

APHL Position/Policy Statement

The Role of the Private Laboratory Sector in Public Health Newborn Screening Programs

A. Statement of Position

Screening of newborns for treatable congenital conditions is a quintessential public health program where the benefit of protecting the infant from harm invokes the states' powers to supersede even the parental right to control the healthcare provided to their children. The statutory or regulatory authority invoked in states to mandate such screening programs requires that the laboratory testing involved be carefully controlled by the state public health agencies responsible for these programs. Only through this regulatory power is the overall program controlled and participation compelled. The role of private sector laboratories in the provision of state public health newborn screening testing should be limited to contractually prescribed arrangements. Private sector laboratories seeking to offer laboratory testing targeted at the newborn population should be prohibited from describing these services as public health services in the absence of such contractual arrangements. This is not to suggest that private sector laboratories cannot offer test modalities to the newborn population, but that such tests must be clearly described as being distinct from any public health mandated program and outside of the states responsibility for tracking and case management provisions.

B. Background/Data Supporting Position

Non-governmental laboratories flourish in the same sphere as public health laboratories, because private sector laboratories supplement but do not supplant public health laboratories "Some disagreement as to the proper spheres of activity is inevitable," and this has been a long standing issue (see the 1962 Newsletter of the New York State Department of Health.) The debate continues today. (see Hausler, et al.) Where the resources of the state public health system are required to assure testing, case follow-up tracking, and the provision of appropriate health care management of all infants detected as presumptively at risk for one of the specific conditions in the mandated screening panel, it is imperative that the state agency control the content and claims regarding newborn screening programs.

It is also the obligation of a state public health newborn screening laboratory to assure that the mandatory screening panel includes only tests which have been analytically and clinically validated to standards established by the program. The laboratory must provide the scientific basis for determining that the screening program includes in the mandatory screening panel only conditions for which early detection can be followed by interventions known to alleviate the severity of the condition. The laboratory expertise should also be involved to assure that the screening program includes mechanisms for parental education regarding the conditions to be screened, the assays to be used, the treatment options available, the state resources that can be accessed, and the outcomes anticipated. Such parental education should occur to assure parental notice prior to testing. This should be accomplished as early in the pregnancy as possible. The laboratory should also participate in monitoring compliance of all health care providers including the clinical laboratories performing confirmatory diagnostic testing and assure that corrective actions are taken where deficiencies are identified. The laboratory should assist in developing mechanisms for appropriate health care provider education to assure that they understand the testing process, the conditions screened for and their individual roles in infant tracking, referral, or management and the development of policies to assure that the availability of appropriate providers to answer parental questions and concerns.

Participation of private sector laboratories in mandated newborn screening programs should be limited to contractual arrangement to assure their full compliance with all program requirements including method validation, quality assurance and quality control documentation, reporting, tracking, follow-up, and provider education and compliance monitoring. In the absence of such contractual arrangements, activities of private laboratories targeted to clinical testing in newborns must be clearly distinguished from testing performed by mandated public health newborn screening programs.

C. References

Task Force Report on The Public Health Laboratory -- A Critical National Resource, 29 January 1993, Members of Task Force

ASTPHLD

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Consultants

Dr John Liddle (NCEH, CDC, USPHS), Dr Joseph McDade (CID, CDC, USPHS), Dr Eric Sampson (NCEH, CDC, USPHS)

Serving the Family from Birth to the Medical Home: Newborn Screening: A Blueprint for the Future, Report of the American Academy of Pediatrics Newborn Screening Task Force, 106 Pediatrics 389,409-410, 2000.

Health News, 39(10) pp12-19, 1962, Newsletter of the New York State Department of Health.

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