Guide to Newborn Screening Stakeholders

The success of newborn screening (NBS) programs is the result of involvement by a variety of different stakeholders. Each has a unique role and reason for being engaged in NBS, and their input matters to decision-makers. It's important to understand these different groups and their motivations as you engage in the process of shaping NBS programs at the state or national level. Approach them with respect, identify shared goals whenever possible, and ask how you can be helpful to address concerns or differences that may arise.

Each state operates and names things differently, so consider this a general set of descriptors to help you identify the more specific entities that may be involved in the state(s) you're most interested in.

Department of Health

NBS programs generally fall under the oversight of the state's **Department of Health**, though it may have another name in your state. In many states, the ultimate decision for which conditions to add is made by someone in the department or the state's Secretary of Health. The decision-maker(s) rely on advice from NBS advisory boards and experts on which conditions should be included. This includes the public health professionals who manage the program's day-to-day operations.

In addition to being concerned about the public health implications of adding a new screening test to their state's panel, the Department of Health staff must also determine how the added costs for new testing, staffing, notification of results, and other expenses will be paid for. Keep in mind that many state health budgets are under pressure due to cuts in federal funds allocated to states.

Ways to Engage:

- Identify the state's "home" for NBS programs using RARE Foundation's State NBS Map. Click on the state of interest to find a link to that state's NBS program.
- Become familiar with background information about the program, how it's funded and managed, key personnel, and existing opportunities for public engagement before making direct contact.

NBS Advisory Board

Forty-eight states have an advisory board or committee that oversees the Newborn Screening program in some capacity. These are typically volunteer clinicians, geneticists, ethicists, parent advocates, and other experts in rare conditions that present in the newborn period. In many states, these boards advise the Departments of Health on adding conditions, while some state boards have the authority to add conditions to their own state panels.
Two states (CA and NY) don't have permanent, standing NBS advisory boards:

- California has historically relied on the federal Advisory Committee on Heritable Disorders in Newborns and Children (ACHDN) as its advisory board and automatically added any condition that was approved by the U.S. Department of Health and Human Services for the Recommended Uniform Screening Panel (RUSP). [Note: The ACHDNC was disbanded in April 2025, although the RUSP remains the federally recommended screening panel.]
- New York's Public Health Law specifies the screened conditions, which can be modified by the Health Commissioner or through legislative action. The state may convene ad-hoc groups of experts as needed to advise on adding new conditions.

Ways to Engage:

- Become familiar with your state's NBS advisory committee (if one exists).
- Check the committee's webpage to stay informed about any upcoming public meetings or recent updates so you can attend, review meeting materials, or follow up on the discussion or actions taken.

Laboratory Personnel

Some states have labs within the state that process the Newborn Screening blood spots, while 12 states outsource to another state's lab, and five use Revvity, a third-party contract laboratory, as their lab provider. (See this list for which states fall into which category.)
Many labs are understaffed and under-resourced and should be consulted before any legislative action is taken to ensure that any needs are met to enable them to add the condition. If a state uses another state's lab or Revvity, ensure the lab has the capability to screen for your condition before beginning to advocate. This will save time, energy, and resources.
The Association of Public Health Laboratories (APHL) is a key national organization that provides guidance and support for state labs. APHL hosts an annual Newborn Screening Symposium.

Ways to Engage:

- Learn more about state labs and click on your state (don't just hover over it!) on the RARE Foundation's State NBS Map.
- Before engaging with lab personnel, take time to understand your state lab's funding and the legislative framework that governs it. You can learn more about your state's NBS law within the Newborn Screening Action Center.

Healthcare Providers

This is the front line of newborn screening. This group includes neonatologists, pediatricians, nurses, midwives, genetic counselors, and medical specialists who treat the condition of interest. They are responsible for collecting the blood spot samples, communicating results to families, and initiating referrals for confirmatory testing and treatment. Various academies or associations of specialists may also exist in your state, and they likely have an opinion on the conditions a state is seeking to add, as they will be the ones seeing and treating the patients. Some states will be hesitant to add a condition to NBS if there are no specialists in the state who treat that condition. Be ready to help identify specialists in the state who can confirm the diagnosis and manage care for babies identified through screening tests.

Ways to Engage:

- Review your state's public health department website to determine if it maintains a list of contracted healthcare specialists for follow-up related to certain diagnoses or types of disorders.
- Disease-specific patient advocacy organizations often have medical advisory boards composed of leading clinical experts in the field.
- NIH's Genetic and Rare Disease (GARD) Information Center has Information Specialists who may be able to help locate dedicated disease organizations and/or clinical experts.
- Disease-specific patient advocacy organizations often have medical advisory boards composed of leading clinical experts in the field. Browse the GARD site (see above) by disease to identify established organizations.

Researchers Involved in Screening Test Development and Validation

Researchers who develop newborn screening tests include microbiologists, biochemists, geneticists, and other professionals from disciplines such as public health laboratory sciences. Dr. Robert Guthrie, a microbiologist and pediatrician at the State University of New York at Buffalo, is considered the "father of newborn screening" for devising and validating a simple blood test that led to nationwide screening for phenylketonuria (PKU) in the 1960s. Since then, tests for numerous genetic diseases have used similar methods, enabling blood spots collected at birth to be used to test for multiple conditions at once.

Researchers familiar with the laboratory methods and constraints used in newborn screening panels can be helpful in developing tests for new conditions.

Ways to Engage:

- The **Association of Public Health Laboratories (APHL)** is a key national organization whose members may include researchers with experience with NBS tests.
- The **American College of Medical Genetics and Genomics (ACMG)** is a professional membership organization that represents clinical geneticists, clinical laboratory geneticists, and genetic counselors.
- Review the evidence reports submitted to the ACHDNC for conditions added to the RUSP to learn about successful testing programs.

Insurance Companies/Federations

Under the Affordable Care Act (ACA), private medical insurance companies and Medicaid must cover the cost of screening for newborns. Therefore, payers have a vested interest in all birth-related expenses.
Some states have a federation that represents insurers' interests, and it may oppose actions to add conditions if the federation's members do not view the change as in their financial interest. Newborns of families enrolled in Medicaid are automatically eligible for coverage for at least one year, so the costs for their newborn screening are covered by Medicaid.

Ways to Engage:

- The Insurance Information Institute maintains a list of state insurance organizations.

Hospital Associations

Many states have hospital associations that represent their interests. This is relevant to NBS because of how NBS is billed. Most states include the cost of the NBS tests in a bundled payment model, which is either billed to private insurance or Medicaid. If the insurer does not cover the entire bill, the hospital may be forced to cover the remaining cost. Hospitals and their associations are also concerned with logistical burdens that add time and costs, such as training staff and managing specimen collection for new conditions.

Ways to Engage:

- The American Hospital Association maintains a list of state hospital associations.

Patient Advocacy Groups and Family Advocates

Patient advocacy groups, often formed by families affected by a specific condition, are powerful and highly motivated stakeholders. They drive legislative action, educate the public and policymakers, and provide support to other families. Their personal stories and experiences are often key to building political or scientific will to add a new condition to a state's panel.

Ways to Engage:

- If you have not already done so, partner with patient advocacy groups for your condition of interest to determine what NBS advocacy work is already being done nationally and in your state to combine efforts where possible. Browse the NIH Genetic and Rare Disease (GARD) Information Center by disease to identify established organizations.
- Search the internet for news stories about past and current NBS efforts, using prompts like "advocates for newborn screening in [STATE]" to identify individuals who might be working on similar initiatives for other diseases.
- Attend public meetings of the state's NBS advisory committee (see above) and/or Rare Disease Advisory Council (RDAC) (see below); introduce yourself to others in attendance to build relationships with others interested in these issues.

Rare Disease Advisory Council (in some states)

In some states, Rare Disease Advisory Councils (RDACs) have been established, with varying levels of authority and assigned tasks. They may not have the ability to lobby, but can often write letters of support for conditions seeking to be added. Here's a list of states with RDACs.

Ways to Engage:

- Explore the directory of existing state rare disease councils and establish relevant connections to members.

Lobbyists

While the precise definition of "lobbying" and "lobbyist" may vary by state, those who lobby are generally professionals who attempt to influence government action through oral or written communication. Lobbyists might be engaged by one or more stakeholders (working together to independently) to help move – or prevent movement of – a particular idea or legislative proposal. Lobbyists tend to specialize in particular areas and build networks of contacts, both inside and outside of government, to help them assess and understand the political landscape of a specific issue or topic. Their relationships with influential individuals in elected or staff positions can help parties advocating for change (or maintaining the status quo) gain visibility and support for their ideas and desired actions.

Ways to Engage:

- Search online using prompts such as "lobbyist for newborn screening in [STATE]" or "lobbyist for maternal and child health issues in [STATE]."
- Lobbyists with active issues before state Rare Disease Advisory Councils (RDACs) (see above) may attend the Council meetings. You could also ask Council staff if they know any lobbyists active on these issues.

Life Science Companies

Biopharmaceutical companies developing potential therapies or marketing approved therapies for genetic conditions may be interested in supporting efforts to raise awareness about the condition and enable earlier detection and diagnosis, including newborn screening. Some companies may have in-house expertise related to testing methods. Others may have staff with knowledge, experience, and relationships related to state and/or federal policy issues that could be useful.

Ways to Engage:

- Identifying companies that have approved therapies for the condition of interest should be pretty straightforward with the help of an internet search. Connecting with the right person in that company might be less straightforward! You might start by searching LinkedIn for staff from those companies who have “patient advocacy” in their titles. Connect via direct message and politely ask them to help navigate to the right person on their team.
- Use clinicaltrials.gov to search for clinical trials in the condition of interest and refer to the “Contacts and Locations” tab for active studies as a starting point. You might also use LinkedIn to connect with a member of the patient advocacy staff from the company sponsoring the clinical trial.