SUPPLEMENT ARTICLE

Status of Newborn Screening Programs in the United States

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ABSTRACT

BACKGROUND. Newborn screening programs have expanded over the years; currently, many programs screen for dozens of congenital conditions that, if not detected and treated early, could result in catastrophic health consequences, including death. Some programs, however, still require universal newborn screening for only a few conditions. Although all 51 US programs (all states and the District of Columbia) have statutory screening requirements and similarities exist in many parts of the different screening systems, the enabling statutes, rules, regulations, protocols, and financing strategies vary dramatically. Consequently, there is a significant lack of equity in newborn screening services across the country.

METHODS. We investigated program variations existing in and around January 2005 and provide baseline information with which future program comparisons can be made. We used program surveys, electronic searches of legislation, and individual input (validation) from program decision-makers to create a reservoir of program information.

RESULTS. Included is a compilation of pertinent newborn screening statutes, information from genetic privacy statutes that potentially affects newborn screening programs, and a review of state laws that affect specimen and information retention. In addition, program policies related to the use of residual newborn screening blood spots are reviewed, along with the developmental processes affecting program informational brochures, including the information contained and the strategies for brochure dissemination.

CONCLUSIONS. Building on a progressive and successful history, newborn screening continues as an example of an essential population genetic screening program. As the intricacies of screening systems have increased in complexity, so have the policy issues that shape program successes and failures. The summary information in this article provides a basis for national and individual program evaluation. Indeed, some of the information reported here has already been useful for program refinements reported elsewhere in this supplement.

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Key Words
newborn screening, laws, education, public health, public policy

Abbreviations
PKU—phenylketonuria
HIPAA—Health Insurance Portability and Accountability Act of 1996
NNSGRC—National Newborn Screening and Genetics Resource Center
CORN—Council of Regional Networks for Genetic Services
APHL—Association of Public Health Laboratories
CDC—Centers for Disease Control and Prevention

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NEWBORN SCREENING BEGAN in the early 1960s,[1,2] with the intent to decrease or to eliminate the catastrophic effects of preventable mental retardation.[3] Special-interest advocacy led many states to enact legislation that required screening of all newborns for phenylketonuria (PKU). Early laws usually included funding for laboratory testing and related follow-up services. Government funding was justified on the basis of cost savings through avoidance of long-term institutionalization of patients with PKU in state-supported mental hospitals. Since then, all states and most territorial jurisdictions have incorporated mandated newborn screening for PKU into their public health preventive services.

Over the years, increased scientific and medical knowledge, coupled with technical advancements, has allowed newborn screening programs to expand in scope. Policy decisions governing US newborn screening activities have been reviewed by the National Academy of Sciences,[4] the Institute of Medicine,[5] the American Academy of Pediatrics,[6] and others.[7–9] In some cases, a legislative mandate has defined the degree of program expansion; in other cases, expansion has occurred through changes in regulations or other mechanisms permitted in the enabling statute. Legislative approaches to newborn screening issues, such as consent requirements for testing, decision-making processes for testing for additional conditions, and mechanisms and extent of program financing,[6,10] also have varied. As newborn screening evolved into a comprehensive 6-part system,[9,10] policymakers struggled to keep pace with system complexities, and program variations arose.[11]

As a necessary part of newborn screening, identifiable patient information is often available at birthing facilities, offices of health care providers associated with the patient, the screening laboratory, the state/territorial health department, and possibly confirmatory laboratories and subspecialty clinics, among others. Because newborn screening is included in the broader definition of genetic screening, genetics privacy laws may affect newborn-screening activities directly. In many instances, state/territorial governments have enacted legislation and established regulations providing for the confidentiality of individually identifiable genetic information. Often consent or refusal options have been included, to give individuals greater control over their personal information or that of their newborns. Depending on the language used in statutes or regulations, these options may apply to personal information or to specimens from which personal (genetic) information can be extracted, such as blood specimens. It is now the case that newborn screening programs must be aware of how they are affected not only by newborn screening statutes and regulations but also by other genetic privacy restrictions, including national laws such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[12]

To ensure that parents and health care providers who participate in newborn screening are knowledgeable about the screening system and their roles in it, programs devote considerable resources to education. As the number of conditions available for inclusion in screening increases steadily (and sometimes quickly), programs are faced with the need to provide timely accurate information to a host of different entities. Newborn screening programs have developed basic information for parents to address some of these educational issues. Demand for rapid production of new educational materials may not allow for adequate attention to preparation of materials (with respect to content, literacy, and cultural sensitivity), thoughtful distribution of materials, and assessment of the effects of materials. As part of this project, limited background information on distribution and content was obtained, to provide a basis on which to refine and to improve educational pamphlets for parents.

Newborn screening programs are also faced with issues regarding storage and management of residual specimens that remain after newborn screening tests are complete. Whereas previously these specimens were viewed as primarily useful for program quality assurance and perhaps as final testing material that could be reanalyzed in cases of late or misdiagnosed conditions, they have become increasingly important as possible sources for genetic research. This is of particular importance because newborn screening specimens represent the most comprehensive population testing program currently in operation, and specimens are obtained from essentially every newborn.

This article is intended to summarize the current state of affairs in critical areas in US newborn screening programs. We acknowledge that many activities are ongoing in the newborn screening arena, and we sought to take a snapshot of these activities in or around January 2005. This baseline information should prove useful as changes in newborn screening policymaking evolve in response to recent federal initiatives regarding selection of conditions for screening. Included in the article are various summation tables that describe the current status of testing, privacy, and educational activities. Legislation pertinent to these issues also is reviewed. Included are appendices that delineate important program information extracted from pertinent laws and regulations. To ascertain the extent to which programs have instituted policies for storage and future use of residual blood spots, this project investigated the simple question of whether policies exist currently and the role of privacy laws and regulations, if any, in current storage policies and practices. Program personnel acknowledged at the end of the report assisted in the validation of the information presented.

METHODS

Privacy and Confidentiality

To identify newborn screening laws and regulations and privacy laws and regulations pertaining to newborn screening, a computerized search of the Westlaw database was conducted with variations of the following terms: infant, birth defect, congenital, genetic, hereditary, infant, neonate, newborn, phenylketonuria, and screening. Therefore, this search was limited by the ability of the database to detect information and by the breadth of the search terms used. Each of the statutes and regulations identified was accessed, read, and evaluated for relevance to privacy and other policy issues. In addition, comparison was made to a summation of newborn screening laws reported previously,[13] to ensure comprehensiveness of the information accessed. The latest available published national summation data on newborn screening[14] were also reviewed for pertinent information on births, samples received, number of screens required or recommended strongly, and number of conditions mandated. Updated information on disorders included in screening programs was obtained from the National Newborn Screening and Genetics Resource Center (NNSGRC) through its online database.[15]

Individual newborn screening statutes and regulations were examined to identify confidentiality and consent requirements, to determine prescribed methods for selecting conditions for inclusion in newborn screening mandates, and to identify and to analyze provisions concerning the use and storage of dried blood spots. Newborn screening statutes that either specified confidentiality policies or required the health department to promulgate regulations to address confidentiality issues were noted. Statutes and regulations that required consent or written authorization as part of the screening process were also identified. Genetic privacy laws were analyzed to determine whether newborn screening or public health programs were exempted. Statutes that did not exempt newborn screening were reviewed to identify confidentiality and consent provisions that might apply to state public health employees who provide newborn screening services.

To validate and to update the regulatory information acquired, an e-mail message was sent to the person in each state identified as being most likely to have knowledge of the regulations (for names, see Acknowledgments). Responders were requested to validate and to update the interpretive data for their program, with specific emphasis on current statutes, regulations, and relevant policies. Nonresponding programs were contacted by telephone, and information was obtained from all 51 US newborn screening programs (50 states and the District of Columbia). These validated responses are included in the various tables and appendices of this report.

Educational Materials

To develop information about the process used by programs for educating parents and to provide baseline information for refining basic educational materials, a questionnaire was prepared and disseminated (Table 1). Because the most common form of newborn screening educational information for parents was thought to be pamphlets distributed prenatally or at birthing facilities around the time of delivery, questions focused on the information contained in such pamphlets and the mechanism for pamphlet dissemination. The questions used were suggested by newborn screening personnel as likely to provide useful information for comparison and improvement of the varied educational materials. Indeed, as part of the survey, 50 of 51 programs confirmed that they distributed educational pamphlets for (and, it is hoped, to) parents. The questionnaires were returned initially by almost all programs; the remaining programs were contacted by telephone and responses were obtained, so that all 51 US public newborn screening programs were represented by the data. Other pamphlets from private newborn screening programs were known to exist but were not included in this project.

Residual Specimen Storage and Usage Policies

Guidance published previously by the Council of Regional Networks for Genetic Services (CORN)[16] and supported by the American Academy of Pediatrics Newborn Screening Task Force[6] recommended strongly that newborn screening programs develop policies for retention,

TABLE 1 **Questions to Programs Regarding Educational Pamphlets**

1. Is distribution of a parent brochure mandatory in birthing facilities?
2. Is distribution of a parent brochure a usual activity of prenatal classes?
3. Is distribution of a parent brochure a usual activity of obstetricians?
4. Does the educational material cite legal authority?
5. Does the educational material list disorders included in the screening program?
6. Does the educational material at least briefly describe each disorder?
7. Does the educational material indicate how the specimen will be collected?
8. Does the educational material indicate when the specimen will be taken?
9. Does the educational material indicate when results are available?
10. Does the educational material indicate how results will be communicated to the baby's doctor?
11. Does the educational material indicate how to obtain results?
12. Does the educational material indicate the detection rate or accuracy of tests?
13. Does the educational material indicate the existence of false positive results?
14. Does the educational material indicate the existence of false negative results?
15. Does the educational material discuss what will be done with specimens after testing?
16. Does the educational material discuss the need for retesting in some cases (ie, inadequate or positive results)?
17. Does the educational material discuss the limitation of screening (ie, not all possible disorders are included)?
18. Does the educational material discuss payment for testing?
19. Does the educational material discuss whether the test can be refused and under what circumstances?
20. Does the educational material contain a confidentiality and privacy statement?

storage, and use of residual specimens remaining after completion of initial newborn screening tests. These specimens, although collected initially for immediate preventive health purposes, have the potential to be useful in other studies that may have significant health impact, because they provide a ready source of biological material containing DNA for essentially the entire population of newborns. In many newborn screening programs, the use of specimens beyond the newborn screening analytical process might not have been considered; therefore, other possible uses may not be defined clearly in the law or in the rules and regulations. Consequently, programs may not have clearly defined protocols for specimen storage procedures, which are often established on the basis of potential specimen uses.

To learn whether screening programs developed policies in response to earlier concerns and recommendations about storage and use of residual specimens, we conducted a survey of related program policies and activities in early 2003. A brief questionnaire (Table 2) was sent by e-mail to the newborn screening laboratory supervisor or another person at the program level identified as being most knowledgeable about specimen policies. Programs were asked to mail or fax copies of any regulations, policies, or standard operating procedures relating to specimen storage and use after initial newborn screening laboratory analysis. Programs that did not respond by e-mail were contacted by telephone, so that responses were collected from all 51 US programs.

In addition to the information obtained from the survey, the latest data submitted by the state newborn screening programs to the National Newborn Screening Report[14] were reviewed and clarifying program information was extracted. NNSGRC staff members, in cooperation with an independent consultant knowledgeable in the administrative policies of state public health laboratories, evaluated and summarized the data. As a quality control check, these data were compared with a somewhat similar 2002 survey of state laboratory directors conducted by the Association of Public Health Laboratories (APHL), in cooperation with the Centers for Disease Control and Prevention (CDC).[17] It is common in surveys of newborn screening activities and policies for answers provided by different responders within a public health department to differ slightly. When information discrepancies between the CDC survey and ours were identified, telephone contact was made with the newborn screening laboratory authority to resolve the discrepancy.

TABLE 2 Questions to Programs Regarding Policies for Storing and Using Residual Specimens

1. Is there a regulation or policy requiring consent for screening?
2. Are there written regulations and/or policies on residual specimen storage?
3. Are there written regulations and/or policies on use of residual blood spots?
4. What tests are officially mandated?
5. What is the process to have a test or tests added (ie, board of health, health commissioner, or advisory committee)?
6. Are there written regulations or criteria to follow when adding tests to the screening panel (ie, American Academy of Pediatrics guidelines or internal guidelines)?
7. How was the parent brochure developed?
8. Was input requested from parent groups and consumers?
9. How is the brochure distributed and used (birthing hospitals, obstetrician/gynecologist, prenatal classes)?
10. Is distribution of the brochure mandated?

RESULTS

Privacy and Confidentiality

Because there is no federal law regulating newborn screening, state and territorial statutes and regulations govern newborn screening program implementation within their respective jurisdictions. Currently laws exist that either mandate or allow for newborn screening in all states and the District of Columbia. Although it is desirable to confirm that every newborn obtains a newborn screening test, many programs are not yet able to provide this information because they do not have data integration between the newborn screening program and the vital records (birth certificate) program. Therefore, newborn screening data on the number of specimens received are used to provide approximations of program coverage. Basic information from the most recently published national newborn screening summary data,[14] updated with current information on selected items taken from the NNSGRC Web site (http://genes-r-us.uthscsa.edu), are summarized in Appendix 1. These data include the number of births within the jurisdiction and the number of specimens received during 2001.

The current trend is to use more-general language in statutes and regulations that define screening panels. For example, it is becoming more common to see language such as "other detectable amino acid conditions" or "all detectable conditions" as part of the language of statutes and implementation rules. Examination of the statutes governing newborn screening showed that most program-enabling laws (37 of 51 laws) name $\geq$1 disorder in the program-enabling legislation, usually dating to an original law that mandated screening for PKU. Although several program-enabling laws name >1 disorder that must be included in the screening, all programs report being able to enlarge the number of disorders without changing the law, and only 6 programs (Arkansas, Kansas, Kentucky, South Dakota, Virginia, and Nebraska) indicate that the number of conditions screened is the same as the number included in the statute.

More-detailed information regarding testing and privacy statutes is given in Appendix 2, including statute references. Additional summary information about the various programs is presented in Appendix 3. Although not all states and territories have specific statutes regarding newborn screening, all programs cite statutes that either mandate or allow for newborn screening. As a

result of these laws, most newborn screening occurs routinely at the birthing facility, with parents allowed only an opportunity to refuse screening (opt out) if they object. Thirty-three programs permit refusal of newborn screening on religious grounds, and 12 permit it for religious or other reasons. Five programs do not allow refusal, and the statute and regulations in New Hampshire are silent on the issue.

Newborn screening statutes and regulations include consent requirements in 20 programs. Of these, Maryland, Wyoming, and the District of Columbia require that parents be given the option to consent to screening (opt in), and 18 programs require a parent or guardian to give consent to disclose identifiable information (with limited exceptions, such as for the purpose of service delivery). In Kansas and Maryland, families must consent to accept follow-up treatment. In Texas, public health personnel must obtain consent to deliver services to children with special health care needs. Although consent is required specifically for participation in the Maine expanded newborn screening program, other optional testing programs (ie, tests offered beyond the screening mandate) require or offer consent or refusal options in a variety of ways. A written statement of refusal is usually specified wherever refusal of mandated tests is allowed; in some states, a generic refusal form is provided by the newborn screening program, for uniformity of documentation.

Typical information recorded on newborn screening specimen-collection devices includes the names of the newborn and the parent or guardian, their address and telephone number, a physician associated with the newborn, the infant's birth date, and limited other information.[18] To protect individual privacy, 28 newborn screening statutes include some type of confidentiality provisions that restrict either the use of personal information or the access to actual blood spot specimens. Some states have additional measures to protect the privacy of personal information. For example, Texas law allows submission of newborn screening information to a national roster of newborn screening cases only if the identities of individuals in the roster are protected. Minnesota and Oregon allow a parent or guardian to suggest corrections after examining a child's newborn screening record. Only laws in California, Maryland, Minnesota, and Oregon acknowledge specifically the right of individuals to have access to personal information maintained by the health department and obtained through newborn screening.

Nineteen states/territories have statutes and regulations that permit researchers to access and to use newborn screening information for scientific studies, and 10 of these have laws or regulations that include specifically access to specimens (Appendix 1). In general, research involving specimens or identified patient information requires review by an institutional review board, and restrictions on sharing information, sometimes including publication restrictions, may be required. In all programs that permit research on residual dried blood spots explicitly, researchers are required to protect the confidentiality of patient information.

Genetic information was found to be defined explicitly as personal property in 5 states, ie, Alaska, Colorado, Florida, Georgia, and Louisiana. (Currently Alaska is the only state extending this property right to DNA.) Generally it is held, however, that parties involved in the newborn screening process, such as laboratory personnel, health department personnel, and primary care physicians, are permitted access to individually identifiable information for service delivery or for birth defect tracking and monitoring. In these circumstances, individuals or entities acting as part of the newborn screening process may exchange personal information.

Privacy protections for an individual's genetic information (so-called genetic privacy laws) may affect newborn screening policies. A Westlaw search showed 30 states/territories with such laws (Appendix 2). Eight of these laws were found to have possible application to newborn screening, because public health activities such as newborn screening were not exempted specifically from the statute. However, depending on the definition of genetic information or genetic testing given in a particular statute, current technologies used in newborn screening may not meet the definition of genetic testing and may not be included. The remaining 22 privacy laws either exempt public health agencies that conduct newborn screening or do not name them in the list of affected entities.

Thirteen states (California, Delaware, Florida, Georgia, Idaho, Indiana, Maine, Michigan, Mississippi, Oregon, South Carolina, Tennessee, and Utah) have specific penalties for the violation of state newborn screening laws or regulations. Punishments for violating the privacy of newborns screened or failure to maintain the confidentiality of newborn screening specimens and results range from establishment of grounds for filing a complaint against the relevant state licensing board (in Indiana) to up to $250 000 in damages and reasonable attorney fees (in Oregon). A violation of newborn screening laws or regulations in states with criminal penalties is a misdemeanor, with the exception of Utah, where the hospital or practitioner must report medical neglect to the state if a parent fails to comply with state laws or regulations. In Nebraska, the attorney general or the county attorney may enforce the law through a civil proceeding if a parent fails to respond to a report of a presumptive positive screening test.

Educational Materials

A review of statutes and regulations that affect education showed 20 programs (Appendix 2) with requirements for health department personnel or other individuals involved in newborn screening to provide specific infor-

mation to a parent or guardian before screening takes place. Requirements included the provision of oral or written information, or both. Educational items identified varied but included information on the right to refuse screening, the panel of newborn screening disorders, the consequences of treatment or nontreatment, the need for follow-up testing, retention and storage of samples, and confidentiality and privacy issues. Interesting issues were sometimes raised by the use or omission of wording in the statute. In Arkansas, for example, the health department must "disseminate information and advice to the public concerning the dangers and effects of phenylketonuria, hypothyroidism, and sickle-cell anemia," but the education is not required specifically before newborn screening. In Nebraska, the health department is required to develop an educational brochure, but how or when it should be distributed is not included. Kansas regulations require prenatal care providers to "discuss and distribute written material describing the newborn screening program."

Follow-up coordinators from all 51 US newborn screening programs responded to our questionnaire regarding preparation and dissemination of educational pamphlets for parents (Table 3). One program responded that it lacked such a pamphlet and was working on its development. Of the 50 programs with a newborn screening pamphlet, 10 programs (20%) reported that distribution was a usual activity of obstetricians; 14 programs (27%) reported that pamphlet distribution was a usual activity of prenatal classes. Although it is thought that most birthing facilities distribute program information pamphlets as part of their information packets for new mothers, only 19 programs (<40%) reported having a mandate for such distribution.

The content of program pamphlets was assessed through answers to the remaining 17 survey questions. All programs reported including information listing the conditions included in the program and describing when the specimen would be collected, and most reported including a brief description of each condition (94%), reference to the collection procedure (98%), and discussion of the need for retesting in some situations (94%). More than one half of the programs reported including information that described how results could be obtained by the parents (72%), how results would be reported to the primary care physician (62%), and legal authority for the program (58%). Less than one half of the programs reported including information that described the possibility of false-positive results (48%), when results would be available (40%), and the conditions for refusal (38%). Information that described the accuracy of testing (24%), the limitations of testing (24%), false-negative results (22%), cost/payment for testing (22%), retention of specimens (14%), and privacy/confidentiality (8%) was included rarely. All programs graciously submitted copies of their pamphlets for additional evaluation of literacy and cultural sensitivity, the results of which are reported elsewhere in this supplement.[19]

Residual Specimen Storage and Usage

During 2001, US screening programs reported receiving almost 5.3 million specimens for analysis.[14] The number of specimens received was 33% higher than the reported number of births, in part because 8 programs required 2 specimens for every newborn (1 obtained before hospital discharge and 1 obtained ~2 weeks later), and each reported >90% compliance. Several other states strongly recommended a second specimen, to the extent that compliance exceeded 80%; essentially all remaining programs required a second sample when the first was obtained too early (defined as before 24 or 48 hours of age, depending on the program), and all reported receiving some repeat specimens.

Because laboratory protocols, as well as specimen storage and later use, can affect whether a second specimen is obtained, it is useful to review the various laboratory service models operating currently within the country (Fig 1). In situations where 1 laboratory serves multiple states, it is not necessarily the case that all states served screen for the same conditions. For most jurisdictions, newborn screening is performed as part of the services of the jurisdiction's public health laboratory; for a few, screening is contracted to other laboratories (public or private), usually through competitive bidding. Several of the northwestern states, Hawaii, and Alaska use the services of the Oregon State Public Health Laboratory, Wyoming contracts with the Colorado Department of Public Health and Environment, North Dakota contracts with the Iowa University Hygienic Laboratory (the Iowa public health laboratory), and most of the New England states use the laboratory at the University of Massachusetts Medical School (affiliated with the Massachusetts Department of Public Health). The Indiana program contracts with the Indiana University Medical School, and the Arizona program contracts with the Arizona Department of Public Health Services laboratory (through competitive bidding).

Public/private partnerships exist in several programs. The Minnesota Department of Health Laboratory contracts with the Mayo Clinic to perform part of the testing panel, which requires sharing portions of each blood specimen submitted. In California, there are 8 private contract laboratories under the supervision of the state public health laboratory in Berkeley. The South Dakota Department of Health contracts with a private in-state pathology laboratory (which subcontracts with another laboratory to offer additional metabolic testing), and the health departments in Mississippi, Nebraska, and the District of Columbia contract with a private screening laboratory in Pennsylvania (Pediatrix Screening). The Pennsylvania Department of Health has contracts with

TABLE 3 Responses to Survey of Processes Related to State/Territorial Newborn Screening Information Brochures

Jurisdiction	Distribution			Information Contained in Newborn Screening Brochure																
	1. Distribution of Brochure Mandatory in Birthing Facility	2. Distribution of Brochure Usual in Prenatal Classes	3. Distribution of Brochure Usual in Obstetrician/ Gynecologist Office	4. Cites Legal Authority	5. Lists All Conditions Included in the Screening Program	6. Briefly Describes Each Condition	7. Indicates Specimen Collection Method	8. Indicates When Specimen Will Be Taken	9. Indicates When Testing Results Will Be Available	10. Indicates How Results Will Be Sent to the Doctor	11. Indicates How to Obtain Results	12. Indicates Detection Rate or Accuracy	13. Indicates Existence of False-Positive Results	14. Indicates Existence of False-Negative Results	15. Discusses What Happens to Specimens After Testing	16. Discusses the Need for Retesting in Some Cases	17. Discusses the Limitations of Screening	18. Discusses Payment for Testing	19. Discusses Option(s) for Refusal If Applicable	20. Contains Confidentiality or Privacy Information
Alabama				Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y		Y	
Alaska	Y			Y	Y	Y	Y	Y								Y				
Arizona	Y				Y	Y	Y	Y			Y		Y			Y				
Arkansas	Y			Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y				
California	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y			Y	Y	Y	Y	Y	Y	Y
Colorado					Y	Y	Y	Y		Y	Y		Y							
Connecticut	Y				Y	Y	Y	Y		Y	Y					Y				
District of Columbia	Y	Y	Y	Y	Y	Y	Y	Y		Y						Y			Y	Y
Delaware	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y						Y			Y	
Florida				Y	Y	Y	Y	Y	Y	Y	Y	Y				Y				
Georgia		Y		Y	Y	Y	Y	Y		Y	Y	Y			Y					
Hawaii	Y	Y		Y	Y	Y	Y	Y			Y		Y			Y		Y	Y	
Idano				Y	Y	Y	Y	Y		Y	Y					Y			Y	
Illinois		Y			Y	Y	Y	Y			Y		Y	Y	Y	Y	Y		Y	
Indiana					Y	Y	Y	Y	Y	Y	Y		Y			Y	Y			
Iowa				Y	Y	Y	Y	Y		Y	Y		Y		Y	Y	Y		Y	
Kansas					Y	Y	Y	Y	Y	Y	Y					Y		Y		
Kentucky		Y	Y		Y	Y	Y	Y								Y				
Louisiana				Y	Y	Y	Y	Y				Y								
Maine				Y	Y	Y	Y	Y	Y	Y	Y		Y	Y		Y	Y		Y	
Maryland	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	
Massachusetts	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y		Y	Y		Y	Y	Y	Y	
Michigan				Y	Y	Y		Y	Y	Y	Y		Y		Y	Y				
Minnesota				Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y				Y		
Mississippi		Y	Y	Y	Y	Y	Y	Y		Y						Y	Y			
Missouri	Y			Y	Y	Y	Y	Y								Y				
Montana				Y	Y	Y	Y	Y		Y	Y	Y				Y				
Nebraska				Y	Y	Y	Y	Y					Y		Y	Y	Y		Y	Y
Nevada					Y		Y	Y								Y		Y		
New Hampshire					Y	Y	Y	Y			Y					Y				
New Jersey				Y	Y	Y	Y	Y								Y			Y	
New Mexico		Y			Y	Y	Y	Y	Y	Y	Y					Y				
New York	Y				Y	Y	Y	Y	Y	Y	Y		Y			Y	Y			Y
North Carolina	Y				Y	Y	Y	Y			Y					Y				
North Dakota					Y	Y	Y	Y		Y			Y			Y				
Ohio	Y	Y			Y	Y	Y	Y			Y					Y				
Oklahoma	Y				Y	Y	Y	Y	Y		Y					Y				
Oragon				Y	Y		Y	Y	Y	Y	Y	Y	Y	Y		Y		Y	Y	
Pennsylvania	Y				Y	Y	Y	Y	Y	Y	Y	Y				Y			Y	

Rhode Island	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
South Carolina				Y	Y	Y	Y	Y	Y	Y	Y	Y	Y			Y				
South Dakota		Y	Y		Y	Y	Y	Y					Y	Y		Y				
Tennessee	Y				Y	Y	Y	Y		Y	Y					Y				
Texas		Y	Y		Y	Y	Y	Y								Y				
Utah				Y	Y	Y	Y	Y			Y	Y				Y				
Vermont					Y	Y	Y	Y		Y	Y					Y				
Virginia					Y	Y	Y	Y	Y		Y					Y		Y	Y	
Washington	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y		Y		Y	Y		Y	Y	
West Virginia			Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y			Y				
Wisconsin				Y	Y	Y	Y	Y		Y	Y		Y			Y	Y	Y	Y	
Wyoming	Y			Y	Y	Y	Y	Y				Y	Y	Y		Y			Y	
Total Yes	19	14	10	29	50	47	49	50	20	31	36	12	24	11	7	47	12	11	19	4

Y indicates yes; blank, no; NA, no brochure.

the New England Regional Newborn Screening Laboratory and Pediatrix Screening, with hospitals being allowed to submit specimens to the contracted laboratory of their choosing. In Louisiana and Maryland, hospitals may send their specimens to other laboratories, although a central public health laboratory provides most of the screening. As a result, some hospitals in both states use Pediatrix Screening, and one large hospital in Louisiana provides testing for its own patients.

Results indicate that 9 states (Appendix 1) have specific statutory or regulatory requirements for the retention of newborn screening information and specimens. The prescribed retention periods vary from 1 month to indefinitely. In some state/territorial jurisdictions, parents can choose whether to request the return or destruction of a sample or to continue its storage for research purposes after a specified time interval (eg, 2 years in South Carolina and Minnesota). Florida, Idaho, and Ohio have requirements relating to retention of newborn screening records that do not specify whether the specimens themselves are included as a record. Laws and regulations in California, Maine, and Washington declare newborn screening samples to be the property of the state; however, in Maine a parent is permitted to object to state ownership in writing. The remaining programs seem to be able to destroy or to retain newborn screening samples and information as long as they are compliant with general record-retention and sample-storage laws or regulations and internal departmental policies.

Our survey of newborn screening laboratory practices (Appendix 1) found that 37 programs have written policies regarding the storage of newborn screening dried blood spots after completion of the newborn's screening tests, leaving 14 programs with no policy. Storage practices were variable, with 24 programs reporting storage times of ≤6 months, in contrast to 8 programs that reported indefinite storage. Of the remaining 19 programs, 6 stored specimens for 1 year, 7 stored specimens for 2 to 7 years, and 6 stored specimens for 21 to 23 years. Although it was not requested specifically, 2 states reported saving specimens from diagnosed patients for longer periods, compared with their routine specimens. Twenty-three programs reported having policies governing the use of residual newborn screening specimens, leaving 28 programs with no written usage policy.

DISCUSSION

Laws and Regulations

All 51 US newborn screening programs identified legal mandates that either provide specifically for the establishment of a newborn screening program or allow a newborn screening program to be created under a broader health mandate. The newborn screening statutes and related policies seek to balance the rights of

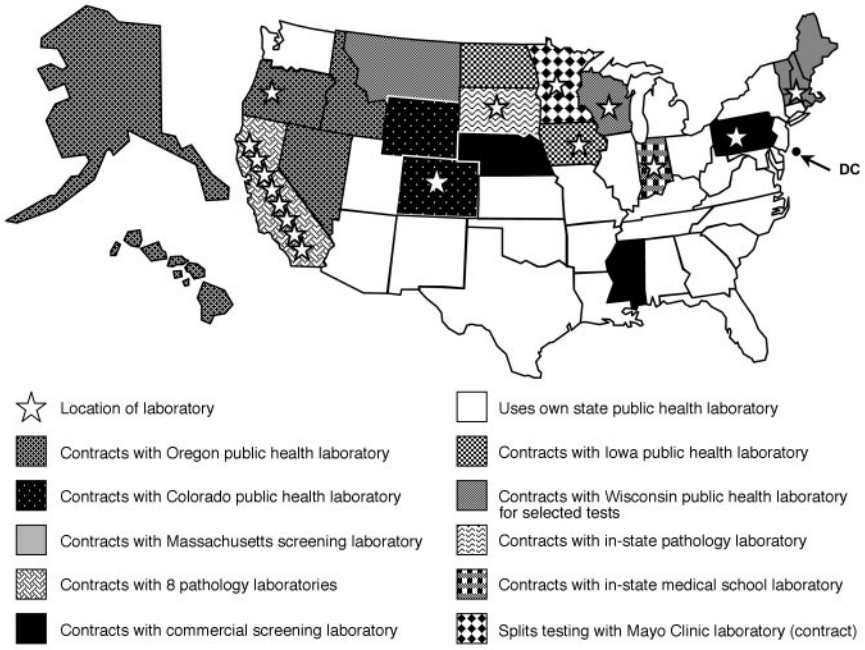

FIGURE 1
Different models for newborn screening laboratory services within the United States. Hospitals in Pennsylvania may choose either the University of Massachusetts Medical School Laboratory or Pediatrix Screening, Inc, also used by Nebraska, Mississippi, and the District of Columbia. Hospitals in Louisiana and Maryland also may choose to use the state public health laboratory or to contract with other screening laboratories. Subcontracts also exist in South Dakota such that tandem mass spectometry screening is provided by the Institute for Metabolic Disease in Dallas and cystic fibrosis testing is provided by the University of Massachusetts Medical School laboratory.

individual autonomy with the overall public good in determining whether screening should be voluntary or mandatory. Confounding the issue are considerations about the well-being of the child versus the family's decision-making rights and the fact that many newborn screening conditions have rapid severe consequences if left undetected and untreated. The result is considerable variation in opinions about the need for consent for a mandated screening program and the decision in 2 states and the District of Columbia to allow parents the opportunity to consent to newborn screening. Although most of the other states allow parents an opportunity to opt out of newborn screening, primarily for religious reasons, it is interesting that 5 programs do not allow for refusal. In Nebraska, the state's right not to allow refusal of required testing was upheld recently by the Nebraska Supreme Court. In programs where additional newborn screening tests are available but not mandated, there is usually a consent or refusal option. An option to participate is also the usual case when new screening tests are offered as part of a research protocol or in a pilot study to determine testing feasibility.

Related to the issues surrounding consent and refusal are the issues of genetic privacy and adequate and appropriate parental education in the decision-making processes. In addition to statutes and regulations that address newborn screening privacy specifically, broader health laws, regulations, or policies may affect newborn screening programs. In particular, general public health and genetic privacy measures may establish consent, confidentiality, or other privacy protections that apply to public health programs generally or to anyone who might use the genetic information identified by the program. Whether privacy restrictions apply depends on the type of information and the specific features of the situation in question. Privacy and confidentiality protections typically are strongest in cases where personal identity is readily available. Laws or regulations may have fewer safeguards for unlinked or encrypted information, because a layer of protection exists between the identity of the patient and the personal information or the newborn's specimen.

The sharing of patient information for public health program purposes, including newborn screening, is often exempted from general health privacy laws and regulations. For example, the Department of Health and Human Services Standards for Privacy of Individually Identifiable Health Information require health plans, health care providers, and other entities covered by HIPAA to provide patients with greater control over their personal health information. HIPAA rules[12] allow specific exceptions for public health agencies and permit disclosure of individually identifiable health information to authorized public health agencies without consent "for the purpose of preventing or controlling disease, injury, or disability, including but not limited to public health surveillance, investigation, and intervention."[20] In the case of newborn screening, public health personnel have access to personal information and are considered HIPAA exempt when delivering newborn screening services, including follow-up testing and related medical and public health assistance. In cases where research involves the use of newborn screening information or specimens, generally institutional review boards govern the degree of informational privacy. Federally funded anonymous or unlinked research is exempt from HIPAA

rules and other federal regulation under the Common Rule, which establishes pertinent human subject protections.[21,22]

Nearly all states have laws or regulations that protect the privacy and confidentiality of personal information collected and stored by state public health departments.[23] Typical methods of securing such information include access restrictions and specific limitations on information disclosure and use. Public health privacy laws and regulations may also stipulate different privacy requirements for different types of information. Because anonymous or unlinked statistical information is usually considered to be public record, a health department may be required to deidentify or unlink information shared in this way. Although it increases personal information protection, unlinking data for such purposes usually increases program costs, because of the time and effort required to meet these privacy requirements.

Although statutes and regulations pertaining to birth defects registries were not specifically researched for this report, newborn screening programs might be affected by such statutes and regulations when there are linkages between the 2. General public health privacy laws and regulations usually safeguard the information accumulated in birth defects registries, which often is used for research into the prevalence and causes of birth defects. Of the 45 states with an operational or developing birth defects registry,[24] most have laws that provide special privacy and confidentiality protections for case-specific demographic information. Generally these laws restrict access, limit disclosure, and specify the purposes for which researchers may use registry information. Generally exceptions, when they exist, allow public health personnel to access identifiable information to offer follow-up services or to request an affected child's participation in a research study.

Education

The need for sound education for parents and health professionals is well understood by newborn screening programs, and most report having some components of an education program in place. The most basic parent information is contained in program brochures intended to provide easy access to fundamental program information for parents. Basic information for health professionals is contained in a widely disseminated specimen-collection videotape.[18]

Our study of current program practices showed that parent education materials may be shared at a nonoptimal time for education (eg, after delivery).[25] It is agreed generally that prenatal newborn screening education is a more opportune way to provide the needed information about the screening experience. The need for prenatal education is acknowledged specifically in the Kansas regulations, which require prenatal providers to provide newborn screening education. Surprisingly few programs (~20%) reported that distribution of educational pamphlets about newborn screening was a usual activity of obstetricians, and only slightly more (~30%) reported that it was a usual activity of prenatal classes. These low rates illustrate the lack of involvement in newborn screening programs that obstetricians have had traditionally, although in some programs the law may assign the responsibility to ensure newborn screening to the "person attending the birth of the newborn." Similarly, although newborn screening advisory committees often include pediatricians and family practice physicians, they often overlook the benefits that could be obtained by including an obstetrician on the committee. As determined from information obtained from newborn screening program reviews, the most common method for providing educational information about newborn screening is through information packets provided as part of the overall information/education process for new parents. Obstetricians represent a potentially more effective and efficient means of transmitting information to large numbers of women, who could benefit from having the information before they arrive at the hospital for the birth and subsequent screening of their newborns.[26] Efforts to include the obstetrics community in newborn screening activities, particularly education, seem to be a pressing need for most newborn screening programs.

Retention and Storage

Procedures and policies for the management of the residual dried blood spots that remain after newborn screening continue to vary widely. Despite extensive discussions over time, the issues surrounding long-term specimen management have not resulted in consensus solutions. Even the seemingly simple question of how long to store the residual specimens is not resolved. Our survey indicated that, at the time, almost one half of the programs (23 of 51 programs) stored residual specimens for ≤6 months, whereas slightly more than 25% (14 of 51 programs) stored them for ≥21 years. These results compare favorably with a similar study of APHL members (all state and territorial health department laboratory directors) in 2002.[17]

The complexity of the storage issue revolves around the fact that, although the residual specimens remaining after newborn screening may provide usable specimens for some analyte tests when stored for long periods, the validity of the specimens for some tests is questionable or not satisfactory. However, the DNA contained in the specimen seems to be stable indefinitely. DNA analysis cannot be relied on to provide confirmation of initial newborn screening results, for various reasons (eg, multiple mutations associated with the condition or poor genotype/phenotype correlation), and generally the specimens that are stored for long periods (beyond a few months) are not considered useful for quality assurance

regarding the original screening tests (with limited exceptions). Therefore, it is agreed generally that specimens stored for long periods are of interest primarily for their potential research use. This use is made more complex by the fact that most newborn screening programs do not need to obtain consent for testing; therefore, the use of specimens beyond the newborn screening procedure itself raises various legal and ethical questions.

The storage and usage issues related to residual blood spots after newborn screening were discussed at some length in a report from CORN.[16] The CORN report also recommended that screening laboratories should develop policies for storage and use of the residual spots. Our survey indicated that ~25% of screening laboratories (14 of 51 laboratories) still do not have written policies regarding storage, and more than one half (28 of 51 laboratories) reported having no written policy regarding usage. When these data were pursued, in many cases program personnel reported handling requests for access to residual specimens on a case-by-case basis and noted that requests for residual specimens had been minimal or had not been encountered. However, many programs reported several requests annually, primarily related to additional analyses to determine the cause of death in cases of sudden infant death syndrome or in other unusual circumstances in which a cause was not readily apparent. Occasional anecdotal requests for use of specimens for forensic purposes were also reported (eg, positive identification of infants when no other means of identification were available).

Despite the variations in program policies, regulations, and laws that might affect the storage and use of specimens, the potential for research use of population screening specimens is extensive. The CDC, in cooperation with APHL, convened a small working conference in September 2002 to discuss the possibilities for research use of these specimens, including the possibilities for consolidating specimens from programs to provide larger collections of available specimens for possible research. As might be expected, the tremendous variations in program approaches to the issues surrounding the use of residual specimens seemed to present a significant barrier to specimen consolidation. Nonetheless, conference participants seemed to embrace the possibilities of a virtual bank of specimens in which a data manager would maintain information regarding specimen availability for research, storage conditions, and limited other specimen information, such that an inquiring researcher might be directed to appropriate specimens for anticipated projects. However, before such a system is put in place, it will be necessary to address the considerable concerns related to privacy and consent. If these barriers can be overcome, then it may be possible to create a virtual national centralized specimen management system that would be useful for various types of research. Other ethical, legal, and social issues related to the question of using residual newborn screening specimens remain, and it seems that extensive use of newborn screening specimens accumulated nationally for research purposes outside the newborn screening process itself is not likely in the near future.

CONCLUSIONS

Newborn screening represents a successful population genetic screening program. The fact that a national newborn screening law or financing scheme does not exist in the United States leads, at least in part, to the current state of variation from program to program. Different legislative and regulatory approaches, coupled with a range of policies and practices, create a complex diversity of available services, consumer and professional involvement, and quality of components of the individual newborn screening systems.

Policymakers in states or territories that have yet to address definitively the issues discussed in this article may want to consider whether these issues might best be developed statutorily, through rule-making adjunctive to statutes already in place, through program policy changes, or through some combination of these approaches. Statutes or rules may provide a stricter means of enforcement and a more visible assurance to the public that government has taken action to alleviate concerns about privacy, confidentiality, and services. However, allowing program personnel the flexibility to create and to implement policies may provide a mechanism for faster reactions to change as technology and medical knowledge advance. Increased input from health care professionals involved closely and regularly with the newborn screening system can provide an increased sense of community ownership and involvement, with better responses to local needs and concerns. The information synthesized in this article should find use in comparative analyses between programs and across time as programs continue to be refined on the basis of new science and new national recommendations.

APPENDIX 1 **Newborn Screening Program Specimen Overview Information**

State	Births by Occurrence (2001) (From National Center for Health Statistics)	Screens Required for All Newborns	Specimens Received (2001)	Conditions Named in Statute	Can Conditions Be Changed Without Statute Change?	A Newborn Screening Advisory Committee Is Rs—Legally Required, N—Not Required, but Exists. X—Has Not Been Established	Required Conditions (January 2005)	Optional/Pilot Conditions (January 2005)	Screening Fee (January 2005) (Fee Structure Varies)	Statute or Regulations Specify Specimen or Information Retention Time	Written Specimen Storage Policy Exists	Written Specimen Usage Policy Exists	Statute or Regulations Specifically Permit Specimen Use[a]	Statute or Regulations Specifically Permit Information Use[a]	Period for Which Residual Blood Specimens Are Retained	Additional Comments
Alabama	59 766	1	181 488	3	Yes	N	14	0	$139.33	No	Yes	No	No	No	3 mo	Stored at 4°C
Alaska	9907	1	17 833	1	Yes	R	>30	0	$55.00	No	Yes	No	No	No	3 y	
Arizona	85 757	2	147 028	0	Yes	R	8	0	$20.00	No	Yes	No	No	Yes	3 mo	Policy in laboratory manual
Arkansas	36 301	1	37 767	4	Yes	N	4	0	$14.83	No	Yes	Yes	No	Yes	1 y	
California	528 539	1	531 148	1	Yes	X	>30	0	$78.00	No	Yes	Yes	Yes	Yes	Indefinitely	Stored at −20°C
Colorado[b]	67 100	2	123 749	6	Yes	N	7	0	$53.25	No	Yes	No	No	No	3 mo	
Connecticut	43 179	1	90 041	1	Yes	N	>30	1	$28.00	No	Yes	No	No	No	3 mo	
Delaware	11 360	2	21 796	0	Yes	N	29	0	$64.00	No	Yes	No	No	No	4 mo	Stored at 4°C
District of Columbia	15 037	1	15 474	6	Yes	R	7	0	No fee	No	No	No	No	No	Indefinitely	Defers to Pediatrix Screening; 2-y minimum
Florida[c]	205 991	1	295 407	1	Yes	R	5	27	$15.00	Records: 3 y in accordance with departmental procedures.	No	No	No	No	5 y	Unwritten internal understanding on use of specimens
Georgia[d]	134 402	1	202 561	8	Yes	R	10	0	No fee	No	No	No	No	No	6 wk	
Hawaii	17 127	1	17 045	2	Yes	N	>30	0	$47.00	Specimens: at least 1 y	Yes	No	No	Yes	1 y	Oregon laboratory contract
Idaho	20 161	1	20 353	1	Yes	X	>30	0	$23.00	Records must be retained[e]	No	No	No	No	1 y	Oregon laboratory contract
Illinois	181 086	1	187 696	3	Yes	R	>30	0	$47.00	No	Yes	No	No	No	2 mo, 4 mo, indefinitely	Routine specimens; at risk specimens; diagnosed cases
Indiana	86 710	1	113 980	8	Yes	R	>30	0	$62.50	No	Yes	No	Yes	Yes	23 y	
Iowa	37 756	1	38 880	1	Yes	R	>30	0	$56.00	Specimens and records for 1 mo, then incinerated unless kept for program evaluation or released for research purposes	Yes	Yes	Yes	Yes	1 mo	
Kansas	39 052	1	46 643	4	Yes	N	4	0	No fee	No	Yes	No	No	No	1 mo	Stored at −20°C
Kentucky	53 227	1	74 778	4	Yes	N	4	0	$14.50	No	Yes	Yes	No	No	6 mo	Stored at 4°C
Louisiana[f]	65 620	1	90 490	4	Yes	N	5	5	$18.00	No	No	No	No	No	1 mo	First 2 wk at 4°C
Maine	13 567	1	13 532	0	Yes	R	9	18	$44.00	Specimens and records: 5 y	Yes	Yes	Yes	Yes	5 y	Massachusetts laboratory

APPENDIX 1 **Continued**

State	Births by Occurrence (2001) (From National Center for Health Statistics)	Screens Required for All Newborns	Specimens Received (2001)	Conditions Named in Statute	Can Conditions Be Changed Without Statute Change?	A Newborn Screening Advisory Committee Is Rs—Legally Required, N—Not Required, but Exists, X—Has Not Been Established	Required Conditions (January 2005)	Optional/Pilot Conditions (January 2005)	Screening Fee (January 2005) (Fee Structure Varies)	Statute or Regulations Specify Specimen or Information Retention Time	Written Specimen Storage Policy Exists	Written Specimen Usage Policy Exists	Statute or Regulations Specifically Permit Specimen Use[a]	Statute or Regulations Specifically Permit Information Use[a]	Period for Which Residual Blood Specimens Are Retained	Additional Comments
Maryland	68 663	1	151 345	0	Yes	R	>30	0	$42.50	No	Yes	Yes	No	No	6 mo.	Stored at −20°C; some specimens at Pediatrix Screening; 2-y minimum
Massachusetts	82 237	1	90 831	2	Yes	R	10	20	$54.75	No	Yes	Yes	No	No	Indefinitely	Policy: minimum of 10 y
Michigan	132 159	1	141 694	8	Yes	N	11	0	$55.72	Specimens stored for unspecified period	Yes	Yes	Yes	Yes	21.5 y	
Minnesota	67 428	1	68 877	0	Yes	R	>30	0	$61.00	Parents may request sample destruction after 2 y	Yes	No	No	Yes	Indefinitely	
Mississippi	41 145	1	42 227	5	Yes	R	40	0	$70.00	No	No	No	No	Yes	3 mo	Pediatrix Screening
Missouri	76 690	1	96 789	5	Yes	N	14	0	$25.00	No	Yes	Yes	No	No	1 mo at −20°C	
Montana	10 935	1	14 327	0	Yes	N	4	22	$39.34	No	No	No	No	No	6–8 wk at 4°C	
Nebraska	25 107	1	25 043	6	Yes	N	6	27	$30.75	Records for 25 y; specimen disposal within 30 days after 90-d retention period	Yes	Yes	Yes	Yes	3 mo	Pediatrix Screening at 4°C with desiccant
Nevada	31 007	2	58 160	1	Yes	R	>30	0	$60.00	No	No	No	No	No	1 y	Oregon laboratory
New Hampshire	14 055	1	14 860	5	Yes	N	6	1	$18.00	No	No	No	No	No	7 y	Massachusetts laboratory; advisory committee agenda item
New Jersey	112 639	1	124 115	3	Yes	R	20	6	$71.00	No	No	No	No	No	23 y	
New Mexico	26 808	2	51 140	1	Yes	N	6	0	$32.00	Specimen and records until 1 y past age of majority; printouts from screening database retained 2 y	Yes	No	No	No	3 mo	
New York	255 029	1	290 887	7	Yes	N	>30	0	No fee	Specimens and records: no period of time specified	Yes	Yes	No	No	Indefinitely at 4°C	
North Carolina	119 132	1	133 635	0	Yes	N	26	0	$10.00	No	Yes	No	No	No	2 y	

North Dakota	8839	1	9332	0	Yes	N	29	0	$36.00	Specimensandrecords; indefinitely	Yes	Yes	No	Yes	Indefinitely.	Laboratorypolicy: minimumof 10 y
Ohio	152 033	1	160 994	0	Yes	R	30	0	$33.75	Records: 21 y	Yes	Yes	No	No	21 y	
Oklahoma	48 895	1	52 884	1	Yes	R	7	0	$75.59	Records: 21 y	Yes	Yes	No	No	4 wk	
Oregon	46 200	2	90 105	1	Yes	N	26	8	$54.00	Specimens and informationup to 1 y	Yes	No	Yes	Yes	1 y	
Pennsylvania	143 957	1	145 904	3	Yes	N	6	>30	No fee	No	No	Yes	No	No	5 y	2 contracting laboratories; specimens stored for 3 mo at 4°C with desiccant
Rhode Island	13 319	1	13 292	0	Yes	N	9	0	$59.00	No	Yes	Yes	No	No	23 y	Massachusetts laboratory
South Carolina	53 255	1	60 314	0	Yes	N	30	0	$42.00	Return or destruction at 2 y or ongoing storage for research	Yes	Yes	Yes	Yes	Indefinitely	
South Dakota	10 784	1	12 501	3	Yes	N	3	30	$18.53	No	Yes	Yes	No	No	2 mo at 4°C	Stored in sealed bags
Tennessee	83 521	1	86 689	4	Yes	R	>30	0	$47.50	No	Yes	No	No	Yes	3 mo at 4°C	Abnormal specimens: indefinitely
Texas	370 482	2	662 978	2	Yes	N	5	0	$19.50	No	Yes	Yes	No	No	2 y	
Utah	49 041	2	99 889	1	Yes	R	4	25	$31.00	No	Yes	Yes	No	No	3 mo at 4°C	
Vermont	6349	1	6014	0	Yes	N	21	0	$33.30	No	No	No	No	No	Indefinitely	Massachusetts laboratory
Virginia	96 535	1	114 216	9	Yes	N	9	0	$32.00	No	Yes	Yes	No	Yes	6 mo	Abnormal specimens: 10 y
Washington	79 078	1	145 814	1	Yes	N	9	0	$60.90	Specimens and records; 21 y	Yes	Yes	Yes	Yes	21 y	
West Virginia	21 000	1	31 125	3	Yes	N	4	0	No Fee	No	No	No	No	Yes	3 mo	
Wisconsin	68 006	1	67 475	0	Yes	N	26	0	$65.50	No	No	Yes	Yes	Yes	1 y at 4°C	
Wyoming	5758	1	9049	0	Yes	N	7	0	$45.00	No	Yes	No	No	No	3 mo	
Total	4 031 531		5 342 276													

R indicates legally required; N, not required but exists; X, has not been established.

[a] Research may have to meet certain criteria. See the state summaries in Appendix 3 for details.

[b] Individuals in Colorado have a personal property right to their genetic information under the state's genetic discrimination in health insurance law. Genetic information is not defined in the state law, but genetic testing is defined as "any laboratory test of human DNA, RNA, or chromosomes that is used to identify the presence or absence of alterations in genetic material that are associated with disease or illness." Genetic testing is limited to "such tests as are direct measures of such alterations rather than indirect manifestations thereof" (Colorado Revised Statute §10-3-1104.7).

[c] Individuals in Florida have a personal property right to the results of DNA analysis under the state genetic privacy law. The law does not exclude newborn screening activities. DNA analysis is defined as "the medical and biological examination and analysis of a person to identify the presence and composition of genes in that person's body. The term includes DNA typing and genetic testing" (Florida Statute Annals §760.40).

[d] Individuals in Georgia have a personal property right to genetic information. Genetic information is not defined in the state genetic privacy law, but genetic testing is defined as "laboratory tests of human DNA or chromosomes for the purpose of identifying the presence or absence of inherited alterations in genetic material or genes which are associated with a disease or illness that is asymptomatic at the time of testing and that arises solely as a result of such abnormality in genes or genetic material." Genetic testing does not include routine physical measurements; chemical, blood, and urine analyses; tests for abuse of drugs; and tests for the presence of the HIV (Georgia Code §33-54-1–8).

[e] Under Louisiana's a genetic discrimination in Health Insurance Law, genetic information is the property of the insured or enrollee. Genetic information is defined as "all information about genes, gene products, inherited characteristics, or family history/pedigree that is expressed in common language" (Louisiana Revised Statute Annals §22:213.7).

[f] The newborn screening statutes and regulations do not state for how long the state must retain records.

APPENDIX 2 **Information From Statutes and Regulations on State Genetic Privacy and Newborn Screening**

Program	Authority for Newborn Screening or Newborn Screening Regulations[a]	Newborn Screening Regulation Citation[b]	Genetic Privacy Statute Citation	Consent or Confidentiality Wording in Genetic Privacy Statute May Apply to State Newborn (Genetic) Screening	Grounds for Refusal to Participate in Newborn Screening	Parental Education Required Before Screening	Consent Requirements in Newborn Screening Statutes and Regulations[c]	Confidentiality Provision(s) in Relevant Newborn Screening Statutes and Regulations
Alabama	Alabama Code §22-20-3	Alabama Admin. Code §420-10-1	None	No	Religious	No	None	No
Alaska	Alaska Stat. §18-15-200, 210	07 Alaska Admin. Code 27.510–590	Alaska Stat. §18-13-010–100	No	Any	Yes	None	Yes
Arizona	Arizona Rev. Stat. §36-694	Arizona Admin. Code R9-14-501–505	Arizona Rev. Stat. §12-2801–4; §20-448.02	Yes	Any	Yes	To disclose information	Yes
Arkansas	Arkansas Code Ann. §20-15-301–304	Code of Arkansas R007-13-004	Arkansas Code Ann. §16-43-1101; §20-35-101–3	Yes; consent for research	Religious	No[d]	None	No
California	California Health and Safety Code §124975–125001	17 Colorado Code of Regs. 6500–6510	California Insurance Code §10149.1	No	Religious	Yes	To disclose information	Yes
Colorado	Colorado Rev. Stat. §25-4-1001–1006	5 Code of Colorado Regs. 1005-4	Colorado Rev. Stat. Ann. §10-3-1104.7	No	Religious or personal	No	To disclose information	Yes
Connecticut	Connecticut Gen. Stat. Ann. §19a-55	Regs. of Connecticut State Agencies §19-13-D41	None	No	Religious	No	None	Yes
Delaware[e]	Delaware Code §16.2.201–206	Code Delaware Regs. 40-700-012	Delaware Code §16.2.1220–1227	No	Religious	Yes	To disclose information	Yes
District of Columbia	District of Columbia Code Ann. §7-831–840	District of Columbia Department of Health "Notice of Final Rulemaking"	None	NA	Any	Yes	Informed consent for newborn screening; consent to disclose information	Yes
Florida	Florida Stat. Ann. 29 §383.14	Florida Admin. Code Ann. Rule 64C-7.001–7.012	Florida Stat. Ann. §760.40	Yes; consent to perform DNA analysis or disclose results	Any	No	To disclose information	Yes
Georgia	Georgia Code §31-12-5–7	Georgia Comp. Rules and Regs. 290-5-24-.01–.04	Georgia Code §33-54-1–8	Yes; consent to perform genetic testing; authorization to disclose information derived from genetic testing	Religious	No	None	No
Hawaii	Hawaii Rev. Stat. §321-291	Hawaii Admin. Rules 11-143-1–100	Hawaii Rev. Stat. §431:10A-118	No	Religious	Yes	None	Yes
Idaho	Idaho Code §39-909–912	Idaho Admin. Procedure Act 16.02.12	None	No	Religious	No	To disclose information	No
Illinois	410 ILCS 240/.01–.03	Illinois Admin. Code 77-661.10–.70	410 Illinois Compiled Stat. 513	No	Religious	No	None	Yes
Indiana	Indiana Code §16-41-17	410 IAC 3-3-1–7	None	No	Religious	No	None	Yes
Iowa	Iowa Code §136A.1–7	Iowa Admin. Code §641-4.1–4.3 (136A)	None	No	Any	Yes	To disclose information	Yes
Kansas	Kansas Stat. Ann. §65-180–183	Kansas Admin. Regs. 28-4-501–513	None	No	Religious	Yes	For follow-up treatment; to disclose information	No
Kentucky	Kentucky Rev. Stat. §214.155	Kentucky Admin. Regs. 902 §4:030	None	No	Religious	No	None	No

Louisiana	Louisiana Rev. Stat. Ann. 40 §1299	Louisiana Admin. Code 48 §6303	Louisiana Rev. Stat. Ann. §22: 213.7; §40:1299.6	No	Any	No	None	No
Maine[f]	Maine Rev. Stat. Ann. Title 22 §1531–1533	10-144 CMR 283	None	No	Religious	No	To participate in optional expanded screening; to disclose information	No
Maryland	Maryland Health Code Ann. §13-101–110	Code of Maryland Regs. 10.52.12.01–.012	Ann. Code of Maryland Insurance §27-909, Labor and Employment §49B-15, 16	No	Any	Yes	Consent for screening, follow-up and treatment; to disclose information	Yes
Massachusetts	Massachusetts Gen. Laws 111 §3.4E, 5, 6, 24A, 110A	105 Code of Massachusetts Regs. 270.000	Massachusetts Gen. Laws Ann. §111.70G	No	Religious	No	None	No
Michigan	Michigan Comp. Laws 333.5431	Rescinded	Michigan Comp. Laws §333.17020 §333.17520	Yes; consent for predictive or presymptomatic genetic testing	None	Yes	None	No
Minnesota	Minnesota Stat. §144.125–128	Minnesota Rules §4615.0300–.0760	None	No	None	No	None	Yes
Mississippi	Mississippi Code Ann. §41-21-201–205; §41-24-1–5	Code Mississippi R. 12-000-031	None	No	Religious	No	None	Yes
Missouri	Missouri Rev. Stat. §191.331, 332	19 Missouri Code of State Regs. 25-36.010	Vernon's Ann. Missouri Stat. §375.1309	Yes; consent to disclose	Religious	Yes	To disclose information	Yes
Montana	Montana Code Ann. §50-19-201–211	Montana Admin. Rules 37.57.301–321	None	No	None	No	None	No
Nebraska	Nebraska Rev. Stat. §71-519–24	Nebraska Admin. Rules and Regs. 181-2 §001–010	Nebraska Rev. Stat. §71-1, 104.1	Yes; consent for predictive or presymptomatic genetic testing	None	No[g]	None	No
Nevada	Nevada Rev. Stat. 442.008	Nevada Admin. Code 442.020–442.050	Nevada Rev. Stat. §629.101–§629.201	No	Any	No	To disclose information	Yes
New Hampshire	New Hampshire Rev. Stat. Ann. §132:10-a–d	Rules are currently under revision	New Hampshire Rev. Stat. §141-H:2	No	Silent	No	None	Silent
New Jersey	New Jersey Stat. Ann. §26:2-510 and 511	New Jersey Admin. Code §8:19-1.1–2.13	New Jersey Stat. Ann. §10:5-43–§10:5-49	No	Religious	Yes	None	Yes
New Mexico	New Mexico Stat. Ann. §24-1-6	7 New Mexico Admin. Code 30.6.1–.9; 1 New Mexico Admin. Code 18.665.2090–.2096	New Mexico Stat. Ann. §24-21-1–§24-21-7	No	Any	Yes	None	Yes
New York	New York Public Health Law §2500-a	10 New York Code of Rules and Regs. 69-1.1–1.9	New York Civil Rights Law §79-L	No	Religious	No	None	No
North Carolina	North Carolina Gen. Stat. §130A-125	10A North Carolina Admin. Code 43F.1201–.1204	None	No	Any	No	None	No
North Dakota	North Dakota Cent. Code §23-01-03.1; 25-17-00.1–.5	North Dakota Admin. Code 33-06-16-01–05	None	No	Religious	No	None	Yes
Ohio	Ohio Rev. Code Ann. §3701.50.1–.9	Ohio Admin. Code §3701-55-01–10	None	No	Religious	Yes	None	No
Oklahoma	Oklahoma Stat. §63-1-533, 534	Oklahoma Admin. Code 310:550	None	No	Religious	Yes	None	Yes

APPENDIX 2 **Continued**

Program	Authority for Newborn Screening or Newborn Screening Regulations[a]	Newborn Screening Regulation Citation[b]	Genetic Privacy Statute Citation	Consent or Confidentiality Wording in Genetic Privacy Statute May Apply to State Newborn (Genetic) Screening	Grounds for Refusal to Participate in Newborn Screening	Parental Education Required Before Screening	Consent Requirements in Newborn Screening Statutes and Regulations[c]	Confidentiality Provision(s) in Relevant Newborn Screening Statutes and Regulations
Oregon	Oregon Rev. Stat. §433.285–.295, §192.531–192.549	Oregon Admin. Rules 333-024-0210–0240; Oregon Admin. Rules 333-025-0155	Oregon Rev. Stat. §192.531–549	Yes; and consent to disclose with some exceptions	Religious	No	To disclose information	Yes
Pennsylvania	Pennsylvania Statutes 35 §621-625	28 Pennsylvania Code 28.1–.41; 501.3; 501.49	None	No	Religious	No	To disclose information	No
Rhode Island	Rhode Island Gen. Laws §23-13-14	Rhode Island Code of Rules R.23-13 MET/HRG	Rhode Island Gen. Laws §27-18-52, 52.3, §27-19-44, 44.1, §27-20-39, 39.1, §27-41-53, 53.1	No	Religious	No	None	No
South Carolina	South Carolina Code Ann. §44-37-30	South Carolina Code of Regs. R.61-80	South Carolina Code Ann. §38-93-10–§38-93-60	No	Religious	Yes	To disclose information	Yes
South Dakota	South Dakota Codified Laws Ann. §34-24-17–25	Admin. Rules of South Dakota 44:19:01:01–03:02	South Dakota Codified Laws Ann. §34-14-21–25	No	None	No	None	No
Tennessee	Tennessee Code Ann. §68-5-401–506	Tennessee Comp. Rules & Regs. §1200-15-1-.01–.05	None	No	Religious	Yes	None	Yes
Texas	Texas Code Ann. Health & Safety §33.001–.038	25 Texas Admin. Code 37.51–.67	Vernon's Texas Civil Code §9031	No	Religious	No	To deliver CSHCN services	No
Utah	Utah Code Ann. §26-10-6	Utah Admin. Code R398-1	§26-45-101–106; §31A-22-1601, 2; §34A-11-101, 2	No	Religious	Yes	None	No
Vermont	18 Vermont Stat. Ann. §115	Vermont Code Rules R.13-140-057	Vermont Stat. Ann. §18:9331–§18:9335	No	Any	No	None	No
Virginia	Virginia Code §32.1-65–69	12 Virginia Admin. Code 5-70-10–50	Virginia Code Ann. §38.2-508.4	No	Religious	No	None	Yes
Washington	Washington Rev. Code §70.83.020–.050	Chapter 246-650 Washington Admin. Code	Rev. Code of Washington §70.02.010	No	Religious	Yes	To disclose information	Yes
West Virginia	West Virginia Code §16-22-1–6	Expired	None	No	Religious	Yes	None	Yes
Wisconsin	Wisconsin Stat. Ann. §253.13	Wisconsin Admin. Code HFS §115.01–.06	None	No	Religious	No	To disclose information	Yes
Wyoming	Wyoming Stat. §35-4-801–802	WY Rules and Regs. HLTH 3880-1	None	No	Any	No	Informed consent for newborn screening	No
Total			30	8	45	20	20	28

Stat. indicates Statute; Rev., Revised; Ann. Annals; Admin., Administrative; Gen., General; Regs., Regulations; Comp., Comprehensive; CSHCN, children with special health care needs; NA, not applicable.

[a] This table does not include newborn screening statutes that refer only to fees for services, newborn screening funds or insurance coverage of services.

[b] This table does not include newborn screening regulations that refer only to fees for services, newborn screening funds, or insurance coverage of services.

[c] Consent requirements may have exceptions such as for service delivery.

[d] Arkansas statutes require the health department to "disseminate information and advice to the public concerning the dangers of phenylketonuria, hypothyroidism and sickle-cell anemia," but the law does not specifically require education before screening.

[e] The public health department may not compel a parent or guardian to accept treatment for a disorder.

[f] Participation in expanded screening is voluntary.

[g] Nebraska statutes require the health department to develop an educational brochure but does not establish when the department must distribute the brochure. However, the department reports that distribution of the pamphlet is during the newborn screening process is common practice.

APPENDIX 3. SELECTED NEWBORN SCREENING PROGRAM SUMMARY INFORMATION

Alabama

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The State Board of Health can adjust the disorder panel. There is no mention of an advisory committee; however, a multidisciplinary nonstatutory committee chaired by a geneticist advises the department.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "It shall be the duty of the administrative officer . . . of the institution . . . or physician, . . . or person attending the newborn. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
The statute states, "Initial mass screening tests . . . shall be performed by the Public Health Laboratory."

What Additional System Components Does the Fee Cover?
The fee covers only the laboratory testing.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless the parents object on religious grounds. Newborn screening statutes or regulations do not require the hospital or birthing center to provide a parent or guardian with educational materials before the refusal of screening, and parents are not obligated to provide a written statement of refusal. If a newborn testing positive for a newborn screening disorder is not receiving care, then the department is permitted to contact the child's parent or guardian directly. There is no specific consent or confidentiality requirement for newborn screening or the use of residual dried blood spots, although general public health statutes and regulations may apply.

Alaska

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The statute gives authority to the Department of Health and Social Services. Regulations state, "The department will appoint a committee . . . to consider addition and deletion of tests. . . ." A multidisciplinary advisory committee has been established and is active.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "A physician who attends a newborn child. . . . In the absence of a physician the nurse who first visits the child shall cause the test to be performed."

Are Newborn Screening Laboratory Services Regulated? How?
Regulations state, "The screening . . . must be performed in a single laboratory designated by the department." Currently screening is contracted to the Oregon Department of Health Laboratory.

What Additional System Components Does the Fee Cover?
In addition to laboratory testing, the fee covers administration, follow-up services, and consultation.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
The parent or guardian of a newborn may decline to participate in the program. Grounds for refusal are not specified; however, the attending physician or nurse must inform the Department of Health and Human Services of the decision, and a signed statement of refusal is required. Alaska regulations specify that information obtained through newborn screening is a "confidential medical public health record" and is exempt from the public records statute. Individuals and facilities that generate the information must protect it from loss, tampering, and unauthorized access.

Arizona

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The statute states, "Tests shall be specified by rules of the Department of Health Services . . . consistent with the recommendation of a newborn screening program committee. . . ." The committee is chaired by the director of the department and includes 5 physicians from medical specialties in endocrinology, pediatrics, family practice, and obstetrics.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "The attending physician or other person required to make a report on the birth shall order . . . tests for metabolic disorders."

Are Newborn Screening Laboratory Services Regulated? How?
The statute states, "The newborn screening program committee shall prepare and issue a solicitation . . . to contract for the testing. Proposals may be accepted from hospitals, clinical laboratories, the state laboratory, and any other qualified public or private persons." The administrative code defines the newborn screening laboratory as "an entity contracted with the department to perform the newborn screening test." Currently the Department of Health Laboratory holds the contract.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration, follow-up services, treatment, specialist consultation, the data system, provider/public/parent education, and staff.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
The parent or guardian of a newborn may decline to participate in the program. Grounds for refusal are not specified. Health care providers must report that the test was refused on the specimen collection form, submit the form to the Department of Health Services, and document the refusal in the patient's medical record. Arizona regulations do not require a signed statement of refusal from a parent or guardian. Before the collection of a specimen, health care providers must explain the purpose of the test, on the basis of the information contained in departmental educational materials available to providers for distribution to parents. The newborn screening regulation provides for the confidentiality of newborn screening results, subject to the general public health privacy statutes, which prohibit disclosure of confidential information without the written consent of an individual, a parent or guardian of a minor, or a spouse or legal representative of a deceased individual. The department may disclose confidential information for scientific research or legal proceedings.

Arkansas

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health has authority. There is no mention of an advisory committee; however, a multidisciplinary nonstatutory advisory committee is active.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Regulations state that, in a birthing medical facility, the "governing body and medical staff [must] adopt and enforce policies" concerning newborn screening.

Are Newborn Screening Laboratory Services Regulated? How?
Statute requires the Department of Health to establish a central laboratory. Regulations specify, "Specimens shall be submitted to the Division of Public Health Laboratories."

What Additional System Components Does the Fee Cover?
The fee covers only laboratory services.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless the parents object on religious grounds. The newborn screening laws and regulations do not require a record of refusal. The Department of Health must educate the public about "the dangers and effects of phenylketonuria, hypothyroidism, and sickle cell anemia." There are no specific requirements concerning consent or parental education before collection of the blood sample or refusal of screening. The department must track diagnosed cases for program evaluation and operational purposes and may provide individually identifiable information about diagnosed cases to clinical or research programs with the permission of the infant's parent or guardian.

California

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health has authority. There is no mention of an advisory committee, but legislation is pending.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Regulations state, "Birth attendants, laboratories, and hospitals shall collect specimens. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
The statute states, "The department may provide laboratory testing facilities or contract with any laboratory it deems qualified. . . ." Currently there are 8 contract laboratories located regionally, with oversight from the Department of Health Laboratory in Berkeley.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration, follow-up services, diagnostic testing, quality assurance, and evaluation.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in the program unless the parent or guardian objects on religious grounds. The California Department of Health Services must allow a parent or guardian a reasonable opportunity to object on religious grounds. State regulations require that the physician or birth attendant include a signed written refusal of newborn screening in the infant's medical record. Birth attendants must provide parents with the department's educational brochure, *Important Information for Parents*, during prenatal care and in the hospital before childbirth or collection of the blood sample. Information obtained from individuals through newborn screening, including test results, is confidential, but all other information pertaining to the program is public record. The statute provides for individual access to

test results and personal information generated through newborn screening. Positive test results must be reported to the health care provider. With written consent of the parent, guardian, or individual, if older than 18 years, the department may release individually identifiable information. The written consent is compliant with HIPAA and must include the scope of the information requested, the parties requesting the information, and the purposes for the release. An institutional review board approves informed consent for the written disclosure of personal information for research purposes. Newborn screening blood spots and related information are the property of the State of California. The state may use the specimens and information for program evaluation or research by the department or department-approved scientific researchers, provided the confidentiality requirements described above are met. The department must translate all forms or brochures referenced in state newborn screening regulation to the native language of the parent or guardian if necessary. State statute provides that an individual may receive compensatory and civil damages not greater than $10 000, in addition to attorney fees and the cost of litigation, for a breach of confidentiality by the program.

Colorado

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Board of Health has authority. A nonstatutory advisory committee makes recommendations.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "The physician, nurse, midwife, or other health professional attending a birth . . . shall be responsible for the collection. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
Appropriate specimens . . . shall be forwarded . . . to the laboratory operated or designated by the Department of Public Health. . . . Currently the Department of Public Health Laboratory provides testing.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration and follow-up services.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in the program unless the parents object on religious grounds or have a personal objection to the administration of tests or treatment. All information other than statistical data is confidential. Informed consent is required for disclosure of individually identifiable information.

Connecticut

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Commissioner of Health has authority. There is a nonstatutory advisory committee.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Responsibility is given to "the administrative officer . . . in charge of each institution caring for newborn infants. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
Regulations state, "Specimens shall be submitted to the . . . State Department of Health, or to a laboratory approved for the purpose. . . ." Currently the Department of Public Health Laboratory provides testing.

What Additional System Components Does the Fee Cover?
The statute specifies a fee to "cover all expenses . . . including testing, tracking, and treatment."

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in the program unless the parents object on religious grounds. If a parent declines to participate, then the individual offering screening must report the refusal to the Department of Public Health and place a signed statement of refusal in the infant's medical record. The department must direct diagnosed newborns to treatment centers in a manner consistent with confidentiality requirements. State regulations require that identifying information accompany each specimen for future reference, but they do not comment on specimen storage. The Department of Public Health must maintain newborn screening records for 5 years. These records must include the tests performed and results. The regulations do not mention blood spot storage. Currently blood spot specimens are discarded after 6 months.

Delaware

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
Regulations state, "as recommended by the Delaware Newborn Screening Program with the approval of the Director of the Division of Public Health." There is a nonstatutory multidisciplinary committee that advises the program.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The regulations state, "in order of responsibility: the hospital, alternate birth facility, or other licensed health care facility, the newborn's primary care provider, the parent or legal guardian."

Are Newborn Screening Laboratory Services Regulated? How?
Regulations state, "the laboratory designated by the Division of Public Health." Currently the Division of Public Health Laboratory provides the testing.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration, follow-up services, and medical consultation.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
There is not a state statute pertaining to newborn screening per se; however, reporting requirements under the state's birth defects surveillance system and registry statute (see citation above) include biochemical abnormalities, and the state Board of Health has exerted its authority to adopt regulations for newborn screening under the state statutes requiring the Department of Health and Social Services to protect the well-being of mothers and children. The state is in the process of revising its regulations. Regulations require all newborns to participate in the state newborn screening program unless a parent or guardian objects on religious grounds. Families who decline testing must file an affidavit swearing their religious beliefs. The person who administers screening must provide an informational pamphlet developed by the department. The department must record demographic information on newborns screened, for surveillance and monitoring. Under state statutes, individuals or institutions who believe in treating illness through prayer are not required to participate in the birth defects surveillance system, which includes newborn screening information. A parent or guardian also may refuse to disclose personal information concerning an infant's birth defect on religious grounds. In addition, the department may not compel an individual to participate in "medical or public health examination, treatment, or supervision." The birth defects registry statute protects the confidentiality of information related to the diagnosis or treatment of a biochemical disorder reported to the department and prohibits the disclosure of individually identifiable information. The Department of Health Services is permitted to share personal information in the registry with authorized agencies. Newborn screening regulations state that all newborn screening records are confidential. Release of summary, statistical, or anonymous information is permitted. The department may release data for approved research projects. The type of data that may be released is not specified. A violation of state newborn screening regulations is punishable by a fine of not less than $100 or more than $1000.

District of Columbia

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The statute allows the mayor to add or to delete disorders on the advice of the Committee on Metabolic Disorders. Established by statute, this committee (9 members appointed by the mayor, ie, 4 consumers, 4 physicians including a geneticist or endocrinologist, and the director of the Department of Human Services) must consider, among other issues, the medical, psychological, ethical, social, and economic effects of programs to identify and to treat metabolic disorders.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "Each hospital and maternity center . . . shall make available [screening] for. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
The statute states, "a laboratory designated by the mayor. . . ." Currently Pediatrix Screening (Bridgeville, PA) provides testing services.

What Additional System Components Does the Fee Cover?
There is no fee; however, hospitals are billed for tests by the contracting laboratory.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
Participation in the District of Columbia newborn screening system is voluntary. Hospitals and birthing facilities must inform parents of the availability and purpose of tests. Parental consent for newborn screening is required. Parents may decline to participate in the program. Hospitals and birthing facilities are required to document consent or nonconsent in the infant's medical record. The District of Columbia statute prohibits discrimination against or stigmatization of carriers of metabolic disorders. All information gathered through the newborn screening process is confidential medical record except for deidentified statistical data. The department may disclose personal information with parental consent; however, the department must first explain the scope of the information requested and the purpose of the disclosure.

Florida

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health has authority, "after consultation with the Genetics and Infant Screening Advisory Council. . . ." Council members include 2 consumers, 3 practicing pediatricians, 1 representative of each of 4 medical schools, the Secretary of Health (or a designee), and representatives from 2 department child health programs.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "the attending health care provider."

Are Newborn Screening Laboratory Services Regulated? How?
Regulations allow testing in an "approved laboratory" meeting defined criteria. Currently the Florida Department of Health Laboratory performs testing.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration and follow-up services.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
Parents may refuse to participate in newborn screening for any reason. The refusing parent must sign a written refusal, to be given to the physician or person administering screening. The Florida Department of Health must maintain a confidential registry of infants testing positive in newborn screening, for delivery of services, administration of the program, and epidemiologic studies. The department must safeguard the information sufficiently to ensure the confidentiality of individuals in the registry, which is exempt from the public records statute. The newborn screening statute references specifically general health records statutes, which prohibit the release of any record by department personnel without consent. The laboratory must maintain records of screening results and follow-up testing for 3 years. Specimen storage is not addressed. A violation is punishable as a misdemeanor, with a penalty of up to 60 days in jail and a $500 fine.

Georgia

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The director of the Division of Public Health must "seek the advice and guidance of the Newborn Screening Advisory Committee." A multidisciplinary committee of professional and consumer representatives with knowledge and expertise in newborn screening programs is mandated by regulation.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Regulations note that the physician attending the newborn must "have a specimen . . . taken before . . . discharge." For nonhospital births, the person in charge of the facility must supply written notice to the parents.

Are Newborn Screening Laboratory Services Regulated? How?
Regulations state "a laboratory approved by the Department of Human Resources. . . ." Currently the Division of Public Health Laboratory provides all testing.

What Additional System Components Does the Fee Cover?
There is no fee, but the statute defines a 5-component system, ie, "screening. . . ; retrieving potentially affected. . . ; diagnosis; . . . therapy; . . . assessing programs."

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in the program unless the parents object on religious grounds. If an infant's physician is unable to reach the parents regarding test results, then the local health department may contact the family directly. Violations of the regulations are punishable as misdemeanors.

Hawaii

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health has the authority. An advisory committee is not required; however, there is a Newborn Screening Advisory Committee that meets 1 or 2 times each year and more often if needed.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "the person in charge of each institution . . . physician attending the birth . . . person assisting the birth of a child not attended by a physician. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
Regulations require testing at a laboratory designated by the Department of Health. Currently the Oregon Department of Health Laboratory performs testing.

What Additional System Components Does the Fee Cover?
The statute allows the fee to be used for "the payment of its lawful expenditures, including but not limited to laboratory testing, follow-up testing, educational materials, continuing education, quality assurance, equipment, and indirect costs." The fee is used to pay for the salaries and fringe benefits of the newborn screening program staff members; FedEx overnight courier ser-

vices; specimen collection and handling charges; a contracted nutritionist, pediatric endocrinologist, and metabolic specialist services; and newborn screening services for the indigent.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in the program unless the parents, guardians, or other persons having custody or control of the child object on religious grounds. The Hawaii Department of Health must distribute an informational brochure about newborn screening to parents and all individuals and institutions involved in the process. If parents, guardians, or other persons having custody or control over the child refuse screening, then the person overseeing the screening process must explain the medical implications of refusal to the family, include a written objection in the patient's medical record, and send a copy of the written objection to the department. Hawaii statutes require the Department of Health to adopt rules regarding the retention of records and related data, educating parents, and confidentiality. Accordingly, state regulations require that laboratories store specimens so that retesting is possible for ≥1 year and that they develop a system to log and to track specimens. The department also must make an informational brochure available to parents. The newborn screening program and physicians consider all information, including records, correspondence, and individually identifiable information, confidential. The department may use such information only for the purposes of medical intervention, counseling, scientific research, or fulfilling reporting requirements, while keeping the name of the patient confidential at all times. The newborn screening regulations refer to Hawaii's general medical records statute, which requires public agencies to store records for 7 years after the individual who received services reaches the age of majority; however, public health screening is exempt.

Idaho

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The director of the Department of Health and Welfare has authority. There is no mention of an advisory committee, and none currently exists.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "It shall be the duty of the administrative officer . . . or the person responsible for the registration of the birth. . . .

Are Newborn Screening Laboratory Services Regulated? How?
Regulations state, "The department shall provide access to newborn screening laboratory services." It goes on to describe duties for "all laboratories receiving dried blood specimens on infants. . . ." Currently the Oregon Department of Health Laboratory performs laboratory testing.

What Additional System Components Does the Fee Cover?
The fee covers only laboratory costs; however, the program provides some follow-up services.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless the parents object on religious grounds. State newborn screening regulations refer to general Department of Health and Welfare rules concerning medical records, which require written authorization for use and disclosure of health information outside the department. The form must specify the type of information requested, as well as the intended purpose and the user. The administrator of the responsible institution or birth registrant is required to keep a record of specimens, identifying the patient, attending physician or attendant, date of collection, and person who collected the sample. In addition, the department must maintain records of all infants with PKU and other preventable diseases and must oversee the local health department's treatment of individuals with disease. Under state statutes, a violation of newborn screening regulations is punishable as a misdemeanor.

Illinois

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Public Health has authority. Regulations specify an advisory committee to advise on the selection of consultants to work with subprograms within the newborn screening program.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states that primary responsibility lies with the "physician on attendance at or immediately after birth of the newborn. . . ." The statute also allows the physician to delegate this responsibility.

Are Newborn Screening Laboratory Services Regulated? How?
Regulations state, "All specimens . . . shall be submitted to . . . Illinois Department of Public Health. . . ."

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration, follow-up services, and treatment.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in the program unless the parents object on religious grounds. The parent or guardian must provide a written statement of objection to the physician or individual who administers the test. The birthing facility or health care provider must keep the written statement of refusal and notify the Department of Public Health, in writing, of the refusal. The department must maintain a registry of cases for the purpose of diagnosis and treatment of confirmed positive cases. The department must maintain the confidentiality of patient information and may request an annual update on the developmental progress of an affected child from a consultant or health care provider.

Indiana

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health has the authority "after consultation with medical authorities. . . ." Indiana's Newborn Screening Task Force makes recommendations concerning the addition of screening disorders.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "Each hospital and physician shall take or cause to be taken a blood sample. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
The statute states, "The state [health] department shall designate at least one laboratory. . . ." The statute also states that this section "does not prevent other facilities from conducting tests for disorders." Currently testing is performed at the Indiana University Medical Center.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration, follow-up services, and treatment.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate unless the parents object on religious grounds. The person who administers screening must inform parents of the implications of refusal and place a signed written statement of refusal for participation in the child's medical record. The Indiana State Department of Health must have a confidential registry for tracking and follow-up monitoring of all newborns and a system for using residual dried blood spots for epidemiologic research without identifying information. The newborn screening laboratory must maintain confidential records, in accordance with requirements of the Indiana State Board of Health. These records are open to examination by board personnel or designated agents for administrative purposes. The local health department may contact families directly for follow-up testing if necessary. Failure to comply with state newborn screening regulations is grounds for filing a complaint with the appropriate licensing board.

Iowa

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The State Board of Health has final approval. The Birth Defects Advisory Committee advises the Department of Health director regarding program issues. Regulations specify committee representation from "professional groups, agencies, legislators, consumers, and individuals with an interest."

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The regulations state, "the licensed attending health care provider. . . ." A health care provider is defined as a licensed physician, physician assistant, nurse, nurse practitioner, or certified nurse midwife.

Are Newborn Screening Laboratory Services Regulated? How?
Regulations state the University of Iowa Hygienic Laboratory (the state public health laboratory).

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration, follow-up services, and a metabolic formula fund.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
A parent or guardian may refuse to participate in newborn screening on any grounds. The attending health care provider must inform the parent or guardian of the type of specimen, the collection method, the nature of the disorders screened, and the consequences of treatment and nontreatment. If testing is refused, then the health care provider must have the parent or guardian sign the official Iowa newborn screening waiver form, must add the form to the child's medical record, and must submit a copy to the Birth Defects Institute. The Birth Defects Institute maintains a central registry that includes statistical information on genetic disorders. Identifying information is confidential. The department may release confidential information to a parent or guardian, to a health care provider with consent of the parent or guardian, or for approved research. State reg-

ulations specify that the specimen collection form must include the sample and attached identifying information. The central newborn screening laboratory must retain specimen collection forms attached to identifying information for 1 month, in a secure area. Forms may then be incinerated or retained for program evaluation or research. If specimens are released for research, then they must be made anonymous, so that they are unable to be linked back to the patient. The Iowa Birth Defects Committee, Iowa Department of Public Health, and Human Subjects Review Committee must approve research proposals.

Kansas

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Secretary of Health and Environment has authority. There is no mention of an advisory committee; however, a nonstatutory committee of health department staff members is active.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "the administrative officer . . . or attending physician caring for infants. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
The statute designates the Department of Health and Environment Laboratory.

What Additional System Components Does the Fee Cover?
There is no fee; however, the statute mandates education, screening, follow-up services, and treatment.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in the newborn screening program unless a parent or guardian objects on religious grounds. Prenatal care providers must inform parents about the newborn screening program. The person who obtains the specimen must provide the same information, as well as the right to refuse participation. Consent is required to monitor infants who receive follow-up testing or treatment. The Kansas Department of Health and Environment must maintain a registry of confirmed cases, including identifying information. The parent or guardian of a diagnosed infant must notify the department of an address change or a change in health status within 3 months after its occurrence.

Kentucky

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Secretary for Health Services designee "shall apply for any federal grants . . . to expand or improve programs to provide screening. . . ." There is no mention of an advisory committee; however, a multidisciplinary nonstatutory committee, including representatives from Medicaid, meets regularly.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "the administrative officer or other person in charge of each institution. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
Regulations state, "Hospitals and institutions may submit blood samples to the Cabinet for Human Resources . . . Division of Laboratory Services. . . ." In addition, "Hospitals and institutions may conduct their own testing program within . . . or through a licensed medical laboratory." Results of hospital testing must be reported to the state laboratory. Currently no testing is being reported by hospitals, and the state laboratory performs all testing.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers part of the cost for program administration, follow-up services, and treatment.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in the newborn screening program unless the parent or guardian objects in writing on religious grounds. Kentucky newborn screening statutes or regulations contain no other specific provisions with respect to confidentiality and privacy regarding newborn screening information and samples, consent or the right to refuse screening, or the use of samples.

Louisiana

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health and Hospitals may add to the genetic conditions tested "after consultation with medical geneticists from each of the state's medical schools." There is no requirement for an advisory committee; however, one has been established and meets twice yearly.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "the physician attending a newborn . . . or the person attending a child who was not attended by a physician." In cases where repeat testing is necessary, the regulations state, "Repeat screening should be arranged by the primary pediatrician; however, it may be done by any primary health care provider

of clinical facility qualified to perform newborn screening specimen collection."

Are Newborn Screening Laboratory Services Regulated? How?
The statute states, "The Department of Health and Hospitals shall establish and maintain a diagnostic laboratory. . . ." Regulations state, "The Office of Public Health maintains a laboratory . . . the newborn screening battery may also be available through other approved laboratories." Currently Pediatrix Screening and Women's Hospital (Baton Rouge, LA) are approved laboratories.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration, follow-up services, limited treatment, surveillance, and education.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
A newborn whose parent or guardian objects to participation is exempt from newborn screening. The state public health laboratory may conduct experiments, projects, and other undertakings to develop tests for detection of metabolic and genetic conditions. There is no mention of whether the laboratory may use newborn screening samples and information for this purpose. The statute on genetic conditions and newborns provides for the confidentiality of prenatal and postnatal genetic test results, with the exception of those for which reporting is mandated specifically by statute, such as newborn screening test results. A genetic test, as used in this section of the statutes, is not defined. If the infant does not have a designated health care provider, then the newborn screening laboratory must contact a parent or guardian directly concerning positive test results. The newborn screening laboratory must consider national guidelines and recommendations with respect to its operation.

Maine

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
Regulations state, "The department will consider changes in conditions to be screened as requested by the Bureau of Health, the medical community, or the public." Also, "The department shall appoint an advisory committee to advise the program on issues related to the screening of newborns."

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Regulations state, "the responsible hospital, birthing center, physician, principal birthing attendant, or health care provider. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
The statute allows the Division of Maternal and Child Health to "enter into agreements and contracts for the delivery of genetic services." Another section on contract eligibility states that the contracted project or activity "shall include some or all of the following services . . . newborn metabolic testing, laboratory services. . . ." Currently the University of Massachusetts provides testing.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers program administration, follow-up services, education, and counseling.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in the newborn screening program unless a parent or guardian objects on religious grounds. A parent or guardian must provide a written objection, which is then included in the child's medical record. The hospital or birthing center must inform the Bureau of Health in the Department of Human Services of the refusal. Counseling and educational services provided to women at risk for maternal PKU, offered through a genetics program, are voluntary. The bureau may offer additional tests available through the newborn screening laboratory, on a voluntary basis. The parent or guardian must consent before the laboratory conducts additional testing. Results of optional tests also are reported to the bureau. The department is responsible for the storage of residual dried blood spots in a secure stable area for 5 years, in a manner that allows them to be retrieved. After 5 years, the department must destroy the specimens in a way that preserves confidentiality. Unless prohibited in writing by a parent or guardian, dried blood spots and related information are the property of the state. The department may use specimens for program evaluation and research purposes or for department-approved scientific research, "to improve the health of mothers and children," without consent. Published studies using newborn screening samples or information must report anonymous information only. The department may release a specimen with identifying information for research and testing, with the specific consent of a parent or guardian. A violation of state newborn screening regulations is punishable by up to 6 months in county jail.

Maryland

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health and Mental Hygiene can select disorders with the advice of the Advisory Council on Hereditary and Congenital Disorders. The statute specifies the composition and duties of the advisory council.

There are 11 voting members including 1 member from the Senate, 1 member from the House of Delegates, 4 professionals from the fields of hereditary or congenital disorders appointed by the governor, and 5 consumers. There are 5 nonvoting members.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Regulations state, "The individual in charge of an institution or . . . designated representative" and, for births outside an institution, "the person required to prepare and file the certificate of birth" is responsible for offering testing.

Are Newborn Screening Laboratory Services Regulated? How?
Currently regulations state that the Department of Health and Mental Hygiene shall perform all analyses. Revision of this part of the regulations is under consideration.

What Additional System Components Does the Fee Cover?
The fee covers laboratory costs only. The program also offers extensive follow-up and counseling services if requested.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
Participation in any hereditary and congenital disorders program is wholly voluntary. A parent or guardian may refuse to participate for any reason. The individual administering the screening must inform the parents or guardian of the reasons for the test, the risks involved, and the right to refuse; must provide ample time for refusal; and must record consent or refusal in the child's medical record. The parent or guardian must sign a statement explaining the tests as part of the informed consent process. Parental oral or written consent is required for follow-up testing. All information obtained through newborn screening is confidential, including the registry of diagnosed cases maintained by the department. The department must keep newborn screening information coded and must treat it as a confidential medical record. The department may disclose information if the parent or guardian or the individual screened (if >18 years of age) provides informed consent, which must include the scope of the information requested for release and the purpose. Anonymous information is subject to the public records statute. If the responsible party is unable to contact a child's parents regarding test results, then the department may contact them directly. The department must make the infant's medical record, which includes a record of test results, available to parents on request. Maryland statute requires that a carrier of a hereditary disorder not be discriminated against or stigmatized, and it creates a commission to protect the "freedom, health, and well-being of citizens of this state from improper treatment or advice, discrimination, violation of privacy, or undue anxiety that results from any hereditary and congenital disorders program." The statute clarifies that any recommendations made with regard to discrimination do not deprive an individual of the right to redress for discrimination. There is no mention of the use of residual specimens in the current statute or regulations. The Secretary of the Department of Health and Mental Hygiene is required to enforce state newborn screening regulations, but a particular method of enforcement is not specified.

Massachusetts

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Commissioner of Health has authority and "shall establish a permanent advisory committee to advise . . . on matters pertaining to newborn screening. . . ." A committee exists and is active.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Regulations state that the attending physician is responsible.

Are Newborn Screening Laboratory Services Regulated? How?
Regulations state that specimens should be delivered to the Department of Public Health. The statute (111§4E) authorizes the department to conduct its program in conjunction with certain other agencies. An agreement between the Department of Public Health and the University of Massachusetts Medical School designates that testing and other functions of newborn screening be conducted by the University of Massachusetts Medical School.

What Additional System Components Does the Fee Cover?
Regulations allow a fee to cover testing, notification, and follow-up services to ensure treatment of affected newborns. By agreement, the University of Massachusetts Medical School provides the Department of Public Health with all initial and required repeat laboratory testing services, collection kits, sample transport to the laboratory, clinical consultation, administration, data management, research, pilot studies, outreach and education (including printed and Internet materials in multiple languages), and other items necessary for full-service integrated newborn screening.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in the state newborn screening program unless a parent or guardian objects

on religious grounds. The attending physician must document the refusal of screening services by a parent or guardian.

Michigan

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health has authority. A nonstatutory advisory committee makes recommendations to the department.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "a health care professional in charge of the care of a newborn . . . or if none, the health professional in charge at the birth. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
The statute states, "The Department of Health may require that the tests be done by the department." Currently the Department of Health Laboratory provides testing.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration, follow-up services, and some treatment.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in the screening program. Informed consent requirements for genetic testing do not apply to the newborn screening program. The department must have a brochure explaining the nature and purpose of testing, describing retention and disposal policies, and indicating that specimens may be used for research and additional specimens may be obtained for home retention. The Michigan Department of Health must develop a schedule for retention and disposal of residual samples consistent with standards for laboratory accreditation and federal statutes. The department must make a record of the disposal, signed by a witness. The department must permit the use of specimens for research during the retention period if it is confidential and adheres to the Common Rule. A violation of the state newborn screening statute is punishable as a misdemeanor.

Minnesota

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
By statute, the Commissioner of Health has the authority to make changes recommended by the advisory committee. The advisory committee is established by statute to consider ethical issues surrounding testing, treatment, and handling of data and specimens generated through testing requirements. Committee members must include ≥1 person representing "parents, primary care providers, clinicians, and researchers specializing in the screened disorders, genetic counselors, birth hospital representatives, newborn screening lab professionals and nutritionists, and other experts as needed. . . ."

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute assigns the responsibility for newborn screening depending on the circumstances of the birth, ie, the facility administrator in an institution caring for infants <28 days of age or the person required to register the birth of the child or the midwife attending the birth if the birth occurred outside such an institution.

Are Newborn Screening Laboratory Services Regulated? How?
The rules state that specimens are to be sent to the Department of Health Laboratory. Currently specimens are sent to the Department of Health Laboratory with a portion of the specimen removed; that portion is sent to the Mayo Hospital laboratory for tandem mass spectrometry testing.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration and follow-up activities.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
The individual collecting a blood sample must inform parents about the newborn screening program, including the reasons for screening, the right to refuse on religious grounds, and the fact that the state may retain samples. Parents may decline to participate or may have testing performed but request destruction of the sample and records within 2 years. If participation is declined, then a signed written statement by the parents must be added to the child's medical record. The Minnesota Department of Health must maintain a registry of diagnosed cases with identifying information, for the purpose of follow-up monitoring, and all data must be treated as private under the public health records statute, which is referenced specifically in the state newborn screening statute. The public health records statute permits patients to access data and to suggest corrections if information is incorrect. State statute establishes an advisory committee, the duties of which include consideration of ethical issues surrounding testing, treatment and handling of data, and specimens generated through testing requirements.

Mississippi

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The State Board of Health has authority, on the advice of the Genetics Advisory Committee, which includes "at least 2 pediatricians and 1 consumer . . . from a family . . . with a newborn with an abnormal screening test."

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "the physician or other health care provider attending the infant. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
The statute states, "in laboratories located in the United States." Currently Pediatrix Screening provides testing.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration and follow-up services.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in the newborn screening unless a parent or guardian objects on religious grounds. The Board of Health must create a pamphlet to inform parents about the newborn screening program, but its use is not required. Regulations specifically include diagnosed cases of newborn screening disorders as part of the state birth defects registry. The State Department of Health may obtain records or test results for late-diagnosed cases. The statute provides for security of the registry, to facilitate research and to protect confidentiality. The department may not disclose identifiable information, but statistical data are public record. The department must maintain records of newborn screening tests for 2 years. The storage of samples is not addressed in state statutes or regulations, but it is included in the contractual obligations of the laboratory that performs the testing. Misuse of newborn screening information is punishable with a fine of up to $500 for each occurrence.

Missouri

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health has the authority to change the disorder list. No advisory committee is mentioned; however, a multidisciplinary Newborn Screening Standing Committee is active.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "The attending physician, certified nurse midwife, public health facility, ambulatory surgical center, or hospital shall ensure that appropriate specimens are collected and submitted to the Department of Health and Senior Services."

Are Newborn Screening Laboratory Services Regulated? How?
The statute specifies the Department of Health and Senior Services Laboratories.

What Additional System Components Does the Fee Cover?
The fee is for the newborn screening tests only. The program provides a formula for the treatment of inherited diseases of amino acids and organic acids based on income eligibility after all benefits from third-party payers are exhausted.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in the state newborn screening program unless a parent or guardian objects on religious grounds. The person who administers screening must provide educational materials, including the consequences of treatment and nontreatment. A signed written refusal is required; it must be made part of the infant's medical record and sent to the Department of Health and Senior Services.

Montana

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Public Health and Human Services has authority to determine the screening panel and to promulgate regulations. An advisory committee is not required; however, an ad hoc committee of the Family and Community Health Bureau Advisory Council has been convened as needed to provide recommendations to the department.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "a person in charge of a facility wherein a child is born . . . or cared for or a person responsible for the registration of the birth. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
The statute states, "an approved laboratory . . . the laboratory of the department, or a laboratory approved by the department." Currently the department's laboratory provides testing, with optional testing performed by the Wisconsin Department of Health Laboratory.

What Additional System Components Does the Fee Cover?
The fee covers laboratory testing only.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
Montana newborn screening statutes or regulations contain no provisions with regard to confidentiality, privacy, consent or the right to refuse screening, or the use of residual samples.

Nebraska

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health and Human Services has authority. A nonstatutory advisory committee exists.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states the attending physician or person registering the birth.

Are Newborn Screening Laboratory Services Regulated? How?
The statute states, "the laboratory designated by the department. . . ." Currently Pediatrix Screening provides testing.

What Additional System Components Does the Fee Cover?
The $10 fee is available for administration, follow-up services, and treatment, but currently it supplements treatment costs entirely.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
The Department of Health and Human Services must provide a pamphlet explaining the nature of tests performed as part of newborn screening, the purpose and value of retaining a specimen, the procedures for retention and disposal, and the possibility of use for research. Although state statutes or regulations do not specify details of pamphlet distribution, distribution as part of the newborn screening process is reported to be common practice. Refusal of newborn screening is not allowed. A legal challenge is currently in process. The newborn screening program must maintain a central database of reported data, for the purposes of program evaluation and quality assurance. The department may disclose anonymous or statistical reported data for research. The hospital or birthing institution must provide the department with necessary information to track, to monitor, and to provide for the care and treatment of newborns diagnosed with a disorder. State regulations for retention and disposal of samples must comply with nationally recognized standards for laboratory accreditation and federal statutes, require the destruction of samples in the presence of a witness, and provide for a record of disposal. The newborn screening laboratory must maintain for 25 years an index or catalog of specimens processed, including an identifier for each specimen, test results, a record of disposal or specimen release for research, and the signature of the individual who disposed of or released the specimen. If a specimen is not released for research, then the laboratory must dispose of the specimen within 30 days, in a manner that protects the identity of the individual screened. If a parent fails to respond to notification of an infant's presumptive positive screening results, then the attorney general or county attorney may enforce the statute through a civil proceeding.

Nevada

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The State Board of Health, on recommendation of the state health officer, has authority to change the testing panel. Tests are not put into regulation. The Board of Health is kept informed of the current test battery and any need for changes. There is input from a statutory Maternal and Child Health Advisory Committee appointed by the governor.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "any physician, midwife, nurse, obstetric center, hospital . . . or mother of any infant. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
The Board of Health adopts regulations governing examinations and tests to detect preventable inheritable disorders. Regulations stipulate that, "The sample must be placed in a kit supplied by the health division . . . and mailed . . . within 24 hours after the sample is taken." A contract is for laboratory services. Currently the Oregon Department of Health Laboratory provides testing.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration and follow-up services.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
Parents may file a written objection to participation in newborn screening. All information obtained by the state or local health department is confidential. The state health officer and the Bureau of Children's Services chief must ensure the confidentiality of information and must inform individuals involved in newborn screening of confidentiality policies. Parental consent to disclose information is required, with the exception of summary, statistical, or other anonymous information; however, the state health officer or a designee may review identifiable records and contact the family of a newborn to

inform them that the newborn may have a disorder, to confirm a diagnosis, or to offer services.

New Hampshire

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Commissioner of the Department of Health and Human Services has rule-making authority, with approval of the legislature. An advisory committee is not required but a multidisciplinary committee of individuals with an interest and/or expertise in newborn screening has been formed to make recommendations regarding issues of policy and procedure and to ensure the highest program standards.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "the physician, hospital, nurse midwife, midwife, or other health care provider attending a newborn. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
The revised rules will designate a screening laboratory. Currently the University of Massachusetts Medical School provides testing by contract.

What Additional System Components Does the Fee Cover?
The fee covers the contracted laboratory costs, including testing, transport, pamphlets, reporting, and consultation.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
New Hampshire's newborn screening statute contains no provisions with regard to confidentiality, privacy, consent or the right to refuse screening, or the use of samples, but the statute requires the Commissioner of the Department of Health and Human Services to adopt rules and regulations to carry out the program. Legislative approval is required. Current regulations have expired, and revision, in conjunction with the advisory committee, is underway.

New Jersey

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The statute states, "The Department of Health, in consultation with appropriate advisory groups, shall. . . ."

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Regulations give responsibility to the birth attendant or responsible physician.

Are Newborn Screening Laboratory Services Regulated? How?
Regulations specify the Department of Public Health and Senior Services Laboratory.

What Additional System Components Does the Fee Cover?
The current $34 fee covers only laboratory services. If approved, the new fee would include follow-up services and limited treatment services.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in the newborn screening unless parents object on religious grounds. The person administering screening must inform parents of the purpose of the test and the need for screening, provide educational materials, and document refusal in the infant's medical record. It is the responsibility of the chief executive officer of a hospital or other birthing facility to ensure that parents are informed and supplied with educational materials provided by the state newborn screening follow-up program. Newborn screening information is confidential. Only nonidentifiable information is public record.

New Mexico

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Secretary of Health and Environment has the authority to change the panel, with recommendations from the New Mexico Pediatrics Society. There is no mention of an advisory committee; however, the program has formed an ad hoc advisory committee.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
"Every hospital shall take a first blood sample from each infant born. . . ." If the infant is not born in a hospital, "the attending physician, nurse, nurse-midwife, midwife, or responsible person shall arrange to have the blood sample taken by a physician, a hospital, or a representative of the department's local health office."

Are Newborn Screening Laboratory Services Regulated? How?
The statute states that the department may provide laboratory services or contract with another agency or state. Currently the New Mexico Department of Health Laboratory performs testing.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration, follow-up services, confirmatory testing, education/training, and contracts for genetic services (metabolism and dysmorphology clinics).

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
Parents may decline participation in the newborn screening program for any reason. A signed written statement of refusal is required and is entered into the child's medical record. Physicians must explain newborn screening before parents' refusal of testing, so that parents may make an "informed decision." State statutes or regulations do not specify the extent of information to be provided. The New Mexico Department of Health maintains confidential records and a database of diagnosed cases for tracking infants and administering the program. Records and initial and secondary specimen forms are stored until 1 year after the child reaches the age of majority. The contents of records and the database and specimen collection forms are confidential. Printed information from the database is also confidential and is retained for 2 years.

New York

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Commissioner of the Department of Health has authority. There is no mention of an advisory committee; however, a multidisciplinary newborn screening task force is constituted for advice as needed.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
By statute, the administrative officer or other person in charge of institutions caring for infants or the birth attendant (for a nonhospital birth) is responsible.

Are Newborn Screening Laboratory Services Regulated? How?
Regulations specify the Wadsworth Center Laboratory of the Department of Health.

What Additional System Components Does the Fee Cover?
There is no fee. The program provides follow-up tracking and educational services.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless parents object on religious grounds. New York State Department of Health regulations require that the birthing facility, physician, or public health officer inform parents about the purpose and need for screening and provide them with educational materials. Specimens must be stored with accompanying identifying information. According to state regulation, the department also must store newborn screening information in electronic format. The state laboratory must record requested diagnoses and case follow-up information and must maintain tracking records for diagnosed cases.

North Carolina

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Commissioner of the Department of Health has authority. The State Board of Health director appoints members to a nonstatutory advisory committee.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The regulations state the attending physician is responsible.

Are Newborn Screening Laboratory Services Regulated? How?
Regulations specify the North Carolina State Health Department Laboratory.

What Additional System Components Does the Fee Cover?
The fee covers only testing. Follow-up services, education, and treatment are supported by state funds.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
Physicians must submit a blood sample for newborn screening unless a parent objects for any reason. The North Carolina Department of Health and Human Services is required to develop educational materials about newborn screening for parents, although state statutes and regulations do not require the distribution of the information at a particular time. Parents who decline screening must provide written documentation of refusal, which must be added to the child's medical record.

North Dakota

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The State Health Council has authority. There is no mention of an advisory committee; however, a nonstatutory advisory committee is active.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "the physician attending a newborn child, or the birth attendant in the case of an out-of-hospital birth."

Are Newborn Screening Laboratory Services Regulated? How?
Regulations state that a laboratory will be designated by the State Department of Health. Currently the Iowa Department of Health Laboratory provides testing.

What Additional System Components Does the Fee Cover?
The fee covers only laboratory costs. The program provides short-term follow-up services and education. A quarterly metabolism clinic is funded by another state program.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless parents object on religious grounds. The person who administers the test must obtain a signed statement of refusal to be added to the child's medical record, and a copy of the statement must be sent to the Department of Health. The department must maintain a registry of diagnosed cases. Public access is limited to statistical and nonidentifiable information. The physician, dietician, and Children's Special Health Services Program of the Department of Human Services may access identifiable information to provide services and service coordination. Researchers with proposals approved by the department, sponsored by an appropriate entity, and subject to an institutional review board may have access to information. Studies must protect the confidentiality of medical information, and researchers must return all documents provided by the department and copies of documents with identifiable information. As part of the approval process, researchers must explain the intended purpose of the study and procedures for maintaining security of confidential information, must consent to supply copies of written materials before submission to a publisher, must provide written consent for reproduction of documents by the department, and must agree to pay all departmental costs incurred as a result of the project. The department may retain newborn screening information and testing materials, including blood samples, indefinitely or destroy them after 10 years. The department may destroy <10-year-old information and materials with the state health officer's written approval. The method of destruction must preserve confidentiality.

Ohio

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Director of Health has the authority, with the advice of the Newborn Screening Advisory Council. The 14-member multidisciplinary council is appointed by the director and includes representatives with interests and expertise in newborn screening. Regulations give examples of groups to be included.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Ohio Administrative Code regulations state, "the child's attending physician, the certified nurse-midwife, the certified nurse practitioner, or the clinical nurse specialist. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
The statute allows the Director of Health to designate the laboratory. Regulations specify the Ohio Bureau of Public Health Laboratories.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration, follow-up services, and treatment (including formula).

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless parents object on religious grounds. Participation in optional testing is voluntary. The hospital or birthing center must provide parents with written notice of screening, which includes a description of the newborn screening program and the opportunity to receive additional optional tests. If parents decline screening, then the hospital or birthing center must send a written refusal of testing to the Ohio Department of Health. Hospitals and birthing centers are required to establish written protocols for tracking newborn screening. The department may share information within programs or with others under grant or contract with the department for the purposes of locating a newborn or the newborn's parent or guardian or performing departmental functions and responsibilities. If a physician is unable to reach a parent or guardian regarding a test result, then the department may contact them directly. Families unable to be reached are reported to Ohio regional genetic centers. The laboratory is required to maintain records on screened newborns for ≥21 years. Retention requirements do not refer directly to specimens.

Oklahoma

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The State Board of Health has authority. Regulations require an advisory committee to be "appointed by the Commissioner of Health to advise the department on newborn metabolic disorder screening issues."

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Regulations state that the physician or licensed or certified birth attendant is responsible. Regulations also define roles for the hospital, providers, and screening program in ensuring that screening occurs.

Are Newborn Screening Laboratory Services Regulated? How?
The statute states, "The State Board of Health is authorized to set up laboratory facilities and use existing facilities. . . ." Regulations state the "Newborn Metabolic Disorder Screening Laboratory means a laboratory operated . . . or certified by the department. . . ."

What Additional System Components Does the Fee Cover?
The fee covers laboratory testing only.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless parents object on religious grounds. Hospitals are required to distribute educational materials regarding the newborn screening program. The person who administers screening must place a written statement of refusal in the child's medical record and send a copy of the refusal to the newborn screening program. Newborn screening information is confidential. Permissible use is restricted to service delivery, program administration and evaluation, and data analysis. The laboratory must store each sample with an identifier and link patient information and test results to the identifier. The laboratory must maintain information for 21 years.

Oregon

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Human Services has authority. There is no mention of an advisory committee.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Regulations state, in order of responsibility, "the hospital, alternate birthing facility, or other health care facility . . . the practitioner . . . the parent or legal guardian."

Are Newborn Screening Laboratory Services Regulated? How?
Regulations specify the State Public Health Laboratory.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration, follow-up services, treatment, and education.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless the parents object on religious grounds. The person who administers screening must send a written refusal to the Department of Human Services. The refusal must use the wording provided in department regulations. The public health laboratory also must maintain demographic data on newborns for program administration, evaluation, and statistical analysis. Privacy and confidentiality issues for newborn screening samples and information are addressed in Oregon's genetic privacy statute. Newborn screening is excluded from the informed consent requirement to obtain genetic information under the state genetic privacy statute, but the statute requires the department to protect the confidentiality of stored samples and newborn screening information. The genetic privacy statute permits retention of DNA samples or genetic information, including newborn screening specimens and information, as set forth by department regulations. Genetic privacy regulations specify that the department may store newborn screening samples or information for up to 1 year. Samples or information may be used for anonymous research unless an individual chooses to decline participation after notification regarding the research project. Studies must follow department rules for research standards and the Common Rule. Researchers must encrypt or code samples, which must be destroyed at the conclusion of a project or when an individual withdraws from a study, unless informed consent to retain the sample for an extended period is obtained.

An individual can access, and if necessary correct, personally identifiable genetic information being stored by the department. Consent to disclose individually identifiable genetic information, including newborn screening results, is required. A violation of statutes pertaining to consent, confidentiality, or the use of samples is punishable by fines ranging from $100 to $250 000, depending on the intent of the defendant, in addition to attorney fees in some circumstances. The retention of newborn screening samples or disclosure of newborn screening information in violation of statutes is punishable as a misdemeanor.

Pennsylvania

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health has authority, with the approval of the Board of Health. There is no mention of an advisory committee; however, an ad hoc multidisciplinary advisory committee exists.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Regulations state that the birth center or hospital, or the health care practitioner who delivered the newborn, is responsible.

Are Newborn Screening Laboratory Services Regulated? How?
Regulations state that the testing laboratory is "the licensed clinical laboratory under contract with the de-

partment to perform testing. . . .” In addition, other legislation allows hospitals the option of submitting specimens to any laboratory contracted by the state. Currently the University of Massachusetts School of Medicine Laboratory and Pediatrix Screening provide testing.

What Additional System Components Does the Fee Cover?
There is no fee. The program provides testing, confirmatory follow-up testing, assessment, and diagnosis of newborns with abnormal screening results. Optional supplemental screening is provided at most hospitals through contracted laboratory services.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless the parents object on religious grounds. Health care providers must place a written statement of refusal, signed by the parent or guardian, in the child’s medical record. Health care providers also must inform the department of the number of patients who were not screened and must provide an explanation. The newborn screening laboratory, department, or other entities involved in the newborn screening program may have access to test results during various stages of the newborn screening process and may not disclose any identifying information except to a parent or guardian or the designated health care provider. Disclosure by the department is permitted for the purposes of service delivery or with the consent of a parent, guardian, or screened individual who has reached the age of majority, has graduated from high school, is married, or is pregnant. If a health care provider is unable to contact a family regarding an abnormal or unsatisfactory result, then the department may contact the family directly.

Rhode Island

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health has authority. A nonstatutory advisory committee makes recommendations to the department.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The regulation states that the “physician and/or midwife attending a newborn child shall cause said child to be subject to screening tests for. . . .”

Are Newborn Screening Laboratory Services Regulated? How?
By regulation, “The Division of Laboratories shall provide specimen collection testing kits. . . .” In addition, “screening tests performed . . . elsewhere than the Division of Laboratories must be performed by a laboratory approved by the director and include the tests cited. . . .” Currently the University of Massachusetts Medical School provides testing.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration, personnel, equipment, and other related costs.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless parents object on religious grounds. Rhode Island newborn screening statutes and regulations contain no other specific confidentiality provisions regarding the privacy of newborn screening information and the use of samples or consent and the right to refuse screening.

South Carolina

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Board of the Department of Health and Environmental Control has authority. There is a nonstatutory advisory committee, which submits recommendations to the board.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Regulations give responsibility to the “attending physician” or “person in attendance” if no physician is present; if the birth is unattended, then “the parents or legal guardian shall notify the health department . . . within 3 days of delivery so that a specimen may be collected.”

Are Newborn Screening Laboratory Services Regulated? How?
Regulations state that all screening tests shall be performed at the Department of Health and Environmental Control.

What Additional System Components Does the Fee Cover?
The fee covers only laboratory testing.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless parents object on religious grounds. The Department of Health and Environmental Control must develop and provide educational materials to inform parents about newborn screening, the benefits of blood storage, and blood storage options, and hospital staff members or others at the place of birth, under the direction of the attending physician, must document that they provided an informational brochure to parents. If

parents decline to participate, then they must complete the departmental religious objection form. All departmental newborn screening forms must include information on the benefits of newborn screening and blood sample storage. By regulation, the department is required to store all medical records, specifically including newborn screening tests, in an environment that prevents unauthorized access and deterioration. Newborn screening records must be treated as confidential and retained until the screened individual reaches the age of 18 years. If a physician is unable to contact the parents or guardian regarding test results, then the department may contact them directly. Information obtained through the newborn screening system is confidential. Disclosure is permitted, after the completion of a departmental request form, to parents or guardians, an infant's physician, or a screened individual who has reached the age of majority. In addition, the department may release specimens that are deidentified but coded for later departmental use in anonymous, confidential, scientific studies approved by a departmental institutional review board, unless prohibited by parents, guardians, or a screened individual who has reached the age of majority. The decision to prohibit participation in research studies must be documented on the departmental blood sample storage options form. A parent or guardian can request the return of a blood sample 2 years after testing, destruction of a blood sample 2 years after testing, or storage for anonymous confidential study. Identifiable information may not be released for use in research. If research reveals information that may be beneficial to the individual whose specimen was obtained, then the department may contact the parent, guardian, or screened individual who has reached the age of majority. Samples collected before the effect of legislation enacted in 2002 are retained unless the parent or guardian of a child whose specimen is stored requests its destruction or return. A violation of the state newborn screening statutes is a misdemeanor punishable by up to $50 000 and 3 years of imprisonment.

South Dakota

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health has authority. An advisory committee is not required by statute or regulation, but an ad hoc committee exists.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Regulations state, "The parents, guardian, or custodian of each infant is responsible . . . the attending physician, other health professional, hospital, or public health facility shall notify parents . . . of the responsibility. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
Regulations state, "The department shall designate the laboratories that are authorized to perform newborn screening services. . . ." Currently Sioux Valley Clinical Laboratories (Sioux Falls, SD) provides testing.

What Additional System Components Does the Fee Cover?
The fee covers only laboratory costs at the contract laboratory.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening. A physician, hospital, or other responsible party must notify legal counsel for the department by telephone within 24 hours if a parent or guardian refuses to participate. South Dakota newborn screening statutes and regulations contain no other specific provisions with regard to confidentiality and privacy of newborn screening information and samples or consent or the right to refuse screening or the use of samples.

Tennessee

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health has authority. The Commissioner of Health "shall appoint a committee to consult with the department . . . composed of 1 representative from each regional genetic and sickle cell center, . . . 2 members at large, and the chief medical officer for the state."

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Regulations assign responsibility to "every chief administrator officer of a hospital and the attending physician," to "any health care provider of delivery services" if the birth occurred in a nonhospital setting, or to "the parent or guardian or custodian" if the birth occurred outside a health care facility and without the assistance of a health care provider.

Are Newborn Screening Laboratory Services Regulated? How?
Regulations specify that specimens "must be submitted to the Division of Laboratories, State Department of Health." Currently the Division of Laboratories provides all testing.

What Additional System Components Does the Fee Cover?
The fee covers only testing. Education, follow-up services, counseling, and treatment are funded by the Division of Maternal and Child Health.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless a parent or guardian objects on religious grounds. Parents who decline must sign a written refusal statement. By statute, people of the state must be "extensively informed" of the nature and effects of PKU, congenital hypothyroidism, galactosemia, and other genetic/metabolic defects. The Department of Health must have a reporting system for data collection and storage and for compilation of statistical information on the causes, treatment, and prevention of newborn screening disorders. Statutes specifically require inclusion of diagnosed cases in the confidential state birth defects registry. Researchers may conduct studies with newborn screening information but must identify and code information and maintain confidentiality. The department must record specific information regarding the information accessed, including the name of the person associated with the information, the date of access, and the purpose. Researchers may publish nonidentifiable statistical information. The state or local health department may contact a parent or guardian directly about a suspected genetic or metabolic disorder. Willful or negligent disclosure of newborn screening information is a misdemeanor. In addition, failure to have the child tested is a class C misdemeanor.

Texas

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health has authority. There is no mention of an advisory committee; however, separate ad hoc advisory committees exist for metabolic, endocrine, and hemoglobin conditions.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "the physician attending a newborn or the person attending the delivery of a newborn . . . not attended by a physician. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
The statute states, "the laboratory established by the department or by a laboratory approved by the department. . . ." Regulations specify, "Analysis of the blood specimens . . . must [also] be performed by the department."

What Additional System Components Does the Fee Cover?
The fee covers laboratory testing only. The program offers administration, follow-up services, and limited treatment if the child is ineligible for other state services.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless a parent or guardian objects on religious grounds. The person who administers the screening must place a statement of refusal, signed by a parent or guardian, in the child's medical record. The department is required by statute and/or regulations to collect data on incidence and prevalence rates of disorders from specimen forms and to maintain a roster of individuals diagnosed with a disorder. The department may cooperate with other states to develop a national roster of diagnosed individuals if information on incidence and prevalence rates is made available to participating newborn screening programs in other states. Programs participating in the national roster would have to prescribe to an agreement to protect the identity and diagnosis of the individuals included in the roster.

Utah

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health has authority to make changes, after consulting with the Genetic Advisory Committee.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Regulations state that, in an institution, "the institution must collect and submit an appropriate specimen"; outside an institution, "the practitioner or other person primarily responsible for providing assistance to the mother at birth must arrange for the collection and submission of an appropriate specimen"; or, if there is no other person attending the birth, "the parent or legal guardian must arrange for the collection and submission."

Are Newborn Screening Laboratory Services Regulated? How?
Regulations specify the Department of Health Newborn Screening Laboratory.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration and follow-up services.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless a parent or guardian objects on religious grounds. The person responsible for newborn screening must inform the parent or guardian of required collection and submission of the specimen unless the infant is born without an attendant. Under that circumstance, the par-

ent must obtain a newborn screening kit. If a parent or guardian declines screening, then a statement of refusal signed by the parent or guardian, the reason for refusal, and information about educational materials provided to the parent or guardian must be documented in the medical record. The practitioner or birthing institution must send a copy of the statement of refusal to the department. The department has access to medical records of the newborn, to identify why the practitioner failed to collect a specimen or to obtain missing demographic data. If a parent or guardian fails to comply with state regulations, then the practitioner or birthing institution must report medical neglect to the department.

Vermont

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health has authority. There is a nonstatutory advisory committee.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
This is not mentioned in the regulations.

Are Newborn Screening Laboratory Services Regulated? How?
The laboratory is not mentioned in the regulations. Currently testing is provided through a contract with the University of Massachusetts Medical School.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration and follow-up services.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
A statute specific to newborn screening does not exist; however, the chronic disease statute acknowledges that information on newborn screening disorders is reported to the Department of Health. The department has statutory responsibility and authority "to develop an early case-finding program . . . concerning chronic diseases," and this has been extended to include newborn screening. According to state regulations, parents may object to participation in the newborn screening program for any reason. The person who administers newborn screening must send a written statement of objection to the Department of Health. The program must operate under standards of practice accepted by the American Academy of Pediatrics, the CDC, and other recognized experts.

Virginia

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The State Board of Health has the authority. There is no mention of an advisory committee; however, a multidisciplinary genetics advisory committee also advises on newborn screening.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statutes states, "the physician, nurse, or midwife in charge of the delivery . . . or the first attending physician. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
The statute and regulations state, "The screening tests shall be performed by the Division of Consolidated Laboratory Services or any other laboratory the department . . . has contracted. . . ." Currently testing is performed by the Division of Consolidated Laboratory Services (the state laboratory agency).

What Additional System Components Does the Fee Cover?
In addition to testing, the program covers administration, education, follow-up services, and limited treatment.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless a parent or guardian objects on religious grounds. The person who administers newborn screening must include a statement of written objection by the parent or guardian in the child's medical record. All medical records associated with newborn screening are confidential. The Board of Health, the commissioner, and the commissioner's agents may access newborn screening records. In addition, the Department of Health may release newborn screening results for research and statistical purposes or with the explicit permission of a parent or guardian. Publications may not disclose identifiable information.

Washington

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The State Board of Health has authority. There is no requirement for an advisory committee; however, the board convenes an advisory group as needed, with focus on the question(s) at hand.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "It shall be the duty of the Department of Health to require screening . . . before they [infants] are discharged from the hospital. . . ." Regulations state, "Hospitals providing birth and delivery services or neonatal care to infants shall . . . obtain a blood specimen. . . ." and "forward the specimen. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
Regulations require that specimens or signed refusals be forwarded "to the Washington State Public Health Laboratory no later than the day after collection." When specimens are received, "the department shall perform appropriate tests for. . . ."

What Additional System Components Does the Fee Cover?
In addition to testing, the screening fee covers administration, follow-up services, program evaluation, program monitoring, and education.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless a parent or guardian objects on religious grounds. The person who administers the screening must inform the parent or responsible party of the purpose of screening, the disorders included, the requirement for newborn screening, and the right to refuse. If refusal occurs, then a signed statement of refusal must be obtained and forwarded to the state laboratory. The department may contact the family directly if necessary, to communicate significant test results. Regulatory revisions approved by the Board of Health address privacy, confidentiality, and the use of residual samples.

West Virginia

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Commissioner of State Public Health has authority. There is no mention of an advisory committee; however, a nonstatutory, multidisciplinary, advisory group exists.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states, "the hospital or birthing center . . . the parents or legal guardians, the physician attending the newborn, or any person attending a newborn not under a physicians care. . . ."

Are Newborn Screening Laboratory Services Regulated? How?
The statute states, "The Bureau of Public Health shall establish and maintain facilities at its State Hygienic Laboratory for testing specimens. . . ." Also, "the State Bureau of Public Health is authorized to establish additional laboratories. . . ." Currently the State Hygienic Laboratory performs testing.

What Additional System Components Does the Fee Cover?
There is no fee.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless a parent or guardian objects on religious grounds. The person who administers screening must fully inform the parents of the purpose of the test and must provide the family with a reasonable opportunity to object. With the exception of anonymous statistical data, the West Virginia Department of Health and Human Resources may not disclose information obtained from a newborn screening specimen or the parent or guardian of an infant.

Wisconsin

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The Department of Health has authority and "shall seek the advice and guidance of medical consultants, staff of the state laboratory, and other persons. . . ." There is no mention of an advisory committee; however, several ad hoc committees advise the department regarding various groups of disorders and education.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
The statute states that the attending physician or licensed nurse who attended the birth is responsible.

Are Newborn Screening Laboratory Services Regulated? How?
The statute specifies the State Laboratory of Hygiene.

What Additional System Components Does the Fee Cover?
In addition to testing, the fee covers administration, follow-up services, counseling, and treatment.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
All newborns must participate in newborn screening unless a parent or guardian objects on religious grounds. The person who administers screening must fully inform the parents of the purpose of the test and must provide the family with a reasonable opportunity to object. With the exception of anonymous statistical data, or as permissible under the state public health records statute, the department may not disclose information obtained from a newborn screening specimen or the parent or guardian of an infant. The state public health records statute holds records confidential and requires informed consent for disclosure of information other than to the parent or guardian, with exceptions, including health care delivery and research that protects the identity of the patient. The state newborn screening laboratory may conduct additional testing on specimens for the purpose of research on congenital or metabolic disorders, as long as

any applicable human research subject protections are followed. The laboratory also may test specimens for the purpose of evaluation.

Wyoming

Who Has the Authority to Change the Panel of Disorders? Is an Advisory Committee Required?
The statute specifies that a committee consisting of the state health officer, the president of the state medical society, a member designated by the state pediatric society, and a member designated by the obstetric/gynecological society shall determine the specific tests.

Who Is Responsible for Ensuring a Newborn Screen Is Performed?
Regulations specify the hospital, attending physician, midwife, or person attending the delivery.

Are Newborn Screening Laboratory Services Regulated? How?
Regulations specify the "regional laboratory." Currently the Colorado Department of Health Laboratory provides testing.

What Additional System Components Does the Fee Cover?
Fees cover only laboratory costs.

How Are Consent, Confidentiality, and Other Privacy Issues Addressed by Statute or Administrative Code/Regulation?
The individual who administers newborn screening is required first to obtain the informed written consent of a parent or guardian. If the parent or guardian objects for any reason, then the newborn is exempt from the program.

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