UNMET NEEDS

• Fund the programs authorized in the Newborn Screening Saves Lives Act of 2007 (S. 1858/H.R. 3825) to build the necessary infrastructure and workforce needed for education, outreach, follow-up care, laboratory quality assurance and contingency planning.

• Provide $10 million to the CDC Environmental Health Laboratory’s Newborn Screening Quality Assurance Program to ensure that laboratory tests used to screen newborns are high quality and that new ones are developed constantly.

BACKGROUND

Newborn screening is a vital responsibility with profound and lifelong consequences for the thousands of infants diagnosed each year with heritable and genetic conditions, such as sickle cell anemia and cystic fibrosis. In many cases, early intervention can mean the difference between relative health and severe impairment… or even between life and death.

APHL and its members are acutely aware of the importance of newborn screening (NBS) and the elements of a high-quality screening program. State public health laboratories are accountable for the NBS test results of 97% of all babies born in the United States—more than 4 million babies each year.

In the past decade, the environment for newborn screening underwent drastic change. On the one hand, new technologies and genetic discoveries led to a major expansion of the NBS testing panel, creating greater opportunity for intervention and also a pressing need for technical training.

On the other hand, unforeseen catastrophes—including hurricane Katrina—demonstrated the vulnerability of state newborn screening programs, which are almost always single-site operations.

One of the major milestone in newborn screening last year was the passing of the “Newborn Screening Saves Lives Act of 2007,” which was signed into public law by President Bush on April 24, 2008, without any appropriated funds.

Newborn screening is an essential, life-saving and effective preventive public health program for early identification of medical conditions that can lead to catastrophic health problems. It identifies thousands of babies born in the US each year with a genetic or metabolic disorder. The cost of these conditions if left untreated is enormous, both in terms of human suffering and in economic terms.

Worldwide, CDC’s Newborn Screening Quality Assurance Program Laboratory is the only
newBorn screening
promoting THE HEALTH of AMERICA’s future

A comprehensive source for ensuring the accuracy of newborn screening tests. Funding the Newborn Screening Quality Assurance Program at $8 million will allow for:

1) The research and development of new laboratory screening methods that expand the number of disorders babies can be screened for.

2) Population-based pilot testing for conditions (e.g., Severe Combined Immune Deficiency, Pompe Disease, Metachromatic Leukodystrophy, etc.) not presently included in test panels.

3) The provision of technical assistance and technology transfer to state newborn screening laboratories, particularly with regard to promising and sophisticated techniques capable of identifying a host of disorders currently not diagnosable in newborns.

4) The testing of new screening tools to ensure the highest possible analytic validity and utility.

COLLABORATION WITH STATE AND LOCAL HEALTH DEPARTMENTS
During the past several years, states have experienced newborn screening service interruptions due to both natural disasters and manufacturer inability to provide testing materials. Contingency planning is needed to lessen the effect of disasters that involve newborn screening program operations. APHL continues to support the funding for newborn screening contingency planning activities that were outlined in the Newborn Screening Saves Lives Act to ensure the availability of newborn screening during an emergency.

OTHER CRITICAL FUNCTIONS
The Newborn Screening Quality Assurance Program Laboratory at CDC:

• Trains state laboratorians on the latest technologies and provides proficiency standards for new materials.

• Supports state laboratories during newborn screening emergency situations, such as the aftermath of hurricanes Katrina and Rita.