screening panel. These conditions should be limited to those where early detection can be followed by interventions recognized as alleviating the severity of the condition.²
- The overall program includes mechanisms for appropriate health care provider education so that they are available to answer parental questions and concerns about newborn screening.
- The overall program includes mechanisms for parental education about newborn screening and parental options in the prenatal period and prior to collecting the specimen.

D. References

Impact of Expanded NBS – United States, 2006. *Morbidity and Mortality Weekly*. 2008; 57:1012-1051.

Calonge N, Green N, Rinaldo P, Lloyd-Puryear M, Dougherty D, Boyle C, Watson, M, Trotter T, Terry S, Howell RR. Committee report: Method for evaluating conditions nominated for population-based screening of newborns and children. *Genetics in Medicine*. January 2010.

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Contact: Celia Hagan, Senior Specialist, Public Policy
240.485.2758, celia.hagan@aphl.org.