Newborn Screening Programs: How Do We Best Protect Privacy Rights While Ensuring Optimal Newborn Health

Rachel L. Schweers

Follow this and additional works at: https://via.library.depaul.edu/law-review

Recommended Citation
Rachel L. Schweers, Newborn Screening Programs: How Do We Best Protect Privacy Rights While Ensuring Optimal Newborn Health, 61 DePaul L. Rev. 869 (2012)
Available at: https://via.library.depaul.edu/law-review/vol61/iss3/8
NEWBORN SCREENING PROGRAMS: HOW DO WE BEST PROTECT PRIVACY RIGHTS WHILE ENSURING OPTIMAL NEWBORN HEALTH?

INTRODUCTION

Each year an estimated four million infants are born in the United States and tested for metabolic and genetic abnormalities in newborn screening programs. Newborn screening programs are conducted in every state by standard procedures in which health professionals obtain blood samples via a heel prick from each newborn, test the samples for various metabolic and genetic disorders, and in some cases, use the samples for research.

This standard blood draw taken within the first forty-eight hours of life may be described to parents as nothing more than a sample to run tests to make sure everything is "okay." Of course, parents want to make sure everything is "okay," but what does this really mean, and what do these tests really do? For many parents, the birth of a child is a rewarding and exciting time accompanied by a healthy dose of anxiety and fear of the unknown world of parenthood. In the immediate aftermath of a child's birth, newly minted parents may be physically and mentally exhausted and may not be best equipped to make decisions regarding their own or their newborn's legal rights, as their primary concern is to leave the hospital with a healthy newborn child. As a personal experience, it was only when I initiated a discussion regarding newborn screening programs with my health care provider that we addressed the existence of these programs. Unexpectedly, I was much more educated than my health care provider about my state's newborn screening policies even after only a brief reading of the law and the refusal rights of parents.

To adequately ensure the privacy rights of newborn citizens and their parents, states should be required to obtain informed consent for newborn screening from every parent that enters into the state medical system for prenatal care. The operation of programs that screen newborns for medical and genetic disorders must, at the least, be done

---

with parents' full knowledge of the program; any other system should be unacceptable to all parents, legal guardians, and citizens of the United States.

A majority of the states conduct opt-out newborn screening programs; only two jurisdictions, Wyoming and the District of Columbia, administer opt-in newborn screening programs requiring informed consent. While both types of programs can responsibly maintain the parents' ultimate control of their newborn's privacy rights, the mandatory data collection under opt-out programs and potential use of newborn samples in later research implicate a myriad of legal and ethical issues, particularly for programs with no requirements for any parental education regarding the screening program. The legal and ethical challenges of newborn screening programs resemble those encountered by adult genetic screening, prenatal screening, diagnostic screening, and tissue sample collection; namely, issues related to informed consent, the right to privacy, test result confidentiality, genetic or medical discrimination, and federalism (due to the lack of a nation-


6. See Mary Ann Baily et al., Exploring Options for Expanded Newborn Screening, 33 J.L. MED. & ETHICS, no. 4, 2005, at 46, 46 (“To be ethical, decision-making for newborn genetic screening must be evidence-based, take the opportunity cost of the newborn screening (NBS) program into account, distribute the costs and benefits of the program fairly, and appropriately respect human rights. . . . Policy decisions raise difficult ethical issues relating to consent to screening, confidentiality, and the use of blood samples for research and quality improvement. The current policy process is not structured to meet [these] ethical requirements.”).


8. See Baily et al., supra note 6, at 46 (“Newborn screening programs must also respect American beliefs about the rights of individuals to make decisions about medical treatment, research participation, and the use of their personal information and body tissues such as blood samples.”).
The central focus of the legal issues implicated by newborn screening programs should always be the interests of the child and parents because screening "principally and substantially affects them." Although most newborn screening programs have gone unchallenged, the lack of required education in the face of mandatory newborn screening programs has created a situation of parental—and even health professional—unawareness of both the test itself and the opportunities available to parents to refuse sample testing, to refuse research use, to set the duration of sample storage, and to opt for availability of accelerated sample destruction.

In addition, the fact that collection of genetic information for adults in almost all states is a consent-based program raises questions of why newborn citizens may be exploited in a way that we do not allow ourselves to be. What are the interests overriding the rights of these children? Is it the commitment to public health interests to ensure the safety and welfare of newborns? Is it the potential research value of the biological samples obtained? Is it the ignorance of the general public to the programs as a whole? Undeniably, there is a strong public health interest in assuring that every newborn in the United States obtains adequate and efficient medical care. However, it seems likely that lack of education about the programs is a more likely reason for not requiring the same level of consent as adult testing. This seems particularly true in light of the fact that many states still do not require parental education, and even in those that do, the implementation of this education is many times not fully realized.

The scientific advancement of technologies and scientific awareness of disease and genetic disorders has pushed the issue of newborn screening to the forefront. In 2008, Congress passed the Newborn Screening Saves Lives Act of 2007 to provide some uniformity and direction for the states to follow. A national response coordinated by Citizens’ Council on Health Care analyzed the scientific literature

---

9. See Jon F. Merz, Psychosocial Risks of Storing and Using Human Tissues in Research, 8 RISK 235, 236–37 (1997); see also Baily et al., supra note 6, at 46; Foral, supra note 7, at 118.
12. See 45 C.F.R. § 46.116 (2010) ("Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative." (emphasis added)).
13. 42 U.S.C. § 300b-8 (2006 & Supp. 2010); see also Pub. L. No. 110-204, 122 Stat. 705 (2008) (describing its purpose of “amend[ing] the Public Health Service Act to establish grant programs to provide for education and outreach on newborn screening and coordinated followup care once newborn screening has been conducted, to reauthorize programs under part A of title XI of such Act, and for other purposes”).
on the effectiveness of newborn screening, delineated the best evidence for screening specific medical conditions, and recommended a more uniform condition panel of diseases to be followed by all states.\footnote{14} However, the states still govern the specific collection, retention, and testing laws for their newborn screening programs, and significant variations exist. For example, some states retain collected blood samples anywhere from a few weeks or months, while others hold samples indefinitely.\footnote{15} In addition, states differ as to the requirement for parental education prior to receiving the parents’ dissent (opt-out) or consent (opt-in).\footnote{16}

The newborn screening programs of Texas and Minnesota were brought into the legal limelight after parents challenged the programs’ constitutionality,\footnote{17} and national efforts are currently underway to provide uniformity to the state newborn screening programs.\footnote{18} Therefore, it is important to focus on the variations between state programs and to determine which state programs best address the current legal and social concerns. The opt-in programs, while in the severe minority, are better structured to protect privacy rights and guarantee parental education regarding awareness of the testing, as well as the diseases and conditions screened during testing. Opt-in newborn screening programs are more beneficial than opt-out programs on numerous levels.

First, consent-based programs respect the parents’ and patients’ right of privacy and their choice in their medical treatment and care.\footnote{19} Second, adopting a consent-based program requires physicians to engage with their patients to educate them about the options available to their child.\footnote{20} Third, consent-based programs, through incorporation of education and express parental consent for various research uses,
may provide greater research use of samples than is currently available.\textsuperscript{21}

On the other hand, mandatory opt-out programs ensure that every newborn is tested for disorders that are known to benefit from early detection and treatment, and that the state is fulfilling its public health role in screening newborns and evaluating data about the health and well-being of both individuals and the state's newborn population as a whole.\textsuperscript{22} However, any concern of diminished participation in opt-in programs may be ill founded, as a recent study has shown that opt-in programs generate equivalent participation when compared to opt-out programs.\textsuperscript{23}

Why then are forty-eight jurisdictions administering opt-out newborn screening programs,\textsuperscript{24} some with opt-out conditions strictly limited to religious beliefs? Are the hesitancies surrounding a shift to opt-in programs justified? Is the basis of bettering the public health through research access to newborn blood specimens sufficient when measured against the barrier to parental and infant rights? Are the states justified in lowering the privacy rights in infant genetic samples, as compared to adult genetic samples, which require express consent?

To address these questions, Part II of this Comment provides a profile of the current newborn screening programs, specifically identifying the general panel of diseases tested, the role of parental consent, and the requirement of parental education prior to specimen collection.\textsuperscript{25} This profile focuses on comparing the two jurisdictions with

\begin{enumerate}
\item See id. at 124.
\item See Jeffrey R. Botkin, Assessing the New Criteria for Newborn Screening, 19 Health Matrix 163, 164 (2009) ("The original justification for this approach was that the benefits of screening are so dramatic for conditions like PKU that the state is within its parens patria authority to mandate screening for newborns"); see also Foral, supra note 7, at 118 ("The principal justification offered for mandatory screening is the claim that society's obligation to promote child welfare through early detection and treatment of selected conditions supersedes parental prerogatives to refuse any minor medical intervention.").
\item See Beth A. Tarini et al., Not Without My Permission: Parents' Willingness to Permit Use of Newborn Screening Samples for Research, 13 Pub. Health Genomics 125, 125, 127 (2010) (describing an Internet-based survey analyzing 1,508 parent respondents over the age of eighteen). Tarini found that if permission was obtained, 76.2% of parents were "very or somewhat willing" to permit use of newborn samples for research, whereas only 28.2% of parents were "very or somewhat willing" to permit use of samples for research if permission was not obtained. Id. at 125.
\item Nebraska is not included as an opt-out state due to the fact it is the only state that has a strictly mandatory newborn screening program with no statutory exceptions allowed, even for religious beliefs. See Neb. Rev. Stat. §§ 71-519 to -524 (2008); Therrell et al., supra note 5, at S226-28.
\item See infra notes 28-157 and accompanying text. The various aspects of current U.S. newborn screening programs (for example, the requirement of consent, sample storage duration, permissibility of research uses, and panel of diseases screened) are compared to a comprehen-
opt-in programs to a subset of those that have enacted mandatory opt-out programs. Part III of this Comment analyzes the newborn screening program profile in light of two recent legal battles in which state newborn screening programs were challenged as implementing unconstitutional searches and seizures. In light of these controversies, this Comment proposes the components of a model statute and guidelines that avoid the legal concerns raised by these cases. The model statutory components emphasize (1) parental consent and education to ensure privacy rights; (2) the creation of a tiered system for the panel of diseases screened, varying in their requirements for parental consent, to ensure screening is limited to medically meaningful testing; and (3) the regulation of storage and research uses for samples collected to ensure privacy rights. Lastly, Part IV of this Comment discusses the impact a widespread adoption of opt-in programs would have on the landscape of the current newborn screening programs.

II. BACKGROUND

To provide an appreciation of the variations within newborn screening programs, this Part begins with a brief history of newborn screening programs in the United States, followed by a discussion of specific state statutes and some recent case law challenging those statutes. It additionally explores the historical and current debates in the legislative and media arenas to highlight the basis for implementing opt-in or opt-out newborn screening programs. In particular, this Part focuses on the two opt-in jurisdictions of Wyoming and the District of Columbia and three opt-out jurisdictions; namely Texas, Minnesota, and Maryland—a recent convert.

A. History of Newborn Screening Programs

Newborn screening programs are state-run programs that involve testing biological samples (most commonly blood collected within the first forty-eight hours post-birth) for abnormalities in levels of enzymes, metabolites, and other chemicals. In addition, newborn

---

26. See infra notes 158–89 and accompanying text.
27. See infra notes 190–91 and accompanying text.
screening detects the presence of specific genetic sequences that correlate with the presence or onset of particular diseases.\textsuperscript{29}

The original purpose of newborn screening programs was twofold. First, the programs created a comprehensive early checkpoint for the American health care system to adequately monitor the health of the infant population via the relatively easy access to a vast majority of newborns.\textsuperscript{30} Second, the programs were intended to detect metabolic abnormalities known to have severe consequences, including death, that were discoverable by a simple blood test and easily treated during postnatal infancy.\textsuperscript{31}

Mandated newborn screening newborn programs were initiated in Massachusetts in 1963 due to advances in testing methods for phenylketonuria (PKU), a rare genetic disorder that can cause mental retardation but is treatable by diet modifications if detected early.\textsuperscript{32} By 1975, many states had followed Massachusetts's lead, resulting in ninety percent of all newborns in the United States being tested for PKU.\textsuperscript{33} Currently, all states and the District of Columbia have imple-
mented newborn screening programs for various metabolic and genetic disorders, including PKU and congenital hypothyroidism.34

B. Recent Expansion of the Diseases Tested in Newborn Screening Programs

As a result of the increasing relevance of biological and genetic information and the advancements in disease testing methodologies,35 states have expanded screening in their newborn testing programs. Many disease panels include not only those diseases known to benefit from intervention at infancy (such as PKU), but also diseases for which there is no known intervention or treatment available and diseases for which a prediction of diagnosis is given based on genetics.36 This has resulted in many organizations coming forward in the last few decades to make recommendations for implementation of more uniform and successful programs. These recommendations have focused on the types of diseases and abnormalities included in the screening (treatable, nontreatable, or predictive), the level of consent required, and the parental education required.37

In 2006, the American Academy of Family Physicians (AAFP) published an issue brief stating that local AAFP chapters should recommend (1) "that their states give

35. Tandem mass spectroscopy (TMS) has become the principal tool for analysis of newborn screening samples. See generally Am. Coll. Med. Genetics/Am. Soc'y Human Genetics Test & Tech. Transfer Comm. Working Grp. (ACMG/ASHG), Tandem Mass Spectrometry in Newborn Screening, 2 GENETICS MED. 267 (2000) (noting that the mass spectrometer determines the types of molecules present in a sample and the quantity of those molecules present, such as amino acids and acylcarnitines—both critical components to disease detection as they can accumulate in the blood when a child has a metabolic disorder); see also Sam Crowe, A Brief History of Newborn Screening in the United States (Mar. 2008) (President's Council for Bioethics Staff Discussion Paper), available at http://bioethics.georgetown.edu/pceh/background/newborn_screening_crowe.html ("Tandem mass spectrometry is the most reliable, widely available method for measuring these compounds in a child's blood.") (citing ACMG/ASHG, supra, at 267-69).
36. See Tarini, supra note 1, at 768 ("While recognizing the potential value of new technology for newborn screening, Botkin and colleagues worry about the adverse consequences of rapidly expanding newborn screening without establishing the appropriate research and resource infrastructure needed to provide high-quality medical services to children and their families." (footnote omitted)); see also Baily et al., supra note 6, at 47 ("In developing criteria for selection of disorders, consideration of the prevention potential and medical rationale is needed. This approach required weighing several factors including: identifying a condition that provides a clear benefit to the newborn while preventing a delay in diagnosis and prevention of a developmental impairment or preventing illness or death.").
consideration to mandatory newborn screening for those [diseases] for which the evidence is most rigorously supportive”; (2) “that families be appropriately informed for consent”; and (3) that family physicians and office staff be “prepare[d] to educate families concerning newborn screening, and to respond to questions from families concerning positive tests.”

Many professional medical organizations do not fully support predictive genetic testing to reveal propensity for diseases with no existing treatment or for which there is a belated onset of the disease (post-childhood). A more evidence-based approach to constructing a disease panel would require sufficient data that correlates knowledge of the disease with the benefit to the child, the latter of which “must remain a central criterion” for newborn screening programs.

Generally, a set of five classic criteria, established by Wilson and Junger in 1968, has been influential in defining a disorder or disease suited for inclusion in the newborn screening panel:

(1) the disease must be well-defined and serious . . . ; (2) there must be an accurate testing method available; (3) the costs of the test must be reasonable; (4) there must be available treatment for the

38. Id.; see also Parent and Family Resources, Nat’l Newborn Screening & Genetics Resource Center, http://genes-r-us.uthscsa.edu/parentpage.htm (last visited Jan. 11, 2012) (advising that full comprehensive screening should include parental education, testing, diagnosis, follow-up, and treatment plans).

AAFP considers “appropriate” information to address both benefits and potential harms of reporting diseases that are detected in the “Tandem Mass Spectrometry panel.” AAFP ISSUE BRIEF, supra note 37. The Tandem Mass Spectrometry panel includes screening for various diseases, some of which result in the infant being “diagnosed” with propensity for disease onset at later stages of life. See, e.g., ACMG/ASHG, supra note 35, at 268 (“The issue of informed consent for MS/MS screening is complicated, in part because uniformly effective therapies have not been developed for all the conditions the methodology can detect and because it may detect previously unrecognized metabolites and or disorders.”).


40. Botkin, supra note 22, at 183–84; see also AMA HOUSE OF DELEGATES 2006 ANNUAL MEETING: COUNCIL ON SCI. & PUB. HEALTH, STANDARDIZATION OF NEWBORN SCREENING PROGRAMS 9 (2006), available at http://www.ama-assn.org/resources/doc/csaph/a06csaph9-full text.pdf [hereinafter AMA HOUSE OF DELEGATES REPORT] (“In spite of the fact that newborn screening programs have been in place for more than 40 years in this country, much of the evidence demonstrating screening program effectiveness is based on expert opinion rather than randomized controlled trials. In addition, there is a lack of formal evidence demonstrating clinical differences in outcomes that can be attributed to therapies initiated as a consequence of pre-symptomatic testing. While preliminary results indicate that children identified by screening have fewer developmental and health problems than children identified clinically, an urgent need remains for long-term tracking of data to enhance understanding of health outcomes, clinical course of disease, and effective treatments.” (emphasis added) (footnotes omitted)).
disorder; and (5) there must be adequate medical management facilities to refer infants for confirmatory diagnosis and treatment.41

In an effort to identify information to aid in the creation of a more uniform disease screening panel among the states, the Maternal and Child Health Bureau sponsored a study conducted by the American College of Medical Genetics.42 A group of medical and research experts developed principles and criteria for determining which conditions should be evaluated, resulting in three main categories: (1) “clinical characteristics”; (2) “analytical characteristics of the screening test”; and (3) “diagnosis, treatment and management of the condition in both acute and chronic forms.”43 After evaluating each condition relative to the above categories, the experts applied an evidence-based review that looked at the conditions currently tested in state newborn screening programs. They reconsidered each condition’s inclusion in newborn screening panels based on the scientific evidence as to “the availability of a screening test; [a]n efficacious treatment; [a]n adequate understanding of the natural history; [w]hether the condition was part of the differential diagnosis of another condition; and [w]hether the screening test results related to a clinically significant condition.”44

The conditions were classified into three categories: a core panel (primary targets), secondary targets, and those not appropriate for newborn screening.45 According to the study, in order to be included as a primary target, a condition must (1) “be identifiable at a phase . . . at which it would not ordinarily be detected”; (2) have “[a] test with appropriate sensitivity and specificity . . . available for it”; and (3) have “demonstrated benefits of early detection, timely intervention


43. MATERNAL AND CHILD HEALTH BUREAU REPORT, supra note 42.

44. Id.

45. Id.
and efficacious treatment." The experts determined that of the conditions being screened in 2004, approximately one-third of them would be considered in the core panel and another third of them would be considered not appropriate to include.

C. The Current Newborn Screening Program Landscape

Currently, states vary in the diseases included in their newborn screening panels, though some states have formed regional groups to establish guidelines for their newborn screening programs in an effort to minimize the variation and provide more uniform services in larger regions. Despite these efforts, there is still a need for greater uniformity among the states not only for the panel of diseases screened, but also for other critical aspects of the programs, such as consent and education.

Since the introduction of state newborn screening programs, some states, such as Texas and Minnesota, have either made or proposed changes to their newborn screening programs, motivated in part by the legal challenges encountered and the media attention received. Dr. Bradford Therrell of the National Newborn Screening and Genetics Resource Center, along with others, reported a comprehensive summary of the newborn screening programs in all fifty-one U.S. programs. The article notes:

Although all 51 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.

46. Id.
47. Id. The resulting core panel included 29 conditions considered appropriate for newborn screening. Id. The study identified another 25 conditions identified in the secondary panel. Id. Lastly, there were 27 conditions that were not considered appropriate for newborn screening, either because they met too few evaluation criteria or lacked a screening test. Id.
48. See Tarini, supra note 1, at 768 ("The number of disorders screened across states ranged from 0 to 8 disorders in 1995 and from 7 to 52 in 2005." (footnote omitted)).
49. See, e.g., Who We Are, NEW ENG. NEWBORN SCREENING PROGRAM, http://www.umassmed.edu/nbs/who/index.aspx?linkidentifier-id&itemid=65346 (last visited Nov. 20, 2011) ("The New England Newborn Screening Program is a comprehensive public health screening program for newborns, providing service for five New England states. The program provides high quality, timely, low-cost laboratory screening, clinical follow-up and research to prevent or minimize the effects of disorders that can lead to death, mental retardation and life-compromising conditions in newborns.").
Consequently, there is a significant lack of equity in newborn screening services across the country.\textsuperscript{52} The majority of states conduct opt-out newborn screening programs, despite the fact that during the creation of these programs influential decision makers, such as the American Medical Association (AMA) and scientific researchers concentrating in metabolic disease, advocated for newborn screening programs to be consent based.\textsuperscript{53} Refusal provisions allow parents to opt out for any reason in some states, but only for religious reasons in others. Most states collect and test newborn samples after providing little, if any, educational primers to the parents.\textsuperscript{54} In fact, Michigan, Montana, Nebraska, and South Dakota do not currently provide any statutory grounds for refusal to participate.\textsuperscript{55} The reality is that many of these tests on newborns are likely conducted in the midst of parental unawareness, due in part to the lack of required parental education.\textsuperscript{56}

As of early 2009, only Maryland, Wyoming, and the District of Columbia had opt-in newborn screening programs requiring explicit consent for screening from at least one biological parent or guardian.\textsuperscript{57} All three of these jurisdictions require parental education before screening.\textsuperscript{58} Maryland has since modified its regulatory practices, effective March 2009, and no longer requires retention of documented parental consent, but it still allows for refusal based on any reason, effectively switching from an opt-in program to an opt-out program.\textsuperscript{59} Some states, such as Massachusetts, have adopted a mixed-consent program that is opt-out based on religious reasons for the “routine”

\textsuperscript{52} Id. at S212.

\textsuperscript{53} Paul, supra note 32 (discussing the opposition to mandatory screening by the AMA and many medical societies and researchers in the field who “believed it premature to mandate that every infant be tested for PKU”).

\textsuperscript{54} See Therrell et al., supra note 5, at S226–28.


\textsuperscript{56} See Foral, supra note 7, at 109 (“This routine testing of newborns seems relatively uncomplicated and has, in fact, become a part of common practice and accepted public policy with little thought having been given to the implications.” (emphasis added) (internal quotation marks omitted)).

\textsuperscript{57} See Therrell et al., supra note 5, at S226–28; see also Botkin, supra note 22, at 164.

\textsuperscript{58} Therrell et al., supra note 5, at S226–28; see also H.B. 0119, 60th Leg., Gen. Sess. (Wyo. 2009) (amending Wyo. Stat. Ann. § 35-4-801(c) to require parental education).

testing, which includes disorders thought to be treatable. In addition to the “routine” testing, there is an additional disease panel available; this “optional” testing is opt-in, requiring parental consent to participate and screening for disorders that the Massachusetts Department of Health has determined are not yet supported by “enough evidence to require (mandate) routine newborn screening.” The optional testing includes diseases that are being investigated in terms of the extent of benefit gained from newborn screening, the frequency with which the disorders occur, and the accuracy of the screening tests for the disorders. There is a small subset of opt-out states that do require consent for follow-up treatment or to disclose medical information.

1. Opt-in Programs

a. Wyoming

From the beginning, Wyoming has shown a commitment to providing an opt-in newborn screening program. Wyoming’s newborn screening program explicitly states that “[i]nformed consent of parents shall be obtained” and requires educational information regarding the testing procedures, the diseases screened, and the consequences of participating in or refusing screening. As originally proposed by the Wyoming legislature in 1980, the Newborn Screening for Metabolic Diseases Act did not address informed consent. However, prior to the bill’s passage, the legislature added explicit language to ensure informed consent was obtained. In addition, Wyoming has no statutory limitations for refusal of testing. As more recent amendments to the newborn screening program have been enacted (adding a newborn hearing screening program and parental education requirements), no changes have been made to the consent-based as-

62. Id.
63. See Therrell et al., supra note 5, at S226–28. (showing that Arizona, California, Colorado, Delaware, and others require consent to disclose information and that Kansas requires consent for follow-up treatment).
67. Id.
pect of the program in spite of the clear minority in which Wyoming sits as an opt-in program.68

b. The District of Columbia

The District of Columbia’s newborn screening program also requires informed consent: the “hospital and maternity center shall inform the parent(s) of the availability of these tests and shall, unless parental consent is withheld . . . , take appropriate blood samples for analysis . . . .”69 The testing must be “wholly voluntary,” and each parent must be “fully informed of the purpose of testing” and be “given a reasonable opportunity to object to such testing.”70 Although it is not identified as an informed consent program in its statutory language as clearly as Wyoming, the now-defunct President’s Council on Bioethics71 characterized the District of Columbia program as requiring informed consent.72 With respect to the information that must be disclosed to parents, the District of Columbia newborn screening law also requires that

[all participants . . . be informed of the nature of risks involved in participation in such a program or project, be informed of the nature and cost of available therapies or maintenance programs for those affected by metabolic disorders, and be informed of the possible benefits and risks of such therapies and programs . . . .73

---

68. See H.B. 0119, 60th Leg., Gen. Sess., 2009 Wyo. Sess. Laws 178. The Wyoming House Bill would amend § 35-4-801(c) with the following statement requiring informed consent: “The department of health shall provide educational information to healthcare providers for distribution to the parent containing information on the testing procedures, the diseases being screened and the consequences of screening or nonscreening.” Id.


70. Id. § 7-834(3). The language of the District of Columbia code details a voluntary program where consent is obtained from parents informed of the procedure.

71. The President’s Council on Bioethics was established in 2001 by President George W. Bush and comprised of a group of individuals appointed by him to “advise the President on bioethical issues that may emerge as a consequence of advances in biomedical science and technology.” Exec. Order No. 13,237, 3 C.F.R. § 821 (2001).


73. D.C. Code § 7-834(3)(C).
2. Opt-out Programs

a. Texas

Texas's newborn screening program allows for exemptions based only on religious reasons. To refuse screening in Texas, a parent must be a member of a "recognized religious organization, the teachings of which are contrary to the testing requirement." The hospital is then required "to inform the parent of the consequences of refusal (possible infant death or retardation) and require the parent to complete a statement indicating the declination of newborn screening." This statement is retained in the infant's medical records.

A group of parents recently challenged Texas's newborn screening program as unconstitutional for authorizing research use of blood samples without parental consent. In Beleno v. Texas Department of State Health Services, parents alleged that the Texas Newborn Screening Program, which permitted newborns' dried blood specimens to be retained after they were used for mandated disease screening and later made available to researchers without parental consent, constituted an unconstitutional search and seizure. The case settled with no monetary award to the plaintiffs, but the state agreed to destroy more than five million blood samples collected over a seven-year period and to disclose how the samples were used.

Legislators responded by making changes to the newborn screening program. The Texas legislature explicitly considered both opt-in and opt-out choices, but ultimately maintained an opt-out program with disclosure requirements, reasoning that economic savings and avoidance of logistical difficulties outweighed constitutional concerns. Prior to the Beleno settlement, the legislators proposed modifications to the statute concerning the elective destruction of newborn samples.

74. Tex. Health & Safety Code Ann. § 33.012(a) (West 2010) ("Screening tests may not be administered to a newborn child whose parents, managing conservator, or guardian objects on the ground that the tests conflict with the religious tenets or practices of an organized church of which they are adherents." (emphasis added)).
75. Newborn Screening—Specimen Collection Requirements, Tex. Dep't State Health Servs., http://www.dshs.state.tx.us/LAB/nbs_collect_reqs.shtm (last updated Feb. 8, 2011).
76. Id.
77. Id.
78. See Beleno Complaint, supra note 17.
79. See id. at 3, 5; see also Carnahan, supra note 4, at 305–09; Katherine Drabiak-Syed, Legal Regulation of Banking Newborn Blood Spots for Research: How Bearder and Beleno Resolved the Question of Consent, 11 House J. Health L. & Pol'y 1, 29–34 (2011).
80. Dana Barnes, Texas DNA Showdown, Mayborn, 2010, at 40, 40.
81. See id.; see also H.B. 1672, 81st Leg., Reg. Sess. (Tex. 2009).
82. See House Research Ore., Major Issues of the 81St Legislature, Regular Session and First Called Session 129 (2009).
the confidentiality of the samples collected, and the information obtained from them.\textsuperscript{83} The original bill did not require a disclosure statement about retention of genetic materials, nor did it provide authorization for parents to request sample destruction; however, the bill was amended to address these issues.\textsuperscript{84} The new statute requires notification of the screening program, classifies information relating to newborn screening as confidential and not subject to subpoena or disclosure (except as provided by the bill), and provides parents with the opportunity to (1) limit the use of the genetic material through a written statement prohibiting use for any purpose other than the newborn screening tests authorized under the statute and (2) prohibit retention of the sample through a written statement, upon which the sample will be destroyed after sixty days.\textsuperscript{85} Parents who allow the use of their newborn’s samples in medical research are informed that the blood samples are “de-identified” to maintain confidentiality so that recipients cannot trace the specimens back to the newborn submitting the sample.\textsuperscript{86}

Supporters highlighted the fact that the amendments “provide a straightforward method by which parents could direct [the Department of State Health Services (DSHS)] to destroy their children’s genetic material so it could not be used for future research.”\textsuperscript{87} Supporters also noted that the amendments acknowledge the “invaluable public health purpose” that newborn samples serve while honoring the wishes of “parents [who] have personal concerns about the retention of their children’s genetic material.”\textsuperscript{88} Even if parents’ concerns arise at a later date, their awareness of the program and the

\textsuperscript{83. See} Tex. Health & Safety Code Ann. ch. 33 (West 2010); Tex. Occ. Code Ann. § 58.103 (West 2004); H.B. 1672; House Research Org., Major Issues of the 81st Legislature, Regular Session and First Called Session 129 (2009); see also Barnes, supra note 80, at 40-41 (“Even before the settlement, legislators voted overwhelmingly to require notification and allow parents to opt-out of the post-screening testing program. Since mid-2009, when the state was required by the new law to give new parents a disclosure form, only 7 percent have chosen to opt out of the program. For parents who want to support medical research that might come from the spots, the health department’s website offers reassurance that blood samples given to researchers are ‘de-identified’ so that recipients ‘cannot trace the specimen back to the baby from which it came.’”).

\textsuperscript{84. See} H. Journal, 81st Leg., Reg. Sess., at 1053 (Tex. 2009).


\textsuperscript{86. See} id. § 33.017. The Code of Federal Regulations defines “de-identified” as “[h]ealth information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual.” 45 C.F.R. § 164.514(a) (2005); see also Barnes, supra note 80, at 40-41 (explaining the privacy risks associated with DNA research using a blood card and the possibility of identifying a sample based on genetic similarities to relatives’ DNA, which may be known or in an accessible database).

\textsuperscript{87. House Research Org., supra note 82, at 128.}

\textsuperscript{88. Id.}
option of sample destruction can still be exercised.89 Supporters further argued that an informed consent process would be “unnecessarily burdensome and costly to the state and health providers,” as well as “unnecessary in light of current privacy safeguards,” such as de-identification and a structured research request process.90

An additional justification given by supporters for a mandatory programs addressed the potential for a consent-based system’s “elaborate nature” to cause “alarm among parents who previously would not have been concerned about retention of the genetic material.”91 Accordingly, supporters postulate this alarm would result in a “disproportionate number of parents . . . declin[ing] consent” and fewer newborns being screened.92 The Senate Research Center’s Bill Analysis also noted that it would be “impractical to obtain and track written consent for each de-identified piece of information that could help with quality assurance and program improvement because of the volume of newborn screening results (nearly 800,000 per year).”93

Opponents of the amendments argued that, while the modifications require parents to be informed about the retention of samples, they provide no method to ensure that all parents are in fact made aware of the retention process and how they can prohibit the use of their child’s sample.94 Though a parent may be comfortable with the current permissible uses of the retained samples, there is the possibility that modifications or expansions of the permissible uses may fall outside some parents’ comfort zone.95 Opponents stated:

By using an informed consent or “opt-in” process, there would be no question about whether a parent was aware that the genetic ma-

89. Id.
90. Id. at 129 (asserting that, for the DSHS to provide collection, storage and tracking of consent forms would be a costly, extensive process that is unnecessary due to assurances of sample protection of de-identification and limited sample access). As a parallel, the U.S. Department of Health and Human Services’ policy for waiver of informed consent of human research subjects includes consideration of the practical nature of testing, public health benefits at issue, risk of procedure to patients and rights and welfare of the subjects. 45 C.F.R. § 46.116(c)-(d).
91. House Research Org., supra note 82, at 129 (“The genetic material legally obtained through the newborn screening program meets the definition of a state record . . . . As such, this material may be retained for an appropriate amount of time as dictated by state records retention statutes. Despite this fact, some have expressed concerns that the retention constitutes an unlawful search and seizure in violation of the Fourth Amendment of the U.S. Constitution. Such concerns are unfounded because passive consent to retention of the materials would be implicit when parents knew that they could request that the genetic material be destroyed, but did not.”).
92. Id.
94. See House Research Org., supra note 82, at 129.
95. Id.
With a consent form, parents could indicate through signed acknowledgement that they understood and consented to the retention policies and possible uses of genetic materials.96

Opponents cautioned the legislature that the opt-out approach of genetic material retention "affirm[s] in statute a contestable moral judgment that the potential for some measure of public good supersedes the privacy concerns of an individual."97 These opponents poignantly emphasized that if research uses of retained genetic material were so valuable to the public health, the extra cost98 and administrative process to ensure protection of privacy concerns should not be problematic.99

Andrea Beleno, a plaintiff in Beleno, would have preferred a modification that changed Texas's opt-out program to an opt-in program:100

I just wanted people to have the choice to opt-in or opt-out, and for the most part, it's not a perfect system in my eyes, but they have it now . . . . They should look at that form and decide for themselves and their families what is the best choice for them.101

97. Id. at 5–6.
98. See AMA HOUSE OF DELEGATES REPORT, supra note 40, at 8.
99. See HOUSE RESEARCH ORG., supra note 82, at 6 ("If the public health outcomes of the research conducted on retained genetic material are considered valuable, then it should be worth the cost and extra administrative process to ensure that privacy concerns are protected.").
100. [Andrea Beleno] has concerns with the new Texas law, too. She would prefer that parents could opt-in, rather than opt-out . . . .

To Andrea, the complexities surrounding this issue can obscure the point. "It's not about politics, it's not about science, it's about consent and it's about parents' responsibility to make decisions for their kids," she says. Ironically, she would have willingly consented if they had asked her permission. Now, however, she distrusts the government. "Once you have a state agency that will bold-faced lie to you once," she says, "you don't know what else they might be lying about."

If Andrea has another baby, she says, "There is no way I would consent to having my kid's DNA be part of the sample because I just don't trust 'em."

Barnes, supra note 80, at 42.
101. Id. at 45. The reporter who initially uncovered the controversy that led to the Beleno case also felt the issue of consent was critical, asserting that it was not the storage and research use of the samples that was a personal issue for her, but rather the fact that they were collected and used without any notification and consent of the parents.

"I don't really fear Big Brother. I'm not one of those people," [the reporter] says. She understands the point of having an mtDNA research database. "I don't see a whole heck of a lot of problem."

She did, however, see a problem with the lack of consent. "What I tried to be careful about with this story but what got lost in the blogosphere was . . . I did not believe that these blood spots were being used for nefarious purposes like a lot of my readers did." She did feel the state and federal government "were not revealing something that was being done with taxpayer dollars because they feared how people would respond," she
b. Minnesota

Minnesota’s newborn screening statute explicitly authorizes a general refusal to participate not limited to religious reasons. The statute directs the Minnesota Department of Health to inform parents that the samples will be used for testing and that the results of those tests and the samples themselves will be retained by the Department of Health. In addition, the test administrator must inform the parents or legal guardians of the benefits of retaining the blood samples and provide them with the alternatives of declining testing or having samples destroyed within twenty-four months after testing. Any objection or election of an alternative must be signed by the parent or legal guardian and recorded in the infant’s medical record.

In a 2007 public hearing discussing potential changes to the Minnesota screening program, Twila Brase, President of Citizens’ Council on Health Care, addressed the proposed revisions. Specifically, Brase criticized the fact that, although the health department had developed a parent brochure and possessed opt-out forms for parents to sign, there was no requirement to notify hospitals that the law obligated them to inform parents of their ability to (1) refuse all testing by the state’s newborn screening program or (2) request that the infant’s sample be destroyed within two years. The current statutory language ensures these informed dissent choices because it explicitly states that parties with a duty to perform newborn testing “shall advise parents” that they have the options of declining testing or electing two-year sample destruction.

Among the proposed modifications

---

103. See id. § 144.125 subd. 3; see also MINN. DEP’T OF HEALTH, INSTRUCTIONS: REFUSAL OF NEWBORN BLOOD SCREENING (2003), available at http://www.cchconline.org/pdf/nbsrefuseinstructions_01-03.pdf.
104. MINN. STAT. § 144.125 subd. 3; see also MINN. DEP’T OF HEALTH, supra note 103.
105. MINN. STAT. § 144.125 subd. 3; see also MINN. DEP’T OF HEALTH, supra note 103.
106. MINN. STAT. § 144.125 subd. 3; see also MINN. DEP’T OF HEALTH, supra note 103.
108. Id. at 2.
109. MINN. STAT. § 144.125 subd. 3 (“Persons with a duty to perform testing . . . shall advise parents of infants . . . (3) that the following options are available to them with respect to the testing: (i) to decline to have the tests, or (ii) to elect to have the tests but to require that all blood samples and records of test results be destroyed within 24 months of the testing.”); see also MINN. DEP’T OF HEALTH, supra note 103.
to the Minnesota program was a requirement that the refusal forms be written in a simpler, shorter manner so as to not intimidate parents from making that choice and that the requirement that a secondary witness sign the refusal forms be eliminated. The latter of these changes was incorporated into the statutory language, now requiring only one parent or legal guardian to sign the refusal form, which is kept in the infant's medical records.

In Bearder v. State, a group of families sued the state alleging that biological samples and genetic information of their newborn infants, obtained during the newborn screenings, constituted private data on individuals subject to Minnesota’s Genetic Privacy Act. “Unless otherwise expressly provided by law,” the Genetic Privacy Act prohibits “collection, storage, use, and dissemination of genetic information” without “written informed consent.” The plaintiffs argued that, despite the fact that another Minnesota statute mandated the newborn screening program, the Minnesota Department of Health was bound by the Genetic Privacy Act to ask parents’ permission to collect, store, and test infants’ DNA.

Affirming summary judgment in favor of the defendants, the appellate court agreed with the lower court’s conclusion that the newborn screening program acts as “an ‘express’ provision of law that authorizes collection, retention, use and dissemination of blood specimens for the newborn screening program, making the genetic privacy act inapplicable.” In response to the concern for sample use unrelated to the newborn screening program, the appellate court held that these uses would be subject to the written informed consent requirements of the Genetic Privacy Act. Ultimately, because only nine of the twenty-five infants involved in the litigation had their samples collected after the newborn screening program became effective and none of those samples had been used in any public health studies or research, the court determined that the plaintiffs “failed to either present specific facts showing there was a genuine issue for trial, or to offer substantial evidence to support their genetic privacy act claim, or

110. Brase, supra note 107, at 15–16.
111. See Minn. Stat. § 144.125 subd. 3; see also Minn. Dep’t of Health, supra note 103.
112. Bearder v. State, 788 N.W.2d 144, 144–45 (Minn. Ct. App. 2010); see also Carnahan, supra note 4, at 310–12; Drabiak-Syed, supra note 79, at 24–29.
113. Minn. Stat. § 13.386 subd. 3.
114. Bearder, 788 N.W.2d at 149.
115. Id. at 150.
116. Id. (“While the newborn screening statute permits use of newborn screening specimens for purposes related to that program, it does not provide for the specimen remainders to be used for purposes outside the newborn screening program.”).
NEWBORN SCREENING PROGRAMS

their other claims for tort, violation of privacy, or governmental taking.”

In the aftermath of Bearder, the Minnesota legislature has yet to pass a new statute, but it is currently considering at least three bills that would modify the Minnesota newborn screening program. One of the bills, H.F. 1341, would establish that the samples and data collected under the Minnesota Department of Health’s newborn screening program are “not subject to the general genetic information provision of the Data Practices Act.” It would additionally establish “new requirements for informing parents about the screening process and options related to the collection and use of their infants’ genetic data.” Specifically, the bill would require that parents be informed of their rights to object to the testing and storage of samples, while permitting the Minnesota Department of Health to store and use blood samples for up to twenty-four months. Additionally, the Department of Health could use and store the blood samples “for individual health-related studies, or for another purpose” upon written informed consent of the parents.

H.F. 1341 would effectively create an opt-in provision for parents to elect indefinite retention of the blood samples by the state. Whereas the current statute requires a parental signature to limit sample retention to twenty-four months, the proposed statute would require a parental signature to retain samples for an indefinite period that may also include research use, making twenty-four month disposal the operating norm. This does not change the overall structure of the proposed bill as an opt-in provision; rather, it seems to create a program that collects and retains samples for only twenty-four months and provides alternatives to the parent to opt in for longer storage and future research use. At the least, the bill provides more options to parents after mandatory disclosure of the program.

Another bill, S.F. 1478, would create a newborn screening program that is opt-out yet seemingly provides a variety of options available to parents, allowing a more tailored choice in the newborn screening

117. Id. at 151 (citation omitted) (internal quotation marks omitted).
118. See H.F. 1341, 2009 Leg., 86th Sess. (Minn. 2009); S.F. 1478, 2009 Leg., 86th Sess. (Minn. 2009); S.F. 3138, 2007–2008th Leg. Sess. (Minn. 2007). S.F. 3138 was introduced in 2008, but it was vetoed by Minnesota Governor Tim Pawlenty due to its failure to require “written informed consent . . . for long-term storage or use of the blood samples for non-screening research.” Drabiak-Syed, supra note 79, at 20–21 & n.107.
120. Id.
121. Id.
program for their child. For example, parents could dictate the allowed uses and retention time of the samples.\textsuperscript{122} Incorporating the court's ruling in \textit{Bearder}, S.F. 1478 would modify the current Genetic Privacy Act to include a statement explicitly exempting the newborn screening program from the statute.\textsuperscript{123} In addition, the bill would modify the newborn screening statute to require disclosure of the newborn screening test to parents.\textsuperscript{124} Specifically, the bill would require disclosure of the purpose of collecting the sample; the fact that the sample would be retained for two years and that it "may be used for public health studies and research"; and a discussion of the benefits of testing and consequences of a decision of refusal to participate or refusal to retain samples for more than two years.\textsuperscript{125} The bill would provide parents four options: (1) participating in the screening program without modification; (2) participating in the screening program, but only allow the sample to be retained for twenty-four months; (3) participating in the screening program, but not allow the sample to be used in "public health studies and research"; or (4) refusing to participate in the screening program.\textsuperscript{126}

The language of S.F. 1478 differs slightly from H.F. 1341 in regard to the time frame of sample retention. While H.F. 1341 provides for a baseline retention of twenty-four months (unless otherwise allowed by signature of a parent, effectively opting in to longer storage),\textsuperscript{127} S.F. 1478 implies retention for longer than twenty-four months by providing the option of electing for the shortened twenty-four month period (effectively opting out of a longer storage).\textsuperscript{128} While S.F. 1478 may seem more favorable to parents' rights because it presents more options for election of retention time and research use than H.F. 1341, the standard indefinite sample retention timeframe of S.F. 1478 with research use could be less favorable to the parent and newborn, as this option seems limitless in terms of how the sample is later used and disseminated.

\begin{itemize}
\item \textsuperscript{122} See S.F. 1478.
\item \textsuperscript{123} See id. ("[T]he Department of Health's collection, storage, use, and dissemination of genetic information and blood specimens for testing infants for heritable and congenital disorders are governed by sections 144.125 to 144.128.").
\item \textsuperscript{124} See id.
\item \textsuperscript{125} Id.
\item \textsuperscript{126} Id.
\item \textsuperscript{127} H.F. 1341, 2009 Leg., 86th Sess. (Minn. 2009).
\item \textsuperscript{128} S.F. 1478.
\end{itemize}
c. Maryland

Maryland's voluntary newborn screening program states, "Participation in a hereditary and congenital disorders program should be wholly voluntary, and all information obtained about any individual in a hereditary and congenital disorders program should be kept confidential . . . ." Maryland's Code of Regulations governs the protocols by which practitioners implement the Maryland newborn screening program. Previously, these regulations required obtaining informed parental consent. However, in 2008, the Maryland Department of Health and Mental Hygiene submitted a report commissioned by the Maryland legislature upon consideration of House Bill 216. The Maryland Legislative Report addressed whether a coordinated, statewide system for screening newborn infants in the state for certain hereditary and congenital disorders should be applied to all newborn infants in the state and whether such a program should become a mandatory opt-out program. The Report emphasized that major national professional groups and federal agencies, such as the Newborn Screening Taskforce, recommended allowing parents to refuse newborn screening. The Newborn Screening Taskforce convened by the American Academy of Pediatrics recommended that "[p]arents should be informed of testing and have an opportunity to refuse testing; and . . . if after discussions about newborn screening . . ."


130. See Md. Code Regs. 10.52.12.05 (2002) ("Before administration of the test, the parent or guardian shall be informed fully of the reasons for the test and of his or her legal right to refuse to have the test performed on the child. An individual who has been provided and has signed a written explanation of the test approved and furnished by the Department shall be considered fully informed.").

131. Maryland Legislative Report, supra note 59.

132. Id.

In 2000, a very influential national Newborn Screening Taskforce was convened by the American Academy of Pediatrics (AAP) and funded by the Maternal and Child Health Bureau (MCHB) of the federal Health Resources and Services Administration (HRSA) to make recommendations for the future of newborn screening. This taskforce was co-sponsored by the Agency for Healthcare Research and Quality (AHRQ), the Association of Maternal and Child Health Programs (AMCHP), the Association of Public Health Laboratories (APHL), the Association of State and Territorial Health Officials (ASTHO), the Centers for Disease Control and Prevention (CDC), the Genetic Alliance and the National Institutes of Health (NIH). The report of this taskforce, entitled "Serving the Family from Birth to the Medical Home—Report of the Newborn Screening Taskforce," was published in Pediatrics 106: 383-427 (2000).

Id. at 2.
with health care professionals, parents refuse to have their newborn tested, the refusal should be documented in writing and honored."

In addition, the Maryland Legislative Report highlighted statistical analyses of consent-based programs, which conclusively demonstrated that most parents do not refuse newborn screening programs, stating that the twenty-four states that track their refusals “[d]ocumented refusal rates . . . from 0.004% to 0.8%, with most of these states having less than 0.2% refusals.” Perhaps even more impressive, in 2007, the Maryland Department of Health and Mental Hygiene found that the Maryland program screened 78,738 infants and only three parents refused, which corresponds to a state refusal rate of 0.000038%. The report went on to disclose that nine infants in approximately seventy-one million over the course of seventeen years had been “missed” due to parental refusal. This corresponds to a rate of one in 10,000,000, or 0.00001%, of babies born, a number that is significantly lower than that for infants missed due to false negative test results (.001% for TMS techniques; 10% for cystic fibrosis; and 7%-12% for hypothyroidism).

The Maryland Legislative Report also emphasized the “prevailing concern about the effects of mandating screening [as] intrusion of government into medical care and the family” and the fears “that mandatory newborn screening could set a precedent for mandatory governmental programs in other areas where it is clearly inappropriate.” The Report concluded that the statewide newborn screening program “should be applied to all newborn infants unless the parents or guardians of the infant object.” The Report supported informing parents about the program and providing them with educational materials strongly recommending the program, but the Report recommended “that written documentation of consent should no longer be required.”

133. Id.; see also Newborn Screening Taskforce, Serving the Family from Birth to the Medical Home, 106 Pediatrics 383, 387 (2000).
134. Maryland Legislative Report, supra note 59, at 3.
135. Id.
136. Id.
137. Id. ("It is not surprising that relatively few missed cases were identified because very few parents refuse and because the disorders themselves are quite rare. More babies are missed because of false negative results.").
138. Id. at 4.
139. Id.
140. Maryland Legislative Report, supra note 59, at 3.
Consequently, Maryland has adopted a refusal-based, opt-out program. According to the Maryland Department of Health website, "If you decide you really do not want your baby to have newborn screening, someone from the state health department will also call you to discuss newborn screening. You do have the right to decline screening (this is called opting out)." Although Maryland has recently switched from an opt-in to an opt-out newborn screening program, there is still a requirement to inform parents about the screening, but education is only encouraged and not mandated by statute.

3. "Refusal Prohibited" Programs

The statutory language establishing the newborn screening programs of Michigan, Montana, Nebraska, and South Dakota provides no grounds for refusing to participate. Additionally, Nebraska has never allowed parents to refuse. There is no correlation between states that provide no statutory basis for refusal and the states’ sample retention times, given that three of the four states have some of the shortest sample retention times and Michigan has the longest sample retention times.

4. Federal Attempts at Uniformity: National Funding and Program Guidelines

The Newborn Screening Saves Lives Act of 2007 (Newborn Act) became federal law in April 2008. The Newborn Act’s purpose is to

141. The regulatory language has been modified to provide for an opportunity to object to testing rather than the need for obtaining written approval to conduct testing. Compare Md. Code Regs. 10.52.12.06 (2009) (requiring health care providers to explain the reasons for the newborn screening program to parents and to provide an explanation of their right to object to having the testing performed without requiring a signature from the parent unless refusing the test), with Md. Code Regs. 10.52.12.05 (1994) (requiring the signature of parents who have received explanations of the reasons for the testing and their right to refuse, as a demonstration that the parents are “fully informed.”).


144. MARYLAND LEGISLATIVE REPORT, supra note 59, at 2.

145. Therrell et al., supra note 5, at S223-25 (showing two months in South Dakota, six to eight weeks in Montana, and three months in Nebraska, while Michigan’s sample retention is indefinite).

“amend the Public Health Service Act to establish grant programs to provide for education and outreach on newborn screening and coordinated followup care once newborn screening has been conducted.”

It encourages limiting the panel of heritable disorders tested to those that “significantly impact public health.” In addition, the Newborn Act requires the development of a model decision matrix for expansion of the screening programs to include disorders that have a “potential public health impact.” The Newborn Act encourages states to “include recommendations, advice, or information dealing with . . . the availability and reporting of testing for conditions for which there is no existing treatment; . . . [and] public and provider awareness and education.”

In terms of research uses of newborn samples, the Newborn Act sets out a Newborn Screening Research Program by which the Secretary and the Director of the National Institutes of Health (NIH) may coordinate and expand research in newborn screening to include

(A) identifying, developing, and testing the most promising new screening technologies, in order to improve already existing screening tests, increase the specificity of newborn screening, and expand the number of conditions for which screening tests are available;

(B) experimental treatments and disease management strategies for additional newborn conditions, and other genetic, metabolic, hormonal and or functional conditions that can be detected through newborn screening for which treatment is not yet available . . . .

The Newborn Act provides a sort of “catch-all” phrase authorizing the NIH Director to identify and conduct “other activities that would improve newborn screening.” However, it does not address the issues of consent, right of refusal, or any other privacy issues surrounding sample collection.

148. Id. § 4. S. 1858 modifies the duties of the Advisory Committee on Heritable Disorders in Newborns and Children to include additional duties, such as mak[ing] systematic evidence-based and peer-reviewed recommendations that include the heritable disorders that have the potential to significantly impact public health for which all newborns should be screened, including secondary conditions that may be identified as a result of the laboratory methods used for screening; [and] develop[ing] a model decision-matrix for newborn screening expansion, including an evaluation of the potential public health impact of such expansion, and periodically updat[ing] the recommended uniform screening panel, as appropriate, based on such decision-matrix.
149. Id. § 4.
150. Id. § 2.
151. Id. § 7 (emphases added).
152. Id.
In sum, the failure of the Newborn Act to address the role of consent is troubling, particularly in light of the permissive approach to expansion of the disorders screened, some of which have no known treatment. According to Twila Brase, the Newborn Act has problems stemming from the lack of consent and inclusion of expanded testing, the storage of genetic information in nationalized government databases and registries, the government's ability to track individuals with certain disorders, the availability of biological samples for research without consent, and the coercive nature of the programs' funding.153

A report from the now-defunct President's Council on Bioethics discussed the "prudent course" of offering mandatory screening only for situations in which the benefits outweigh the risks and burdens.154 Any conditions that do not satisfy this clear balancing test would require voluntary, informed consent.155 The report also proposed a mixed-consent approach to screening that does not wholly adopt a mandatory or informed consent model, reflecting the approach adopted by Massachusetts.156 As the report stated, this approach is "one that integrates mandatory screening for treatable conditions with elective or optional screening for as yet untreatable conditions that are appropriate targets for biomedical research."157

III. Analysis

To analyze the newborn screening programs in the United States, this Part highlights the pertinent lessons learned from state statutes, case law, and the national efforts towards uniformity, focusing in particular on Maryland, Texas, Minnesota, and the impact of recent legislative and judicial decisions. This Part explores and analyzes the justifications for opt-out versus opt-in newborn screening programs against the backdrop of recent litigations. Finally, it proposes model guidelines for a newborn screening program that appropriately protects the privacy rights of parents and infants by ensuring proper choice and education of parents and legal guardians.

153. See generally Brase, supra note 14.
154. See President's Council on Bioethics Report, supra note 72.
155. Id.
156. See generally id. at 85-86; New Eng. Newborn Screening Program, supra note 49. The New England program provides tiers of testing for routine and optional testing and also contains information about pilot studies. Id. The New England program provides ready access to all this information through its website with information specific to parents and brochures in eight different languages explaining the program and its purpose. Id.
157. President's Council on Bioethics Report, supra note 72, at 86.
A. Lessons from Current Legislative Debates

The recent legal disputes surrounding Texas’s and Minnesota’s newborn screening programs and the legislative reports during Maryland’s flip-flop to an opt-out program provide the justifications for adopting opt-out screening programs. First looking to Texas, the fact that the Beleno litigation resulted in settlement leaves little judicial interpretation for analysis, but perhaps equally important is the legislative debate that surrounded the post-Beleno bill. This debate demonstrates that while the concerns of parental and newborn privacy arising from Beleno may be somewhat alleviated by an opt-out program requiring disclosure of retention and options for sample destruction, the concerns are not entirely addressed.

In electing to maintain an opt-out program, the Texas legislature expressed concern for the burden and cost to the state and health care providers that an informed consent process would impose.\textsuperscript{158} This argument seems disingenuous from a state that presumably has an administrative infrastructure with data management technologies and a tax base that could support the large state population and ensure the protection of the its citizens’ rights. Texas is the largest state in the contiguous United States with a 2010 population of 25,145,561\textsuperscript{159} (of which approximately 1.5% or 400,000 are newborns),\textsuperscript{160} and it routinely maintains records for its citizens, such as motor vehicle records, birth certificates, public school records, state medical institution records, and records from various other state-sponsored programs. Although a practical and real issue, the financial hurdle to implement an opt-in or informed consent program is well worth the assurances and guarantees awarded to protection of parents and infants’ privacy rights.

\textsuperscript{158} House Research Org., supra note 96, at 4 (“DSHS would have to carry out an extensive process to develop the consent form, a system for consent form submission, and a system to store the forms and track whether a parent had granted consent. The associated costs would be particularly unnecessary in light of current privacy safeguards as well as those included in CSHB 1672. Not only is all personally identifiable information removed from the specimens, but only DSHS staff has access to the personal information database, and the research request process is structured to protect confidentiality.”). The Texas state legislature is not the only state voicing its attrition to change due to burden and costs. See Drabiak-Syed, supra note 79, at 36–37 (“California Department of Health Services echoed this problematic rhetoric that research should trump individual interests when it decided to retain [newborn screening] samples for additional research without consent.”).


As discussed previously, the Texas legislature determined that the "elaborate nature" of a consent-based system would "cause alarm among parents who previously would not have been concerned about retention of the genetic material," causing "a disproportionate number of parents to decline consent" and resulting in fewer newborns being screened. Fear of education and information is a dangerous and threatening basis for a government to justify its decision-making process in a truly democratic system. The task of providing concise medical descriptions and informative materials to parents regarding newborn screening may be difficult, but this is within the province of the state and its oversight of the medical care provided to its citizens. To dismiss the requirement for informed consent for fear of reduced participation is troublesome. Citizens should be alarmed by a state government's hesitancy to implement programs that would provide greater education and access to information regarding personal medical issues, particularly when the government believes the outcome may be that citizens decline to participate in the state program. The Texas legislature's reasoning is also flawed in light of the Maryland Legislative Report showing that an opt-in program receives greater than 99.9% participation. The state's preference for less paperwork and lower costs does not justify the failure to fully protect the privacy rights of its citizens.

Turning to Minnesota, although it is not clear as of yet whether the proposed bills will be passed, it will be interesting to watch the Minnesota legislature in the aftermath of the recent Bearder decision, which limited the use of samples collected from Minnesota's current opt-out newborn screening program to only those purposes specified in the newborn screening statute. Many of the proposed changes to the Minnesota newborn screening program statute are in line with Bearder. However, none of the proposed changes explore a transition to an opt-in program. The Bearder court's interpretation of the statute as "expressly authorize[ing] the commissioner to conduct health studies in carrying out its public-health mandate to collect information relevant to refining and improving the newborn screening program" is also problematic as it permits an extremely broad potential reach of the Minnesota statute. As interpreted by the court in Bearder, allowing the Minnesota commissioner to conduct health studies in order to make improvements or refine the newborn screening program could allow for a newborn screening program that extends to diseases

163. Id. at 149.
that have little relevance to the primary goal of newborn screening, which is to provide direct benefit to the child tested.\textsuperscript{164}

The potential exists for inclusion of conditions that are still at the non-therapeutic and experimental research stages in an effort to determine their prevalence in the population or to identify carriers of these conditions—a purpose arguably akin to the controversial dissemination and research uses of newborn samples in \textit{Beleno}. Despite the fact that research advances may later deem some of these conditions worthy of inclusion in the newborn screening programs, it is not appropriate to consider newborn screening programs a testing ground without also requiring explicit consent from at least the parents and, ideally, explicit consent from the subject upon reaching adulthood.

In looking at Maryland, the recent flip-flop state, the legislative debates and reports provide insightful data of the high participation rate opt-in programs generate when paired with the requirement of educating parents about the screening program and their elective choices. The statistical analysis of the opt-in newborn screening program previously conducted in Maryland is difficult to refute; a participation rate of more than 99.9\% in a consent-based program that requires education is impressive.\textsuperscript{165} However, the legislature used the high participation rate from their previous consent-based, opt-in program to justify the change to an opt-out program.\textsuperscript{166}

This is puzzling, as the decision to change to an opt-out program alters a fundamental aspect of freedom of choice for the parents deciding whether to have their newborn participate and may not generate a similar participation rate. The statistics are not an accurate representation of true participation in states that do not require education to parents making this decision, as parents cannot choose to participate in a program they do not know about. The statistics from Maryland show participation of greater than 99.9\% are meaningful due to the fact that Maryland’s previous regulation mandated informing parents of the program and provided them a written explanation of the test, providing an adequate opportunity for notice and for parents to follow up with additional questions.\textsuperscript{167} The high participation rate should indicate that the state’s opt-in program was operating in a

\textsuperscript{164} \textit{President’s Council on Bioethics Report}, \textit{supra} note 72, at 85.
\textsuperscript{165} See \textit{Maryland Legislative Report}, \textit{supra} note 59, at 3.
\textsuperscript{166} Id. at 4.
\textsuperscript{167} See \textit{MD. Code Regs. 10.52.12.00--15} (1994). \textit{10.52.12.05} stated:
Before administration of the test, the parent or guardian shall be informed fully of the reasons for the test and of his or her legal right to refuse to have the test performed on the child. An individual who has been provided and has signed a written explanation of the test approved and furnished by the Department shall be considered fully informed.
NEWBORN SCREENING PROGRAMS

manner that protected the vast majority of newborns from preventable illnesses while respecting their constitutional right of privacy. It is counterintuitive to switch to an opt-out program when the parents have been shown to make the "correct" choice in the eye of the state and society as a whole.

The impact of refusal to test would be most readily seen by the threat of "missing" an "ill" newborn in an opt-in screening program, but it is still less significant than the occurrence of false positives for "healthy" newborns in an opt-out screening program. Statistics show there is little potential to have an "ill" newborn—suffering from a disorder that the newborn screen would detect and permit necessary immediate life-sustaining treatment—slip through the screening system undetected in an opt-in program. "When parents refuse standard treatment for a child who will die or become seriously ill if he or she is not treated, the state properly intercedes to ensure treatment according to the doctrine of parens patriae." This differs from a situation of refusing testing for an otherwise healthy newborn that is not sick and has a less than 0.5% chance of having a disorder that is tested for in the screening panel.

Furthermore, many of the disorders for which the newborns are tested are not considered life threatening and do not require treatment to begin at the newborn stage. Government reach should infiltrate the family only when there is a demonstrated reason to do so (such as the parents' failure to protect or provide adequate care for their children); absent such a demonstration, the parental control of a family should be respected and revered by the state. The impact of public policy, in the instance of newborn screening programs, should not override the requirement for parental choice and education, especially when studies show that participation in an opt-in program is not adversely affected compared to opt-out programs and research participation may be increased.

Additionally, similar to the justification seen with the Texas legislature, the Maryland legislature's justification of "lightening the paperwork burden on hospitals and providers" is weak when balanced against the rights of a parent and a child to have full control over their health care.

168. AMA House of Delegates Report, supra note 40, at 7 ("There is a possibility that children may actually be harmed when unnecessarily placed on medications or restricted diets, and that false-positive results may have a psychological impact on parents who experience guilt and distress over the long-term health of their child." (footnotes omitted)).
169. Maryland Legislative Report, supra note 59, at 3.
170. Id. at 4.
171. See Tarini et al., supra note 23, at 128-30.
biological and genetic information. The financial burden placed on the states for maintenance of records and files related to informed consent is undoubtedly real. There is little financial incentive for states to expend resources to incorporate additional labor and record-keeping in newborn screening programs. However, financial incentives should not be the primary consideration when the privacy rights of newborns and parents are being considered. The state should not shirk its responsibility to protect its citizens, especially the rights of newborns, in the name of alleviating costs associated with the collection of consent and provision of educational materials. This is particularly true given that states are readily engaging in expanded screening that increases testing costs without evidence to show that this expansion is cost-effective. There will rarely be financial incentive to establish programs that require greater record-keeping on the part of the state to provide meaningful choice to its citizens. However, there are many rights that cannot and should not be compared to a financial burden, and privacy rights associated with genetic information are definitely among them. The role of public policy and the responsibility of the state in assuring public safety and welfare is an important one when evaluating the safety of newborns. The state should play a role in providing testing to parents and ultimately ensuring a healthier population, yet the state should also recognize the role it plays as secondary to the parent.

**B. Model Statutory Guidelines for Newborn Screening Programs**

In light of the legal minefield that surrounds newborn screening programs, it seems the best alternative is to avoid stepping in the wrong place and diminishing citizens' privacy rights. Newborn screening programs become minefields when they have no requirement for informed consent, no requirement for educating parents, and no option to protect samples from unauthorized research. Great potential for litigation from parents and infants who feel their privacy rights have been violated looms, as demonstrated by Beleno and Bearder. To avoid these mines, newborn screening statutes should require ex-

---

173. See AMA House of Delegates Report, supra note 40, at 8 ("These discrepancies suggest there is still insufficient information available to support a claim of cost-effectiveness for increased screening. It must be kept in mind, however, that newborn screening is a public health activity focused on saving lives, preventing disability, and improving quality of life. Its cost-effectiveness should not be considered only in terms of financial savings, but also in respect to reducing infant mortality and maximizing health improvements with limited resources.").
plicit parental consent after parents have the opportunity to engage in educational discussions with medical professionals. These discussions should include information regarding (1) the testing of the sample, including the specific disorders tested for and the knowledge and information available for treatment of each disorder; (2) the disclosure of the results and maintenance of confidentiality of the sample itself; (3) the retention time or optional accelerated destruction of the sample; and (4) the permissible research uses of the sample.

The role of informed consent should be explicitly stated in the statutory language and unambiguous to the reader, as demonstrated by the Wyoming statute.\textsuperscript{175} In addition, the model newborn screening statute should require documentation of such consent.\textsuperscript{176} It is also imperative that there be a requirement for parental education; whether the newborn screening program is opt-in or opt-out, a parent must be knowledgeable of that to which they are consenting or objecting. The inclusion of these two provisions, requiring consent and education, would create a program that begins to recognize and respect the privacy rights of parents and newborns.

To ensure that the public health and welfare of the community is also placed in the forefront of consideration, the statute should state the specific educational materials necessary to ensure each parent is in fact making an informed and educated decision. Parents should receive paperwork and be personally told by a medical professional about the newborn screening program during prenatal visits with full disclosure of the parents’ legal options available under state law.\textsuperscript{177} The complexity of genetic information may require the states to make genetic counselors available to parents, as is done with genetic prenatal screening, so that parents have the opportunity to fully understand the ramifications of participating in genetic tests that determine correlations with disease propensity.\textsuperscript{178} Finally, the disorders included in the newborn screening program should be continually reviewed and

\begin{itemize}
\item 175. See Wyo. Stat. Ann. § 35-4-801(c) (2011); see also Drabiak-Syed, supra note 79, at 45 ("[I]nstituting a consent policy in statutory law and health department procedures would amass a robust annotated collection while minimizing dignitary harm to newborn participants."); see also Carnahan, supra note 4, at 329 ("[O]btaining written informed consent from parents exhibits a respect for parental autonomy in making decisions involving their child’s body.").
\item 176. Documentation can be written into the statute by the legislature or mandated by regulations set up by the state’s health department.
\item 177. See Elster, supra note 3, at 188 ("With the increased possibilities for future use of re\textsuperscript{tained} samples, the time may have come for parents or guardians to be informed at the time of testing or during the prenatal period of the screening process itself as well as the retention and potential future uses of any collected samples.").
\item 178. See ACMG/ASHG, supra note 35, at 268 ("The inclusion of additional disorders in the newborn screening menu could increase the number of patients identified each year by 50% to
\end{itemize}
monitored by health professionals and scientists to ensure that only those disorders with proven benefits of early detection are included. Each of these points is discussed in further detail below.

1. Role of Parental Consent

In an opt-in program, parents deciding whether to consent to a newborn screening test retain responsibility and control because only after their action of consenting will their newborns undergo screening. By contrast, in a state-mandated program, parents do not retain full responsibility and control, even if presented with the option to refuse, because their inaction—or the inaction of the health care provider to inform the parents of their right to refuse—results in the newborn being screened. The role of the parent in an opt-in versus an opt-out program is vastly different, with the opt-out program ultimately placing the parent in a position inferior to the state and its public policy. The privacy rights of individual citizens outweigh the costs of implementing procedures to ensure their protection in newborn screening programs. This is especially true when state governments are consistently implementing procedures for documenting individual records. For example, states do not obtain financial incentives to record and maintain birth certificates, yet a second form collected at the same time frame of life for an infant is allegedly prohibitively burdensome and costly for some states. So costly in fact that Maryland sacrificed its consent-based program in favor of a “tree-saving” opt-out program. In situations such as this, in which states receive little financial gain for selecting an opt-in based program, it seems that the states will only take on the burden of extra steps to ensure individual rights when the federal government mandates that they do so.

2. Educational Requirements

Regardless of whether a program is opt-out or opt-in, requiring education for parents prior to testing is necessary because parents cannot effectively consent or decline any procedure when they are not made fully aware of the procedure itself, as well as its benefits, implications, and potential drawbacks.179 Most parents do not have the luxury of operating under a voluntary newborn screening program,

100%, and more physicians, nutritionists, and genetic counselors will be needed to deal with their ongoing medical and nutritional care.”).

179. See Carnahan, supra note 4, at 329 (“Parents deserve straightforward information about what will happen to their child’s DNA sample, how their child’s privacy will be protected, and, to the extent known, the type of research in which the sample will be used, and the conditions under which samples will be shared.”).
but must rely on the disclosure of these programs by medical and health professionals. The time during which parents are involved in the beginnings of their newborn's life is potentially full of complex emotional, physical, and mental exhaustion; therefore, education should be implemented at a stage earlier than the immediate aftermath of the newborn's birth. Incorporation of newborn screening program education should occur early in the prenatal process, ensuring that both parents are aware of the program, the panel of diseases tested, and their options for levels of participation or refusal.

Education must be the cornerstone of any newborn screening program because in its absence informed consent cannot exist. To ensure the proper education is adequately provided, newborn screening programs should require the parents' documented acknowledgment that they received information regarding the program and the disorders screened, that they had the opportunity to discuss this information with a health professional, and that they had subsequently decided to permit or refuse blood samples to be collected from their child for that testing.

3. Panel of Diseases Screened

The standard panel of diseases screened in newborn screening programs should be limited to only those disorders known to benefit from diagnosis and treatment at an early stage of life. Therefore, a system such as the one reviewed by the U.S. Department of Health and Human Services seems appropriate—a system that includes evidence-based research in the evaluation and categorization of diseases into a tier-based system. Nontreatable disorders should be excluded from the standard tier of diseases screened, especially because the screening detects the presence of genetic sequences that only correlate to disease susceptibility. It is difficult to determine what, if any, benefit exists for including these diseases in the screening panel when no treatment can be sought and no comfort can be given to the parents who now have to care for this child, possibly with the knowledge that the child may be more susceptible to disease later in life.

It is undeniable that knowledge of prevalence of certain disorders or risk of certain disorders is beneficial to monitoring public health;
however, a mandatory newborn screening program does not seem the appropriate place to derive this information, as the use is purely research based and should require informed consent of the newborn patient providing the sample. Due to the fact that the vast majority of newborn screening programs in the United States are mandatory, opt-out programs, a program such as the New England Screening Program implemented in Massachusetts, seems an appropriate minimum alternative, wherein a mixed-consent program is opt-out for "basic" testing, but requires consent to participate in the optional expanded screening.

4. Permissible Research Uses

Once a newborn screening program requires informed consent and parental education, one of the remaining issues is the potential use of the blood samples for research. The availability of samples for unlimited research is a risky proposition even if parents provide consent. Based on the rapid pace of scientific advancement, parents may not fully appreciate the type of testing or research for which the sample could ultimately be used. The federal government has taken a stern approach to the genetic testing of adult research subjects, requiring informed consent. However, despite the fact that many research uses of newborn screening samples include genetic testing, these programs are oddly divorced from a requirement of informed consent.

To guarantee the privacy rights of the newborn providing the sample, parents should be given the option of electing sample retention for no longer than eighteen years that prohibits research use. Upon expiration of the permissive sample storage, the state department of health should be obligated to follow-up with the now-adult sample donor and obtain permission for research use. Without such permission given, the blood sample should be destroyed. In addition, the now eighteen-year-old adult should be able to contact the state to provide consent or request sample destruction. Although this later consent system would create an eighteen-year research lag in the research

183. See Drabiak-Syed, supra note 79, at 45 ("State legislatures and health department policy should classify this practice as human subjects research, require it to comport with federal regulations, and re-think how to apply federal regulations based on research that undermines our previous assumptions relating to identifiability.").
185. However, the Massachusetts program does not meet all the advised requirements of this Comment because it does not mandate parental education in its statutory language. See Mass. Gen. Laws ch. 111, § 110A (2003); see also Therrell et al., supra note 5, at S226–28.
because the sample would be untouched until consent of the eighteen-year-old donor was received, it would ensure that any research testing of newborn samples is in fact done with consent of the adult individual who donated the sample, a protocol more similar to that in place for adult human research subject testing. This type of consent-based research use of blood samples has been implemented in at least one state, although not in an ideal manner, as it is coupled with the ability of the parents to release a sample for research use. South Carolina (an opt-out state) requires authorization from either the parents or from the donor of the blood sample upon reaching eighteen years of age for release of samples for research use. In addition, a brochure notifies South Carolina parents that blood samples are retained only for testing and explicitly states that research use is not permitted.

IV. Impact

The prevalence of newborn screening programs highlights their importance to the public health of our nation and its citizens. There is no doubt that states have made thoughtful and educated decisions about their newborn screening programs and that newborns can benefit by being tested. However, there is clearly room for improvement, which will only come at the insistence of the parents and citizens who demand change. Whereas many opt-out states may require education in newborn screening regulations, a vast majority of opt-out states do not. It is incumbent upon parents to be proponents for their children's health and welfare, and to do this they must have full knowledge of how their child's medical and genetic information is handled.

To effectively change all state newborn screening programs to include informed consent, require education, limit conditions tested to those known to benefit the newborn, and inhibit research use without the newborn's personal consent is a daunting task. The patchwork of newborn screening programs currently in the United States provides an opportunity to select what best protects the interests of U.S. citizens and piece together a comprehensive newborn screening program—letting the states serve as the experimental grounds of what works best and fostering those options that best protect the rights of

189. The brochure given to parents in South Carolina regarding newborn screening reads: "[South Carolina Department of Health and Environmental Control] will destroy your baby's blood sample once it is no longer needed for testing. It will not be used in research or for any purpose other than newborn screening." S.C. DEPT OF HEALTH AND ENVTL CONTROL, NEWBORN SCREENING FOR YOUR BABY'S HEALTH (2010), available at http://www.scdhec.gov/administration/library/ML-000032.pdf.
U.S. citizens. The federal government has attempted to provide uniform testing standards linked to funding, yet many states retain policies that allow refusal only on the basis of religious grounds or not at all. The concerns of parents recently voiced in *Bearder* and *Beleno* should not go unnoticed.

The gradual adoption of more-tailored newborn screening programs would alleviate many of the legal and social concerns with mandatory health programs and would result in parents having options to elect the testing array that best suits their children’s and family’s needs. These options should include tiered levels of conditions to test, which would allow parents to select a minimal test that covers treatable disorders known to have an immediate effect on their newborn, as opposed to a more comprehensive test that may include new disorders for which preliminary research data is being collected with the goal of being able to provide future treatment. This type of disease categorization lends itself most appropriately to a national uniform standard determined by top national expert opinion, medical knowledge, and peer-reviewed research.¹⁹⁰ Many states and regions have formed their own coalitions, such as the New England Screening Program, to provide uniformity in their region.¹⁹¹ While these efforts are clearly beneficial, their reach should be extended to all states, and they should be funded in large part by the federal government.

For many states, implementation of informed consent procedures would require new documentation for parents to review and sign to be kept in the newborn’s medical records. The document should, at a minimum, explain the purpose of the test, the diseases screened, and the storage and potential research uses of the blood sample. Additional educational materials explaining the risks and benefits of the diseases screened and the available treatment options should also be required to ensure that parents are adequately informed to provide consent. These procedures, although foreign to the majority of states, are not impossible to implement, as they have been in place in the District of Columbia and Wyoming and were in place in Maryland prior to 2010. Lastly, the storage of the blood sample and any options available to parents for accelerated disposal or for later release of the sample for research use would need to be communicated to the par-

---

¹⁹⁰ *But see* AMA House of Delegates Report, *supra* note 40, at 8 (noting that, while a uniform newborn screening program would minimize variation between the state programs, there are barriers against implementing a uniform screening program, such as “issues relating to cost, scarcity of resources, and a lack of evidence confirming the clinical benefits and cost-effectiveness of current screening programs”).

ents. States vary widely in their options for sample storage and later use, but of the existing options, the example of South Carolina best protects the privacy rights of parents and children, requiring their permission for any research use, including from the donor child.

V. Conclusion

The importance of the privacy rights of newborn and adult citizens mandates a serious reevaluation of where the newborn screening programs stand in the hierarchy of individual decision and choice. Nebraska’s mandatory program, which offers no option of refusal, is unreasonable and cannot be justified in view of the high protections afforded individual genetic information and the constitutionally guaranteed privacy interests of every U.S. citizen. Programs allowing citizens to opt out for religious reasons, while sufficiently recognizing the constitutional right to practice religion, are still inadequate because they do not allow those individuals who may have scientific, non-religious reasons for declining genetic testing. Opt-out programs that allow parental refusal for any reason must also require education about the screening and provide educational materials; otherwise the option of refusal is useless. Only consent-based programs place a sufficient burden on the state to provide the education necessary to fully protect parental and infant privacy rights while ensuring the public health and welfare of our newborn citizens.

The impact of legal change in a democracy is entirely dependent on the desire of the populace to make that change. Until the parents and citizens of each state raise their voices to share the importance of their individual choice in genetic testing for themselves and for their children, the current landscape of newborn screening programs will not change. Health professionals and legislatures of many states have been extremely thoughtful and active in promoting the beneficial medical service that newborn screening programs provide. However, this promotion has not equally emphasized the importance of parental education and choice in the process. Medical providers will prioritize, as they should, the health of their patients and actively engage in anything they can do to ensure a healthier start for a newborn child. Parents should do the same thing, but parents should also be able to play an active role in making a choice that recognizes the limits of the usefulness of medical information for themselves and their infants. Balancing both of these priorities is an achievable goal that requires a newborn screening program that (1) is consent-based, honoring parental and infant privacy rights; (2) is education-focused, ensuring parents are as informed as medical professionals as to the valuable insight the
testing will provide; (3) is limited in scope to disorders that are truly benefited by early detection, ensuring that additional untreatable disorders that can be detected only at a later date are not “tacked-on”; and (4) permits research expansion if the infant so desires her sample to be used in such a manner.

Author’s Note

On November 16, 2011, the Minnesota Supreme Court in Bearder v. State held that the Genetic Privacy Act applies to blood samples collected by the Department of Health for its newborn screening program, reversing the court of appeals. The court reasoned that because the blood samples fall within the definition of “biological information collected from an individual” of the Genetic Privacy Act they are subject to the requirements of being collected, used, stored, and disseminated only with the individual’s written informed consent. The court then turned its analysis to the newborn screening statutes to determine whether these statutes served as express authorization and therefore exceptions to the requirements of written informed consent in the Genetic Privacy Act.

The court concluded that the newborn screening statutes do provide an express exception to the Genetic Privacy Act, but only to the extent that the Department is authorized to test the samples for heritable and congenital disorders, record and report the test results, maintain a registry of positive cases for follow-up services, and storing those test results as required by federal law. The court determined that the newborn screening statutes did “not expressly provide for indefinite storage when no destruction request is received,” and that “no other source of law authorize[ed] the dissemination of blood samples or genetic information beyond that expressly authorized for the reporting of newborn test results.” The court therefore concluded that the newborn screening statutes do not expressly authorize the

192. 806 N.W.2d 766, 774 (Minn. 2011). The dissenting justices found that the majority’s conclusion necessitated the identical term in the Genetic Privacy Act to have two different meanings in the same subdivision of the same statute and, as such, was improper statutory interpretation. See id. at 777–85. One dissenting justice noted that the majority reached the correct policy result, but that “my role as a judge is not to implement my own policy preferences, but to interpret the law as written.” Id. at 784–85.
193. MINN. STAT. §13.386, subd. 1(b) (2011).
194. Bearder, 806 N.W.2d at 771.
195. Id. at 773–74
196. Id.
197. Id. at 776.
198. Id.
Department to engage in any use, storage, or dissemination other than those expressly stated without obtaining informed consent.199

The Minnesota Supreme Court's decision had a direct effect on Minnesota's newborn screening. A routine destruction of all residual blood spots received on or after the date of the supreme court decision began on January 30, 2012, and a litigation hold was placed on all data and specimens from babies born between July 1997 and November 15, 2011 (unless the parents requested destruction).200

The effect of the supreme court's decision in *Bearder v. State* on the pending Minnesota legislation remains to be seen.201 However, the decision's explicit finding that the newborn screening statute is exempt from the Genetic Privacy Act, to the extent it authorizes collection, use, storage, and dissemination of samples, may invite Minnesota (or other states) to simply broaden the scope of the statutory authorization for its state health department and ensure it explicitly captures further use, storage, and dissemination beyond the disorders tested in the screening program itself. The *Bearder* decision, while supporting the requirement of informed consent for uses of samples beyond the statutory purposes of newborn screening does little to encourage the requirement of informed consent for initial collection and testing of the blood sample. However, the Minnesota decision may serve as a first dent to the established newborn screening programs' machinery and encourage other state health departments to place similar restrictions on any research uses, storage, or dissemination outside of any already explicitly contained in their respective newborn screening statutes.

Rachel L. Schweers, Ph.D.*

---

199. *Id.* The court remanded to the district court for a determination of remedy as the facts alleged were insufficient to support whether the appellants' children's blood samples had been used, stored, or disseminated in violation of the Genetic Privacy Act. *Id.* at 777.


201. See H.F. 1341, 2009 Leg., 86th Sess. (Minn. 2009); S.F. 1478, 2009 Leg., 86th Sess. (Minn. 2009).

* Rachel L. Schweers, Candidate for J.D., DePaul University College of Law, 2013; Ph.D., Rice University, 2002; B.A., Augustana College, 1996. The author wishes to thank Professor Christopher Evers and Professor Nanette Elster for their time and efforts reviewing this Comment, and Brett, Owen, and Louis Schweers for their inspiration, encouragement, and support.