

State Laws Regarding the Retention and Use of Residual Newborn Screening Blood Samples

AUTHORS: Michelle H. Lewis, MD, JD,^a Aaron Goldenberg, PhD, MPH,^b Rebecca Anderson, RN, BS,^c Erin Rothwell, PhD,^d and Jeffrey Botkin, MD, MPH^e

^a*Berman Institute of Bioethics, Genetics and Public Policy Center, Johns Hopkins University, Baltimore, Maryland;*

^b*Department of Bioethics, Case Western Reserve University, Cleveland, Ohio; and Departments of* ^c*Pediatrics and* ^d*Nursing, University of Utah, Salt Lake City, Utah*

KEY WORDS

newborn screening, dried blood samples, research, ethics, law, consent, opt-out

ABBREVIATIONS

DBS—residual dried-blood samples

DoH—department(s) of health

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Address correspondence to Michelle H. Lewis, MD, JD, Research Scholar, Genetics and Public Policy Center, Berman Institute of Bioethics, Johns Hopkins University, 1717 Massachusetts Ave., NW, Suite 530, Washington, DC 20036. E-mail: michellelewismd@yahoo.com

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WHAT'S KNOWN ON THIS SUBJECT: Previous research has demonstrated that many state newborn screening laboratories do not have policies regarding the retention and use of residual newborn screening blood samples. Several national organizations have recommended that states develop policies regarding this important issue.



WHAT THIS STUDY ADDS: This study evaluated the extent to which issues related to the retention and use of residual newborn screening blood samples are addressed by state statutes and regulations. The recent lawsuits in Texas and Minnesota regarding this issue also are discussed.

abstract



BACKGROUND: After newborn screening has been completed, many states retain residual newborn screening dried blood samples for various purposes, including program evaluation, quality assurance, and biomedical research. The extent to which states possess legal authority to retain residual dried blood samples (DBS) and use them for purposes unrelated to newborn screening is unclear.

OBJECTIVE: The purpose of this study was to evaluate state laws regarding the retention and use of DBS.

METHODS: State statutes and regulations related to newborn screening of all 50 states plus the District of Columbia were accessed online between November 2008 and December 2009 and reviewed by 2 independent reviewers to determine the extent to which the retention and use of DBS were addressed.

RESULTS: The retention or use of DBS has not been addressed in 18 states. In 4 states, DBS becomes state property. Eight states require that parents be provided information regarding the retention of DBS. Parents in 5 states may request the destruction of their child's residual sample. Parental consent is required under certain circumstances to release DBS for research in 6 states. One state prohibits DBS from being used for research purposes.

CONCLUSIONS: States have wide variability in their policies regarding the retention and use of DBS. Many states have not addressed key issues, and some states that retain DBS may be acting outside the scope of their legal authority. The lack of transparency on the part of states in retaining DBS may undermine public trust in state newborn screening programs and the research enterprise. *Pediatrics* 2011;127:703–712

All 50 states plus the District of Columbia operate newborn screening programs. Newborn screening is mandatory in 49 states, and most of the 4 million infants born each year in the United States undergo newborn screening.^{1,2} After newborn screening has been completed, many states retain the residual dried blood samples (DBS).³ A total of 40% of state public health laboratories have reported retaining DBS for at least 1 year.⁴

DBS have a broad range of potential uses, including the evaluation of state newborn screening programs, quality improvement, and the development of new technology to improve newborn screening. They also may be used for surveillance or other public health activities, for example the detection of HIV seroprevalence rates.⁵ In addition, DBS have been used for forensic purposes and for biomedical research, both related and unrelated to newborn screening (eg, to detect environmental exposures).⁴

Interest in the use of DBS for research purposes is growing, and organizations are developing infrastructures to facilitate the use of these valuable specimens. At the state level, Michigan developed the Michigan Biotrust for Health to make DBS “more useful for medical and public health research.”⁶ Nationally, the National Institutes of Health awarded a contract to the American College of Medical Genetics in 2009 to develop a National Newborn Screening Translational Research Network. One of the goals of the Newborn Screening Translational Research Network is to establish a “repository of residual dried bloodspots that is either virtual or physical and comprised of those stored by state newborn screening programs and other resources.”⁷

However, state newborn screening programs were not created for these

purposes, and state departments of health (DoH) that retain DBS and use them for research without specific authorization may be operating beyond the scope of their legal authority. Despite recommendations from the Council of Regional Networks for Genetic Services⁸ and the American Academy of Pediatrics¹ that state newborn screening programs develop policies for the retention and use of DBS, previous research has demonstrated that a significant number of screening laboratories do not have written policies in place.⁹

The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children noted in 2010 that the storage and use of DBS for “nonstandard uses such as research may not be adequately addressed in current state laws or policies.”¹⁰ Similarly, an Institute of Medicine workshop convened in 2010 to address the challenges and opportunities related to DBS research cited the need for greater transparency and accountability regarding the operation of state newborn screening programs.¹¹

The scope of state authority to retain and use DBS without explicit parental permission was a central element in 3 recent lawsuits. First, in Minnesota, 9 families sued the state DoH,¹² claiming that the retention of DBS without explicit parental consent violated the state's Genetic Privacy Act.¹³ The suit was unsuccessful because the court ruled that the state's Genetic Privacy Act did not apply to the newborn screening program. In 2009, 5 families sued the Texas Department of Health Services for storing DBS indefinitely and using them for undisclosed research purposes without parental permission.¹⁴ In response to the lawsuit, the Texas newborn screening laws were changed to authorize the retention of DBS, and the lawsuit was settled. In the negotiated settlement,

Texas agreed to destroy 5 million DBS that were retained without parental consent before the new legislation took effect.¹⁵

The Texas program subsequently revealed that it had given 800 DBS to the US Armed Forces Pathology Laboratory for use in a forensics database.¹⁶ This revelation prompted an additional lawsuit claiming that the department “sold, traded, bartered, and distributed”¹⁷ DBS without parental permission for “undisclosed purposes” unrelated to the purpose for which the blood was drawn. This lawsuit is pending at the time of this writing. These lawsuits have raised the profile of these issues in state DoH and have led 1 state legislature to consider prohibiting the storage of DBS without parental consent.¹⁸ Expanding interest in the use of DBS and public controversy generated in some states have made the management of DBS a high-priority issue for many state newborn screening programs. The purpose of this study was to evaluate state laws to determine the extent to which issues related to the retention and use of DBS for medical research are addressed.

METHODS

The operation of state newborn screening programs is governed by 2 types of laws, statutes and regulations. In most states, statutes enacted by the legislature require the establishment of newborn screening programs and authorize state DoH to promulgate the regulations necessary to implement the newborn screening program. These regulations have the force of law. In the few states without specific newborn screening legislation, authorization for state newborn screening activities is derived from state public health legislation. Because state regulations are legally binding, the term “laws” is used in this

discussion to encompass both statutes and regulations.

The newborn screening statutes and regulations from all 50 states plus the District of Columbia were accessed online between November 2008 and April 2009 to determine the extent to which specific issues regarding the disposition of DBS were addressed (see Appendix). Changes in Maryland and Texas law that occurred subsequent to initial data collection were added to our data. A majority of state laws were accessed via Web sites maintained by the state legislatures of each state. When access was not possible via this method, other online databases, such as LexisNexis and Westlaw, were used to find the applicable law. Regulations specifically pertaining to the operation of newborn screening programs were obtained for all except 3 states.

To conduct the analysis, a coding system was developed on the basis of a set of initial categories identified by the research team. These categories included topics such as state control over DBS, information provided to parents regarding the retention and use of DBS, and whether parents were permitted to opt out of research. For each state, the applicable newborn screening laws were systematically reviewed independently by 2 reviewers. Using the coding scheme, the reviewers coded specific elements of each state newborn screening law related to the retention and/or use of DBS. Once initial coding was completed, the 2 independent reviewers compared results, discussed inconsistencies, and reached a consensus regarding how to categorize particular elements of these policies.

These results may not accurately reflect current state practices. For example, state DoH may provide parents with information about the retention and possible future use of DBS, although there is no legal requirement

to do so. This practice would not be reflected in the current analysis. Nevertheless, these results demonstrate the extent to which state activities regarding the retention and use of DBS are authorized by state newborn screening laws.

Laws governing the operation of state newborn screening programs were the focus of the recent litigation in Minnesota and Texas. Consequently, this analysis focused on state laws specifically related to newborn screening, particularly those pertaining to the retention and use of DBS for medical research or other uses unrelated to newborn screening. Laws related to quality improvement for existing newborn screening programs were excluded. Other laws that may be applicable to the retention and use of DBS, such as those that govern genetic privacy and the privacy of medical records, also were excluded from this analysis. The exclusion of other types of laws that may be applicable is a limitation of this study, but an analysis of those laws was beyond the scope of this project.

RESULTS

Retention and Use of DBS and Related Information

Laws in 20 states address the retention and/or use of DBS (Table 1). Laws in an additional 13 states address the use of information related to DBS rather than the samples themselves. In 18 states, the retention or use of DBS or related information are not currently addressed by state newborn screening laws.

State Control Over DBS

In 4 states, DBS becomes the property of the state. In 2 of these states, the DBS become the property of the state unless the parents specifically object in writing.

In 10 states, the DoH is granted authority over the use of the DBS. In these

states, it is unclear who retains ownership. Two states grant the state DoH broad authority over the use, retention, and disposal of DBS. Three states grant the DoH authority to approve the researchers who may have access to the DBS. Five states grant the DoH authority to approve specific research projects using DBS. One state specifies the types of entities authorized to perform research using DBS.

Use of DBS

Few state laws address the types of research that may be conducted using DBS, and the extent to which DBS may be used for research unrelated to newborn screening often is unclear. Thirteen states specify the purposes for which DBS may be used, but these purposes often are broad (eg, epidemiologic survey and research purposes, medical research, and research with a significant health benefit). One state prohibits the use of DBS for research purposes under any circumstances.

DBS may be released for anonymous research without parental consent in 7 states. Three of these states permit the use of DBS for anonymous research, unless the parents object in writing. One state requires the DoH to code DBS before release. One state requires the DoH to deidentify DBS it releases, unless informed consent is obtained from a parent.

Confidentiality

Information related to newborn screening is considered confidential in 26 states, but the limitations on that confidentiality vary. For example, in 1 state, information specific to individual newborns is considered confidential, but the information may be used for scientific research so long as the infant's name is kept confidential. There is no requirement that other identifying information be omitted. In another state, the disclosure of any in-

formation that can be readily associated with an individual is prohibited except for use in research authorized by the department's institutional review board.

Confidential information may be released with parental consent in 14 states. Four of these states require that parents be informed of the scope of the information and the purpose of its release. Two states require that parents be informed of the identity of those to whom the information will be released. Statistical data compiled without reference to the identity of individuals is not considered confidential information in 11 states and may be released without parental consent.

Use of Information

Ten states specify the purposes for which information from the DBS may be used. These purposes are generally broad and include public health purposes, scientific research, and research concerning medical, psychological, or sociological issues. One state specifies that information related to newborn screening may be used to study the relationship of various factors determining the frequency and distribution of newborn screening disorders.

Information Provided to Parents

In most states, there is no requirement that parents be informed that their child's DBS may be retained for future use. Eight states require that parents be provided information regarding the retention of DBS. Four of these states require that parents be told of the benefit of retaining DBS; however, the term "benefit" is not defined. Seven of these states require that parents be told of the potential use of DBS. The term "use" is not defined in 3 of these states. There is no requirement in any state that parents be informed of the type of research that may be undertaken with

TABLE 1 State Laws Regarding the Retention and Use of DBS According to State

Retention and Use of DBS	No. of States	States
Retention and/or use of residual DBS	20	CA, HI, IN, IA, ME, MD, MI, MN, MS, MO, NE, NH, ND, OK, SC, TX, UT, WA, WV, WI
Use of information related to DBS	13	AZ, AR, CO, DE, FL, ID, LA, MA, NJ, OR, PA, TN, VA
DBS become property of the state	4	CA, ME, UT, WA
Unless parents object in writing	2	CA, ME
State retains control over use of DBS	10	CA, IN, IA, ME, MO, NE, ND, UT, WA, WI
Broad authority over use, retention, disposal of DBS and related information	2	MO, NE
Department has authority to approve researchers who may have access to DBS	3	CA, ME, WA
Research projects using DBS must be approved by the Department of Health	5	CA, IA, MO, ND, WA
State specifies types of entities that may perform research using DBS	1	ND
Purpose for which DBS may be used specified	13	CA, HI, IN, IA, ME, MI, MO, NE, ND, SC, UT, WA, WI
Research using DBS is prohibited	1	MS
State may charge a fee for use of DBS	4	CA, MO, NE, ND
Fee may not exceed cost of administering the program	1	CA
State may charge reasonable fee for use of DBS	2	MO, NE
Form in which DBS may be released		
DBS may be released for anonymous research without parental consent	7	CA, IA, ME, MO, SC, UT, WA
Unless parents object	3	CA, ME, SC
States required to code DBS before release	1	SC
States required to deidentify DBS, unless parental consent is obtained to release identified DBS	1	UT
Confidentiality		
Information related to newborn screening is considered confidential	26	AZ, AR, CA, CO, DE, DC, HI, ID, IA, LA, MD, MA, MI, MO, NH, NJ, ND, OK, PA, SC, TN, TX, VA, WA, WV, WI
Confidential information may be released with parental consent	14	CA, CO, DC, IA, LA, MD, MA, MO, NH, PA, TX, UT, VA, WA
Parents must be informed of the scope of the information to be released	4	CA, DC, MD, MO
Parents must be informed to whom the information will be released	2	CA, MO
Statistical data not considered confidential and may be released without consent	11	CA, CO, DE, DC, MO, NE, ND, TX, UT, VA, WI
Purpose for which information related to DBS may be used is specified (generally broad)	10	CA, HI, ME, MD, MO, NE, ND, OK, TX, VA
Information may be used to study the relationship of factors determining the frequency of newborn screening disorders	1	MD
Information provided to parents		
Parents must be provided information re the retention of DBS	8	IA, MI, MN, NE, SC, TX, UT, WA
Parents must be told of the benefit of retaining DBS	4	MI, MN, NE, SC
Parents must be told of the potential use of the DBS	7	IA, MI, NE, SC, TX, UT, WA
Use is not defined	3	IA, TX, UT
Parents provided information about the disposition of DBS	6	IA, MI, MN, NE, SC, TX
Parents must be informed that they may request destruction of DBS	3	MN, SC, TX
Parents told that they may be contacted if research reveals information that may be beneficial to child's health	1	SC

TABLE 1 Continued

Retention and Use of DBS	No. of States	States
Parental control over DBS		
Parental consent required under certain circumstances to release DBS	6	IA, ME, NE, NH, UT, WA
Opt out permitted	7	CA, ME, MN, MO, SC, TX, WA
Parents may prohibit genetic material related to newborn screening from being used for any purpose other than newborn screening	1	TX
Parents may request destruction of DBS	5	MN, MO, SC, TX, WA
Children may request destruction of DBS when they reach adulthood	3	MN, SC, TX

States not listed did not have laws that govern the retention and use of DBS at the time these data were collected.

their child's DBS, and no state provides a mechanism by which parents may learn which specific research projects have used their child's DBS.

Six states provide parents with information about the disposition of DBS, but only 3 states require that parents be informed that they may request that DBS be destroyed. Parents in only 1 state are told that if research using their child's residual sample finds information that may be beneficial to their child's health, the DoH may confidentially notify the parents. The department is not required to recontact the parents in these circumstances.

Parental Control Over the Disposition of DBS

Parents retain control over the disposition of their infants' DBS in only a few states. Parental consent is required under certain circumstances to release DBS for research purposes in 6 states. Seven states allow parents to opt out of research using their child's DBS. One of these states authorizes parents to prohibit any genetic material related to newborn screening tests from being used for any purpose other than newborn screening testing. Five states permit parents to request the destruction of their child's residual sample. In 3 states, when children reach adulthood, they may request the destruction of their DBS.

Commercial Possibilities

The commercial possibilities associated with the transfer of DBS are addressed in several states. Four states authorize the DoH to charge researchers a fee for the use of DBS. In 1 state, this fee may not exceed the cost of administering the program. In 2 states, the DoH is authorized to charge a reasonable fee to prepare and supply DBS, but the term "reasonable" is not defined.

DISCUSSION

Since their development in the 1960s, state newborn screening programs have prevented serious health consequences or death in thousands of children. Yet, these programs typically operate with limited knowledge and involvement by parents of the large majority of children who receive normal test results. Limited education of parents about newborn screening is a result of the mandatory nature of most programs and has been justified by the importance of their public health mission. However, the lack of effective education for parents about the retention and use of DBS could foster public distrust, creating barriers to the use of these valuable samples, as demonstrated by the recent destruction of 5 million DBS in Texas.

Furthermore, controversies and lawsuits generated by the unauthorized

use of DBS by state DoH could jeopardize the public health mission of newborn screening programs. Public misperceptions that programs are operating in secrecy with sinister motives could undermine public trust¹⁹ and result in increased refusal rates for newborn screening. The lawsuits in Minnesota and Texas reflect serious concerns by some members of the public about this practice and reflect the need for more comprehensive and transparent state policies. Results of focus groups conducted in 2008–2009 with state Newborn Screening Advisory Committee members from the US Mountain States Region demonstrated that some Newborn Screening Advisory Committee members also have concerns about DBS policies and practices.²⁰

Despite growing interest in the use of DBS, most state legislatures and regulatory bodies have not fully addressed the legal and ethical issues related to their retention and use. As shown by our data, state laws vary substantially regarding which party, the parent or the state, has authority to determine the disposition of DBS and related information, under what circumstances they may be used and for what purposes, and how much information parents are provided about the retention and use of DBS.

In addition, the lack of uniformity in the definition of terms across states may prevent consistent interpretation of state laws. For example, the boundaries of what is considered research using the DBS are not always clear. Quality-assessment activities designed to evaluate the operation of current state newborn screening programs may not constitute research in this context. Additional delineation of what types of research are considered medical research and what types of research, if any, are prohibited should be considered. Recent activities by

the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children and the Institute of Medicine have highlighted this important issue.^{10,11}

The distinction between the residual sample and its related information is another area that needs additional discussion and clarity in policy. Currently, information related to samples mainly consists of test results and demographic information. Laws that address the use of information related to the samples have been primarily designed to prevent breaches of confidentiality.

The distinction between the samples and their related information may become less clear as the ability to sequence large amounts of genetic information improves. In the future, the genetic information generated by the DBS may be as valuable for research purposes as the samples themselves. Current laws intended to address the use of demographic information related to DBS may be inadequate to address the use of genetic information gleaned from them.

State efforts to maintain the privacy and confidentiality of infants and their

families vary widely. A consistent approach should be developed to protect patients' privacy and confidentiality, particularly because it may become increasingly difficult to deidentify biological specimens in the future. The Newborn Screening Advisory Committee member focus-group participants emphasized the importance of communicating specific information to parents and the general public about these privacy protections to bolster public confidence in state newborn screening programs and build support for the retention and use of DBS.²⁰

The commercial possibilities associated with the retention and use of DBS or access by third parties, such as the military or law enforcement, should be addressed. Access to DBS by commercial companies or third parties may be objectionable to parents who might not otherwise object to the use of their child's residual sample for medical research. The recent litigation in Texas demonstrates the importance of this issue.

CONCLUSIONS

Few state laws address the issues related to the retention and use of DBS in a comprehensive manner. Some states

that retain DBS, and use them for research purposes, may be acting outside the scope of their legal authority. The maintenance of public trust in these important programs is paramount, yet state laws often are silent with respect to the education of parents about DBS and parental control over their retention and use. Although the appropriate role of parental decision making is subject to debate, the need for state regulatory bodies to develop a more comprehensive approach to these issues is clear. The appropriate balance between respecting the rights of newborns and their parents versus the potential for public good should be considered carefully. The lack of transparency on the part of states in retaining DBS may undermine the public's trust in state newborn screening programs and the research enterprise.

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APPENDIX Newborn Screening Laws According to State

State	Statute	Regulations
Alabama	Ala. Code §22-20-3 (1991) (www.legislature.state.al.us/codeofalabama/1975/coatoc.htm)	Ala. Admin. Code r.420-10-1.01 through 420-10-1.06 (2008) (www.alabamaadministrativecode.state.al.us/docs/hlth/mcword10hlth1.pdf)
Alaska	Alaska Stat. §18.15.200 through §18.15.210 (2008) (www.legis.state.ak.us/cgi-bin/foioisa.dll/stattx08/query=*/doc/{@8257}?)	Alaska Admin. Code Title 7, §27.510 through 27.590 (1997), (www.touchngo.com/iglcnt/akstats/acc/title07/chapter027/section510.htm)
Arizona	Ariz. Rev. Stat. §36-694 (2007) (www.azleg.state.az.us/FormatDocument.asp?inDoc=/ars/36/00694.htm&Title=36&DocType=ARS)	Ariz. Admin. Code §R9-13-201 through R9-13-208 (2006) (www.azsos.gov/public_services/title_09/9-13.htm)
Arkansas	Ark. Code Ann. §20-15-301 through 20-15-304 (2005) (www.arkleg.state.ar.us/searchcenter/pages/Arkansascodesearchresultpage.aspx?name=20-15-304.administration+by+department+of+health)	"Rules & Regulations Pertaining to Testing of Newborn Infants" (www.sosweb.state.ar.us/elections/elections_pdfs/register/dec-07-reg/007.16.07-001.pdf)
California	Cal. Health and Safety Code §125000 through 125002 (2008) (www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=124001-125000&file=125000-125002)	Cal. Code Regs. Title 17, §6500 through 6508 (2008) (http://government.westlaw.com/linkedslice/default.asp?action=toc&rs=gvt1.0&vr=2.0&sp=ccr=1000)
Colorado	§25-4-801 through 25-4-804 (2008) and §25-4-1001 through 25-4-1006 (2008) (www.michie.com/colorado/lpext.dll?f=templates&fn=main-h.htm&cp=)	Colo. Code Regs. §1005-4 (2008) (www.sos.state.co.us/CCR/Welcome.do)
Connecticut	Conn. Gen. Stat. §19a-55 (2008) (www.cga.ct.gov/2007/pub/chap368a.htm#Sec19a-55.htm)	—
Delaware	Del. Code Ann. Title 16, §122 (1), 122(3)(h), and Title 29 §7904 (2009) (http://delcode.delaware.gov/title16/c002/sc01/index.shtml#topofpage). Note: There is no specific newborn screening statute. Rather, the authorizing legislation for the newborn screening regulations pertains to general authority of the state Department of Health to promulgate rules to promote the health of citizens of the state.	16 Del. Code Regs §4107-1.0 through 4107-11.0 (2007) (http://regulations.delaware.gov/AdminCode/title16/4000/4100/4107.shtml)
District of Columbia	DC Code §7-831 through 7-840 (2008) (www.michie.com/dc/lpext.dll?f=templates&fn=main-h.htm&cp=dccode)	—
Florida	Fla. Stat. §383.14 (2008) (2008->ch0383->Section%2014#0383.14">www.flsenate.gov/Statutes/index.cfm?app_mode=display_statute&search_string=&url=ch0383/sec14.htm&title=->2008->ch0383->Section%2014#0383.14)	Fla. Admin. Code Ann. §64C-7.001 through 64C-7.012 (2008) (www.flrules.org)
Georgia	Ga. Code Ann. §31-12-5 through 31-12-7 (2008) (www.lexis-nexis.com/hottopics/gacode/default.asp)	Ga. Comp. R. and Regs. 290-5-24.01 through 290-5-24.04 (2008) (http://rules.sos.state.ga.us/cgi-bin/page.cgi?department_of_human_services%2Fpublic_health%2Ftesting_for_inherited_disorders_in_the_newborn%2Findex.html&d=1)
Hawaii	Haw. Rev. Stat. §321-291 (2008) (www.capitol.hawaii.gov/hrscurrent/vol06_ch0321-0344/hrs0321/hrs_0321-0291.htm)	Haw. Code R. §11-143-3 through §11-143-13 (2009) (http://gen.doh.hawaii.gov/sites/har/admrules1.11-143.pdf)
Idaho	Idaho Code Ann. §39-909 through 39-912 (2008) (www3.state.id.us/idstat/toc/39009ktoc.html)	Idaho Admin. Code §16.02.12 (2008) (http://adm.idaho.gov/adminrules/rules/idapa16/0212.pdf)
Illinois	Ill. Comp. Stat. 410/240 (2008) (www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1546&ChapAct=410%26nbsp%3BILCS%26nbsp%3B240%2F&ChapterID=35&ChapterName=public+health&actname=newborn+metabolic+screening+act%2e)	Ill. Admin. Code Title 77§661 (2008) (www.ilga.gov/ommission/jcar/admincode/077/07700661sections.html)
Indiana	Ind. Code §16-41-17 (2008) (www.in.gov/legislative/ic/code/title16/ar41/ch17.html)	410 Ind. Admin. Code 3-3-1 through 3-3-8 (2008) (www.in.gov/legislative/iac/T04100/a00030.pdf?)
Iowa	Iowa Code §136A.1 through 136A.9 (2008) (http://coolice.legis.state.ia.us/cool-ice/default.asp?category=billinfo&service=iowacode&ga=82&input=136A)	Iowa Admin. Code §641-4.1 through 641-4.3 (2008) (http://search.legis.state.ia.us/asp/acodocs/rulelist.aspx?pubdate=3-11-09&agency+641&chapter=4)
Kansas	Kan. Stat. Ann. §65-180 through 65-183 (2007) (www.kslegislature.org/legsvrstatutes/getstatute.do?number=24824)	Kan. Admin. Regs. §28-4-501 through 28-4-513 (2008) (www.kslegislature.org/legsvrkars/search.do)
Kentucky	Ky. Rev. Stat. Ann. §215.155(2006) (www.lrc.ky.gov/krs/214-00/155.pdf)	902 Ky.Admin. Regs. 4:030 (2006) (www.lrc.ky.gov/kar/902/004/030.htm)
Louisiana	La. Rev. Stat. Ann. §40:1299 through 40:1299.6. (2008) (www.legis.state.la.us/lss/lss.asp?doc=97136)	La. Admin. Code Title 48 §6301 through 6303 (2008) (http://doa.louisiana.gov/ors/lac/58V01/48v63.pdf)
Maine	2008 Maine Rev. Stat. Ann. Title 22, §1532 through 1533 (2008) (www.mainelegislature.org/legis/statutes/22/title22ch261-asec0.html)	Me. Code R. 10-144 Chapter 283 (2008) (www.maine.gov/sos/cec/rules/10/144/144c283.doc)

APPENDIX Continued

State	Statute	Regulations
Maryland	Md. Code Ann., Health -general, §13-101 through 13-112 (2008) (www.michie.com/maryland/lpext.dll?f=templates&fn=main-h.htm&2.0)	Md. Code Regs. 10.52.12.00 through 10.52.12.15 (2009) (www.dsd.state.md.us/comar/10/10.52.12.00.htm)
Massachusetts	Mass. Gen. Laws ch. 111, §110A (2008) (www.mass.gov/legis/laws/mgl/111-4e.htm , www.mass.gov/legis/laws/mgl/111-110a.htm)	105 Mass. Code Regs. §270.000 (2008) (www.lawlib.state.ma.us/105cmr270.pdf)
Michigan	Mich. Comp. Laws §333.5431 (2008) (www.legislature.mi.gov/(s(yy3gmd45iwicfv55hodaigb3))/mileg.aspx?page=getObject&objectname=mcl-333-5431)	—
Minnesota	Minn. Stat. §144.125 through 144.128 (2008) (www.revisor.leg.state.mn.us/statutes/?id=144.125 , www.revisor.leg.state.mn.us/statutes/?id=144.1255 , www.revisor.leg.state.mn.us/statutes/?id=144.128)	Minn. R. 4615.0300 through 4616.0760 (2008) (www.revisor.leg.state.mn.us/rules/?id=4615&view=chapter)
Mississippi	Miss. Code Ann. §41-21-201 through 41-21-205 (2008) (http://michie.com/mississippi/lpext.dll?f=templates&fn=main-h.htm&cp=)	15-4-01 Miss Code. R. §38 (2008) (www.msds.state.ms.us/msdsite/-static/resources/346.pdf)
Missouri	Mo. Rev. Stat. §191.331 through 191.332 (2008) (www.moga.mo.gov/statutes/C100-199/1910000331.htm , www.moga.mo.gov/statutes/C100-199/1910000332.htm)	Mo. Code Regs. Ann. Title 19, §25-36.010(2007), (www.sos.mo.gov/adrules/csr/current/19csr/19c25-36.pdf)
Montana	Mont. Code Ann. §50-19-201 through 50-19-212 (2007) (http://data.opi.mt.gov/bills/mca_toc/50_19_2.htm)	Mont. Admin. R. 37.57.301 through 37.57.321 (2008) (www.mtrules.org/gateway/print_rv.asp?rv=23967)
Nebraska	Neb. Rev. Stat. §71-519 through 71-524. (2007) (www.nebraskalegislature.gov/laws/browse-chapters.php?chapter=71&print=true)	181 Neb. Admin. Code §2-001 through 2-010 (2007) (www.sos.state.ne.us/rules-andregs/regsearch/rules/health_and_human_services_system/title-181/chapter-2.pdf)
Nevada	Nev. Rev. Stat. §442.008 (2008) (www.leg.state.nv.us/nrs/nrs-442.html#nrs442Sec008)	Nev. Admin. Code §442.020 through 442.050 (2008) (www.leg.state.nv.us/nac/nac-442.html)
New Hampshire	N.H. Rev. Stat. Ann. §132:10-a through 132:10-c (2008) (www.gencourt.state.nh.us/rsa/html/X/132/132-10-a.htm , www.gencourt.state.nh.us/rsa/html/X/132/132-10-b.htm , www.gencourt.state.nh.us/rsa/html/X/132/132-10-c.htm)	N.H. code Admin. R. Ann. He-P3008.01 through 3008.17 (2008) (www.gencourt.state.nh.us/rules/he-p3000.html)
New Jersey	N.J. Rev. Stat. §26:2-110 through 26:2-111.1 (2008) N.J. Rev. Stat. §26:5B-1 through 26:5B4 (2008) (www.njleg.state.nj.us/)	N.J. Admin. Code §8-18-1.1 through 8-18-1.14 (2008) (www.michie.com/newjersey/lpext.dll?f=templates&fn=main-h.htm&cp=)
New Mexico	N. M. Stat. §24-1-6 (2008) (www.conwaygreene.com/nmsu/lpext.dll?f=templates&fn=main-h.htm&2.0)	N.M. Code R. §7.30.6.1 through 7.30.6.9 (2008) (www.nmcp.state.nm.us/nmac/cgi-bin/hse/homepagesearchengine.exe?url=www.nmcp.state.nm.us/nmac/parts/title07/07.030.0006.htm&geturl;terms=screening-newborn)
New York	N.Y. Pub. Health Law §2500-a (2008) (http://public.leginfo.state.ny.us/menugetf.cgi?commonquery=laws)	N.Y. Comp. Codes R. and Regs. Title 10, §69-1.1 through 69-1.9 (2008) (http://government.westlaw.com/linkedslice/default.asp?SP=nycrr-1000)
North Carolina	N.C. Gen. Stat. §130A-125 (2008) (www.ncga.state.nc.us/enactedlegislation/statutes/html/bysection/chapter_130a/130A-125.html)	10A N.C. Admin. Code 43H.0314 (2008) (http://reports.oah.state.nc.us/nac/title%2010a%20-%20health%20and%20human%20services/chapter%2043%20-%20personal%20health/subchapter%20hours/10a%20nac%2043hours%20.0314.html)
North Dakota	ND Cent. Code §23-01-03.1 (2008) N.D. Cent. Code §25-17-00.1 through 25-17-05 (2008) (www.legis.nd.gov/cencode/t23c01.pdf , www.legis.nd.gov/cencode/t25c17.pdf)	N.D. Admin. Code §33-06-16-01 through 33-06-16-05 (2008) (www.legis.nd.gov/information/acdata/pdf/33-06-16.pdf)
Ohio	Ohio Rev. Code Ann. §3701.501 through 3701.503 (2008) (http://codes.ohio.gov/orc/3701.501 , http://codes.ohio.gov/orc/3701.502 , http://codes.ohio.gov/orc/3701.503)	Ohio Admin. Code 3701-55-01 through 3701-55-20 (2008) (http://codes.ohio.gov/oac/3701-55)
Oklahoma	Oklahoma State Title 63, §1-53 through 1-54 (2008) (www.oscn.net/applications/oscn/index.asp?ftdb=stokst63&level=1)	Okla. Admin. Code §310:550-1-1 through 310:550-23-1 (2008) (www.oar.state.ok.us/viewhtml/310_550-1-1.htm)
Oregon	Or. Rev. Stat. §433.285 through 433.295 (2008) (www.leg.state.or.us/ors/433.html)	Or. Admin R. 333-024-0205 through 333-024-0235 (2008) (http://arcweb.sos.state.or.us/rules/oars_300/oar_333/333_024.html)
Pennsylvania	35 Pa. Cons. Stat. Ann. §622 through 625 (2008) (http://government.westlaw.com/linkedslice/default.asp?SP=pac-1000)	28 Pa. Code §28.1 through 28.41 (2008) (www.pacode.com/)
Rhode Island	R.I. Gen. Laws §23-13-14 (2008) (www.rilin.state.ri.us/statutes/title23/23-13/23-13-14.htm)	Rules and regulations pertaining to the Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program and the Newborn Hearing Loss Screening Program (R23-13-MET/HRG) (2008) (www2.sec.state.ri.us/dar/regdocs/released/pdf/doh/5014.pdf)

APPENDIX Continued

State	Statute	Regulations
South Carolina	SC Code Ann. §44-37-30 (2007) (www.scstatehouse.gov/code/t44c037.htm)	SC Code Ann. Regs. 61-80 (2008) (www.scstatehouse.gov/coderegs/c061e.htm)
South Dakota	SD Codified Laws §34-24-16 through 34-24-25 (2008) (http://legis.state.sd.us/statutes/DisplayStatute.aspx?type=statute&statute=34-24)	SD Admin R. 44:19:01:01 through 44:19:04:01 (2008) (http://legis.state.sd.us/rules/44/19/4419.doc)
Tennessee	Tenn. Code Ann. §68-5-401 through 68-5-404 (2008) (www.michie.com/tennessee/lpext.dll?f=templates&fn=main-h.htm&cp=tncode)	Tenn. Comp. R. and Regs. 1200-15-1-.01 through 1200-15-1.07 (2007) (http://state.tn.us/sos/rules/1200/1200-15/1200-15-01.pdf)
Texas	Tex. Health and Safety Code Ann. §33 (2008) (www.statutes.legis.state.tx.us/sotwdocs/hs/html/hs.33.29647.78775.htm)	25 Tex. Admin. Code §37.51 through 37.65 (2008) (http://info.sos.state.tx.us/pls/pub/readtac\$ext.viewtac?tac_view=5&ti=25&pt=1&ch=37&sch=d&rl=Y)
Utah	Utah Code Ann. §26-10-6 (2008) (http://le.utah.gov/~code/title26/h/26_10_000600.htm)	Utah Admin. Code R.398-1-1 through 398-1-18 (2008) (www.rules.utah.gov/publicat/code/r398/r398-001.htm)
Vermont	Vt. Stat. Ann. Title 18, §115 (2008) (www.leg.state.vt.us/statutes/fullsection.cfm?title=18&chapter=003&section=00115)	Newborn Screening Program Regulations (http://healthvermont.gov/regs/newborn_screening_reg.aspx)
Virginia	Va. Code Ann. §32.1-65 through 32.1-69.2 (2008) (http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+TOC3201000002000000000000)	12 Va. Admin. Code §5-71-10 through 5-71-190 (2008) (http://leg1state.va.us/cgi-bin/legp504.exe?000+reg_12vac5-71)
Washington	Wash. Rev. Code §70.83.010 through 70.83.050 (2008) (http://apps.leg.wa.gov/rcw/default.aspx?cite=70.83)	Wash. Admin. Code 246-650-001 through 246-650-991 (2008) (http://apps.leg.wa.gov/wac/default.aspx?cite=246-650&full=true)
West Virginia	W. Va. Code §16-22-1 through 16-22-6 (2008) (www.legis.state.wv.us/wvcode/chapterentire.cfm?chap=16&art=22)	W.Va. Code R. §64-91-1 through 64-91-11 (2008) (www.wvsos.com/csr/verify.asp?titleseries=64-91)
Wisconsin	Wisc. Stat. §253.13 (2008) (http://nxt.legis.state.wi.us/nxt/gateway.dll?f=templates&fn=default.htm&d=stats&jd=ch.%20253)	Wis. Admin Code HFS §115.01 through 115.06 (2009) (www.legis.state.wi.us/rsb/code/dhs/dhs115.pdf)
Wyoming	Wyo. Stat. Ann. §35-4-801 through 45-4-802 (2008) (http://legisweb.state.wy.us/statutes/titles/title35/T35ch4ar8.htm)	Mandatory Screening of Newborn Infants for Inborn Errors of Metabolism, (www.soswy.state.wy.us/rules/rules/6959.pdf)