

Financing State Newborn Screening Programs: Sources and Uses of Funds

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ABSTRACT

BACKGROUND. Financing for newborn screening is different from virtually all other public health programs. All except 5 screening programs collect fees as the primary source of program funding. A fee-based approach to financing newborn screening has been adopted by most states, to ensure consistent funding for this critical public health activity.

METHODS. Two types of data are reported here, ie, primary data from a survey of 37 state public health agencies and findings from exploratory case studies from 7 states.

RESULTS. Most of the programs that participated in this survey (73%) reported that their newborn screening funding increased between 2002 and 2005, typically through increased fees and to a lesser extent through Medicaid, Title V Maternal and Child Health Services Block Grant, and state general revenue funding. All of the responding states that collect fees ($n = 31$) use such funds to support laboratory expenses, and most (70%) finance short-term follow-up services and program management. Nearly one half (47%) finance longer-term follow-up services, case management, or family support beyond diagnosis. Other states (43%) finance genetic or nutritional counseling and formula foods or treatment.

CONCLUSIONS. Regardless of the source of funds, the available evidence indicates that states are committed to maintaining their programs and securing the necessary financing for the initial screening through diagnosis. Use of federal funding is currently limited; however, pressure to provide dedicated federal funding would likely increase if national recommendations for a uniform newborn screening panel were issued.

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Key Words

newborn screening, financing, fees, Title V, public health, child health

Abbreviations

GAO—Government Accountability Office
FY—fiscal year

MCHB—Maternal and Child Health Bureau
SCHIP—State Children's Health Insurance Program

MS/MS—tandem mass spectrometry

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EVERY STATE AND the District of Columbia (hereafter referred to as states) have a newborn screening program designed to detect certain congenital conditions at or near birth and to link children to critical, and at times life-saving, early interventions. However, each state newborn screening program is unique in its administrative and financing structure.¹⁻⁴ These differences reflect variations in public health infrastructure, medical care capacity, and legislative impact. This article examines the sources (revenues) and uses (expenditures) of funds for newborn screening programs, with consideration of program variations and trends.

In general, financing for public health programs in the United States is determined by state policies, and programs use varying amounts of federal funding to augment legislative appropriations and fees.¹⁻⁶ However, financing for newborn screening is different from virtu-

ally all other public health programs. All except 5 screening programs collect fees as the primary source of program funding.⁷ This means that, unlike most public health programs, most newborn screening funding in most states does not come from federal or state general revenues.

Recognizing the variations in how states define and structure newborn screening is important to understanding the context for funding.⁸ For example, many states define their newborn screening responsibility as initial screening and short-term follow-up services through diagnosis (Fig 1). Some short-term follow-up efforts may be limited to a single contact with the physician or facility that submitted the blood specimen. Others may include more extensive follow-up activities, including contact with and assistance for affected families.^{9,10} Some programs include more-extensive data col-

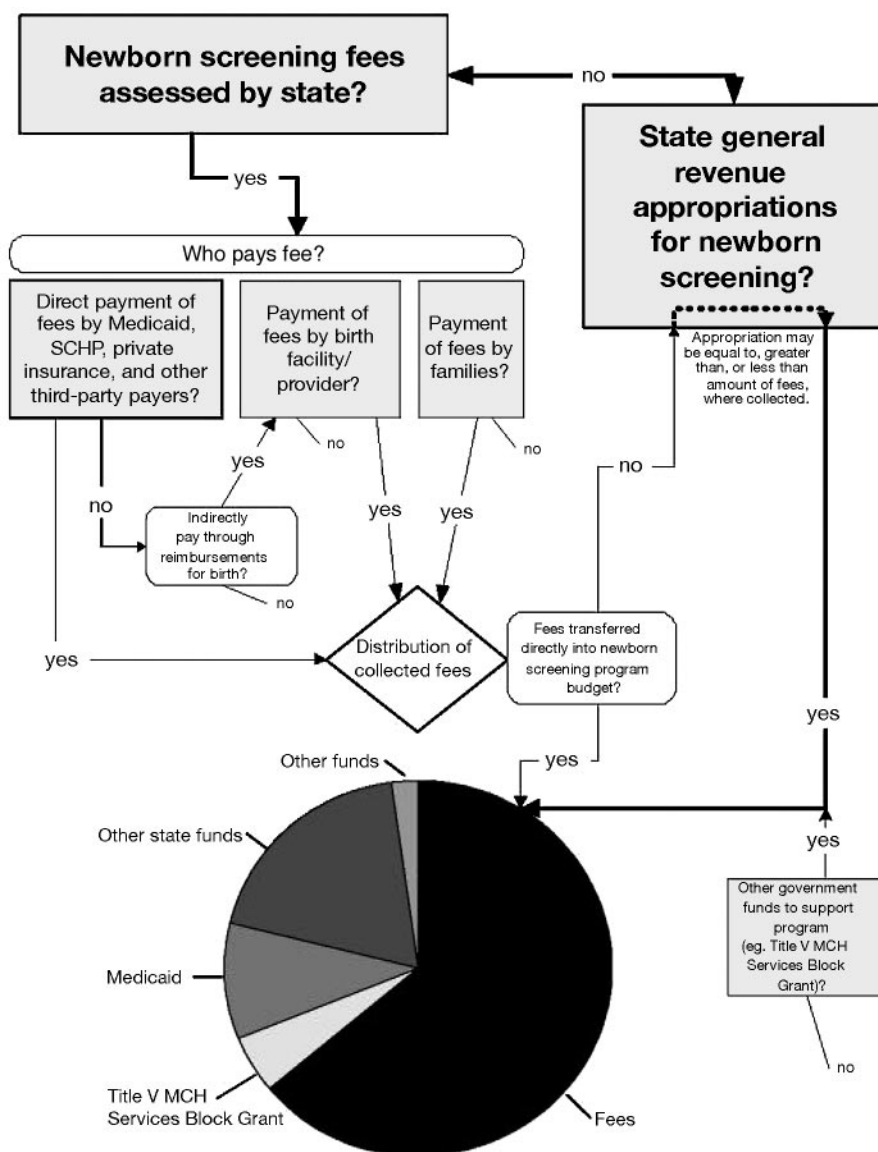


FIGURE 1
Flow of funds to state newborn screening programs.
MCH indicates maternal and child health.

lection and research activities to monitor long-term health outcomes or to study other disease-related issues. In addition, some programs provide financial support for limited clinical services and treatment for affected newborns (eg, nutritional and genetic counseling and metabolic formulas).

Much of the published literature on newborn screening financing emphasizes issues of costs, cost-effectiveness, and cost-benefit ratios.¹¹⁻¹⁸ The evidence presented here and elsewhere suggests that cost-effectiveness may have less importance in today's political environment, with parent advocates and private market forces combining to influence the structure of newborn screening programs.^{19,20} For more than a decade, observers and researchers have predicted a substantial shift in the driving force for newborn screening programs as a result of advances in genetic science.^{3,21} Recent changes relate to genetic science breakthroughs and new laboratory technology. Variations in state screening approaches, program designs, and use of technology have made cost-effectiveness studies less-influential (although not obsolete) analytic tools for decision-making to structure newborn screening programs.^{22,23}

Currently, state public health agencies face the challenge of financing state-of-the-art newborn screening programs that feature tests for more conditions, new laboratory technology, increased technical knowledge among screening staff members, and more-extensive follow-up efforts with families.^{24,25} The newborn screening program expansion pressure on state governments is like a "perfect storm," in which the forces of parental concern, private sector marketing, and public opinion merge. These pressures are leading to increases in screening test panels (ie, the number of conditions for which testing is required) and associated increases in program budgets. This article examines the sources (revenues) and uses (expenditures) of funds for newborn screening programs, with consideration of program variations and trends.

BACKGROUND

Funding Sources

Nationwide data on funding sources and uses for related services for newborn screening services and activities are not collected routinely. A 2003 report by the US General Accounting Office²⁶ (now the Government Accountability Office [GAO]) noted that, in state fiscal year (FY) 2001, more than \$120 million was spent to screen the nation's 4 million newborns, yielding an average of \$30 per infant screened. This GAO study found that two thirds of newborn screening program funds came from fees, 19% from other state general revenues, 10% from Medicaid, 5% from the Title V Maternal and Child Health Services (MCH) Block Grant, and 2% from other funding sources. Figure 1 illustrates the distribution of

these funds, as determined with the GAO estimates, and a typical flow of funds to a state newborn screening program budget.

No direct source of federal funding for state newborn screening programs exists today, although certain federal funds may be used at the state's discretion. Forty years ago, when state newborn screening programs were beginning, state health departments assumed a central role in program implementation and state legislatures provided funding. By 1973, 43 states required newborn screening statutorily.²⁷ In 1976, federal legislation to support screening for inherited (genetic) disorders was enacted by Congress and, in federal FY 1979 and FY 1980, 34 state programs received federal funding under this amendment to Title V.^{28,29} In 1981, when this and other Title V programs were merged into a block grant, newborn screening and genetic service activities became a funding category under Special Projects of Regional and National Significance. In addition, Title V MCH Block Grant funding was supplemented for 3 years in the late 1980s to encourage states to begin screening for sickle cell disease, in support of a consensus recommendation from the National Institutes of Health in 1987. Although related Special Projects of Regional and National Significance projects have been developed over the years since 1981 (eg, for genetics planning and data projects), no routine direct federal funding for state newborn screening programs was available until 2004 and 2005, when funds were appropriated to implement the Heritable Disorders Program authorized under title XXVI of the Children's Health Act of 2000.³⁰

With Title XXVI, Congress authorized the Secretary of Health and Human Services to award grants to a state or local area, or to a consortium of ≥ 2 states or local areas, for the purpose of enhancing, improving, or expanding the ability of states and local public health agencies to provide screening, counseling, or health care services to newborns and children having or being at risk for heritable disorders. In response to this legislative language, the MCHB established 7 regional genetic service and newborn screening collaboratives.³¹

Although Congress has revisited the question of Title V financing for newborn screening in recent years, it has not set up a regular separate appropriation of funds to state programs. Newborn screening activities may be funded as part of the MCH Block Grant program. The uses of these funds are controlled by individual state policies; therefore, the amount of Title V financing for newborn screening varies widely from state to state.

A fee-based approach to financing of newborn screening has been adopted by most states, in response to a growing trend among state legislatures to require public programs to be self-supporting and the need for consistent funding for this critical public health activity. A survey of state newborn screening programs to determine the effect of reduced federal funding related to the

creation of the Title V MCH Block Grant found that most states were unable to make up federal losses in FY 1983 with funds from other sources. Where cutbacks threatened to curtail operations, most state MCH program directors assigned high priority to preserving newborn screening and follow-up services. One third of the states that did not then charge for newborn screening considered adoption of a fee-based approach.³² By 1985, 12 states had enacted laws to establish newborn screening fees and approximately one half of all programs were collecting fees.³³ By FY 2001, 13 programs reported that fees were the sole source of funding and 19 additional programs used fees to support at least 60% of newborn screening expenditures.²⁶ The fee-based approach is now widespread, with 46 programs using fees as a source of revenue for some or all of their newborn screening program budgets (Table 1).

These newborn screening program fees are considered by some to be the administrative equivalent of user fees, in some ways similar to those required for vehicle registration. Most fees are collected from birthing facilities/providers, which pay the requisite amount from the payments they receive for perinatal (birth) services (Fig 1). In some cases, fees are paid directly by third-party payers such as Medicaid or private insurance. Some state governments have added requirements for Medicaid to pay the newborn screening fee through a separate charge. Such actions are linked to increases in fees (eg, from \$15 to \$50) and provider concerns about taking too large a share of global payments for care at the time of birth. For example, in 2003, Indiana adopted rules to increase the newborn screening fee from \$7 to \$30, with assurances that Medicaid reimbursement to hospitals would fully cover the increase in the fee paid for each Medicaid-covered newborn screen.

Traditionally, newborn screening revenues have not been paid directly by third-party reimbursements from private insurance or public coverage (eg, Medicaid or State Children's Health Insurance Program [SCHIP]). Although newborn screening fees might have been derived from the private insurance and Medicaid financing of maternity newborn care, this was a different mechanism than direct payment to a newborn screening program. Today, particularly in the case of Medicaid, it is reported widely that Medicaid reimbursements are below the level needed to pay the newborn screening fee.²⁵ Children's health insurance coverage is important in the context of newborn screening, not only to cover screening costs (directly or indirectly) but also to finance medical services needed by children with detected conditions.³⁴

Alabama provides one practical example of how this works. Alabama state regulations require that the state Board of Health assess and collect newborn screening fees from hospitals and birthing centers or third-party payers. The newborn screening fee is based on the

schedule of laboratory fees established by the Centers for Medicare and Medicaid Services for use by Medicare. The Medicaid agency is billed for newborn screening when the birth is financed by Medicaid. Additional reasonable and necessary fees may be charged to other payers by the hospital or physician in connection with this rule. Fees may be waived because of a patient's inability to pay. Small rural hospitals are not required to pay the fees if there is no third-party payer for these fees (ie, uncompensated care).

Some states deposit collected fees into the state general fund, and the newborn screening program competes with other state programs for its budget appropriation (Fig 1). Some states deposit fees directly into a special budget category and/or restrict the use of fees to the support of genetic or newborn screening programs. With the latter approach, newborn screening programs must be more directly accountable for the cost of the total program and must link budgets to fee levels.³⁵

Funding Uses

The American Academy of Pediatrics Newborn Screening Task Force³⁶ recommended a policy framework for state newborn screening programs. The framework emphasized that state policies should ensure adequate financing for the entire newborn screening system and not just the laboratory testing costs. Task force goals for adequate financing were to have (1) adequate program funds to complete screening, short-term follow-up monitoring, and diagnosis; (2) financing mechanisms for comprehensive care for all individuals with conditions identified for newborn screening; and (3) available financing for quality assurance data collection and ongoing evaluation of the program.

State newborn screening programs routinely test blood spots collected from newborns for ≥ 30 metabolic and congenital conditions, with initial short-term follow-up services to ensure that families are informed of suspect results and linked to additional testing to confirm the child's condition. The screening results may be shared directly with the family or sent to a health professional. Many, but not all, states provide additional follow-up services (ie, beyond informing) for families with infants with conditions identified through newborn screening programs, including efforts to ensure that appropriate diagnostic services are received and that families are linked to sources of treatment. Professional and consumer education is also a widely accepted program responsibility.

Laboratory services may be financed through intergovernmental agreements with public health laboratories or through contracts with private laboratories. Controversy has surrounded the role of private laboratories, with concerns being related more to data and follow-up activities than to financing, although competition may affect costs.³⁷

TABLE 1 Trends in State Newborn Screening Fees

State	Fees							Program Elements Financed ^d
	1996 ^a	1997 ^b	1998 ^a	1999 ^b	2000 ^a	2002 ^c	2004 ^a	
Alabama	NA	\$24.00	\$24.00	\$24.00	\$24.00	\$34.00	\$139.33	L
Alaska (r)	\$24.00	\$24.00	\$24.00	\$24.00	\$24.00	\$24.00	\$55.00	L/A/F
Arizona (2)	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	L/A/F/T
Arkansas	\$14.83	\$14.83	\$14.83	\$14.83	\$14.83	\$14.83	\$14.83	L
California	\$42.00	\$42.00	\$42.00	\$42.00	\$42.00	\$60.00	\$60.00	L/A/F
Colorado (2)	\$33.50	\$33.50	\$33.50	\$33.50	\$33.50	\$43.37	\$53.25	L/A/F/T
Connecticut	\$18.00	\$18.00	\$18.00	\$18.00	\$18.00	\$28.00	\$28.00	L/A/F
Delaware (2)	\$40.69	\$40.69	\$40.69	\$40.69	\$40.69	\$40.69	\$64.00	L/A/F
District of Columbia	No fee	No fee	No fee	No fee	No fee	No fee	No fee	
Florida	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$15.00	L/A/F
Georgia	No fee	No fee	No fee	No fee	No fee	No fee	No fee	
Hawaii	No fee	\$4.00	\$27.00	\$27.00	\$27.00	\$27.00	\$47.00	L/A/F/T
Idaho	No fee	No fee	No fee	No fee	No fee	\$18.00	\$23.00	
Illinois	\$25.00	\$25.00	\$32.00	\$32.00	\$32.00	\$32.00	\$47.00	L/A/F/T
Indiana (r)	\$22.10	\$22.10	\$22.10	\$22.10	\$28.50	\$39.50	\$39.50	L/A/F/T
Iowa (r)	\$28.00	\$30.00	\$30.00	\$30.00	\$33.00	\$46.00	\$56.00	L/A/F
Kansas	No fee	No fee	No fee	No fee	No fee	No fee	No fee	
Kentucky	NA	\$14.50	\$14.50	\$14.50	\$14.50	\$14.50	\$14.50	L
Louisiana	\$12.00	\$12.00	\$12.00	\$18.00	\$18.00	\$18.00	\$40.00	L/A/F/T
Maine	\$18.00	\$18.00	\$18.00	\$26.75	\$26.75	\$33.00	\$44.00	L/A/F/e
Maryland	\$15.75	\$15.75	\$15.75	\$15.75	\$15.75	\$30.00	\$42.00	L
Massachusetts (r)	\$42.00	\$42.00	\$42.00	\$49.55	\$49.55	\$49.55	\$54.75	L/A/F/c
Michigan (r)	\$28.02	\$28.02	\$28.58	\$29.38	\$39.00	\$42.61	\$54.84	L/A/F/T
Minnesota	\$13.00	\$13.00	\$21.00	\$21.00	\$21.00	\$21.00	\$61.00	L/A/F
Mississippi	\$20.00	\$20.00	\$20.00	\$20.00	\$35.00	\$25.00	\$70.00	L/A/F/T
Missouri	\$25.00	\$15.00	\$15.00	\$13.00	\$13.00	\$25.00	\$25.00	L
Montana	\$15.00	\$15.00	\$18.50	\$35.50	\$36.92	\$36.92	\$39.34	L
Nebraska	NA	No fee	\$54.60	\$54.60	\$54.60	\$54.60	\$64.00	L/T
Nevada (2)	NA	\$30.00	\$30.00	\$30.00	\$30.00	\$30.00	\$30.75	L/A/F
New Hampshire	NA	\$12.50	\$12.50	\$12.50	\$18.00	\$18.00	\$18.00	L
New Jersey	\$27.00	\$27.00	\$27.00	\$34.00	\$34.00	\$34.00	\$71.00	L/A/F/T
New Mexico (2)	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$32.00	\$32.00	L/A/F/T/e/c
New York	No fee	No fee	No fee	No fee	No fee	No fee	No fee	
North Carolina	No fee	No fee	No fee	No fee	No fee	\$10.00	\$10.00	
North Dakota	\$15.00	\$15.00	\$15.00	\$16.00	\$17.00	\$18.00	\$36.00	L
Ohio	\$27.00	\$27.00	\$27.00	\$27.50	\$27.00	\$33.75	\$33.75	L/A/F/T
Oklahoma	\$10.50	\$10.50	\$10.50	\$10.50	\$10.50	\$10.50	\$75.59	L/A/F/T
Oregon (2)	\$28.00	\$28.00	\$32.00	\$32.00	\$32.00	\$54.00	\$54.00	L/A/F/T
Pennsylvania	\$18.50	\$12.00	\$18.50	No fee	No fee	No fee	No fee	
Rhode Island	\$59.00	\$59.00	\$59.00	\$55.00	\$59.00	\$59.00	\$59.00	L/A/F/T
South Carolina	\$21.00	\$21.00	\$21.00	\$21.00	\$21.00	\$21.00	\$42.00	
South Dakota	No fee	No fee	No fee	No fee	No fee	No fee	\$16.20	
Tennessee	\$10.00	\$10.00	\$10.00	\$10.00	\$17.50	\$17.50	\$47.50	L/A/F
Texas	No fee	No fee	\$13.75	\$13.75	\$13.75	\$19.50	\$19.50	L
Utah (2)	\$21.00	\$21.00	\$27.50	\$27.50	\$27.00	\$31.00	\$31.00	L/A/F
Vermont (2)	\$21.00	\$21.00	\$21.00	\$27.00	\$27.00	\$27.00	\$33.30	L/A/F
Virginia	\$16.00	\$16.00	\$16.00	\$16.00	\$16.00	\$27.00	\$32.00	L/A/F/T
Washington (r)	\$39.90	\$33.80	\$35.75	\$35.75	\$39.25	\$40.40	\$60.90	L/A/F/T/e
West Virginia	No fee	No fee	\$15.85	\$12.64	\$20.46	No fee	No fee	
Wisconsin	\$43.25	\$44.00	\$45.50	\$55.50	\$55.50	\$59.50	\$65.50	L/A/F/T
Wyoming	\$12.25	\$12.25	No fee	No fee	No fee	No fee	\$45.00	

(2) indicates that, effective in 2004, the state mandates 2 screens and the fee includes both mandated screens; (r) indicates that the fee effective in 2004 includes repeat tests (most of these states strongly recommend 2 screens); NA, not applicable; L, laboratory; A, program administration; F, short-term follow-up services; T, treatment; e, education; c, counseling. Education and counseling may be included in short-term follow-up services without notation. The e and c indicate additional efforts reported by states. Treatment may involve providing or subsidizing formula foods, giving subsidies to specialty providers, or other services.

^a Source: National Newborn Screening and Genetics Resource Center annual report on state newborn screening.

^b Two sources: National Newborn Screening and Genetics Resource Center report and Survey of Nationwide Public Health Genetics Activities, 2002.

^c Source: GAO.

^d Fee approved, effective January 2005. Source: National Newborn Screening and Genetics Resource Center. Available at: www.genes-r-us.uthscsa.edu

Traditionally, states have targeted newborn screening funding to the screening component and core administrative tasks, such as laboratory quality assurance, as opposed to follow-up services or treatment. Although each state has a unique balance of financing, evidence suggests that most funding goes to support the testing performed in the laboratory. Many states use other public resources (eg, state general revenues or Title V MCH Block Grant funds) to offset the cost of space, staff, and materials needed for follow-up efforts, data analysis, and other program management. On average, for example, only approximately one third of funds were allocated to follow-up services in newborn screening programs in 1999.²⁶

States may view their newborn screening program responsibilities as narrow or broad. In many cases, program budgets are not set at a level sufficient to include follow-up contacts with families and diagnostic testing. Still fewer states' programs include funding for treatment such as medical foods and formulas, with supplemental funding from other programs being required to finance these activities.

State newborn screening programs provide very limited financing for treatment, generally only for formula or prescription foods needed by children with metabolic disorders such as phenylketonuria. Some states provide direct support from newborn screening program budgets to specialty providers (eg, geneticists, endocrinologists, and other specialists and subspecialists who are qualified to care for children with rare disorders). Although treatment efforts are largely outside the newborn screening program, financing for treatment is influenced strongly by other state policies related to private insurance regulation, Medicaid, SCHIP, and the Title V MCH Block Grant (specifically programs for children with special health care needs).

One major recent change in usage of funds is related to the laboratory technology known as tandem mass spectrometry (MS/MS). This laboratory technique for newborn screening was introduced into state newborn screening programs in the late 1990s and offers the potential to detect 30 to 80 additional conditions simultaneously from a single newborn screening blood spot. More than 35 state public health agencies are now using MS/MS in their newborn screening programs, and all needed to increase funding to do so; to date, however, only 13 states have used the technology to expand their screening panels greatly to screen for >30 conditions.⁷ State public health agencies have had to decide how and when to pay for this technology. States report additional costs for follow-up staff and subspecialty services to provide appropriate follow-up care for the increased number of infants who test positive for one of several dozen conditions. Most programs report that such costs are offset by the efficiency of the MS/MS technology (eg, the

method is more sensitive and specific, increasing the positive predictive value of tests).²⁶

METHODS

Two types of data are reported here. The primary data come from a survey of state public health agencies conducted between November 2004 and February 2005. These survey data are supplemented with findings from 7 case studies conducted for the Association of State and Territorial Health Officials (included here with permission).²⁵ We participated in the design of the survey and the case studies, as well as analysis of the data reported by the states.

The purpose of the case studies was to learn about states' approaches to sustaining and expanding newborn screening programs in the current fiscal and political environment. The approach for the case studies was a set of state studies in a multiple-case design.³⁸ A varied set of states was selected to illustrate strategies for sustaining newborn screening programs in times of change.²⁵ The criteria for selecting a sample of states reflect the study's aim to illustrate innovations among states with variations in screening panels, financing approaches, approaches to follow-up services, use of public and/or private laboratory services, and regional versus single-state programs. The case study states were California, Maryland, Minnesota, Mississippi, New York, Oklahoma, and Oregon. Evidence was collected through interviews with multiple agency staff members in each state and review of other program documentation (eg, administrative documents, media reports, and Web sites). The semi-structured, key informant interviews were conducted during the summer of 2004.

The survey was designed to collect more-detailed information on state newborn screening financing, on the basis of directions suggested by the case study results. For the survey, a brief, 1-page questionnaire was designed and pilot tested in 3 states. Lead staff members for state newborn screening programs were identified from the listing maintained by the National Newborn Screening and Genetics Resource Center.⁷ In January 2005, the instrument was sent through e-mail to newborn screening program staffs in all 50 states and the District of Columbia. With 2 follow-up contacts, responses were received through fax and/or e-mail from 37 states (72.5% response rate).

RESULTS

Funding Sources

On the basis of previous reports,^{7,26} we asked state program staff to indicate which of the 4 general types of funding is used to finance the newborn screening program. The responses suggested that currently some states are emphasizing maximization of third-party reimbursement from Medicaid and private insurers. Re-

spondents ($n = 37$) describing sources of newborn screening funding for FY 2003 to FY 2005 reported using fees collected from health providers, laboratories, hospitals, and parents (84%); Title V MCH Block Grant funding (57%); direct Medicaid payments, not from fees collected by hospitals (30%); and state general revenue or general public health appropriations (30%). Twenty-four percent of the respondents (8 states) reported receiving additional funds from other sources (eg, private insurance payments or Supplemental Nutrition Program for Women, Infants, and Children funding for formula foods).

States also were asked about the general trend in financing for newborn screening, which the case studies suggested was increasing. Most of the programs that participated in this survey (27 states, 73%) reported that their newborn screening funding increased between 2002 and 2005. Fewer programs reported that they experienced budget cuts (2) or no change (ie, level funding) (9). Increases in funding were primarily from fees (23) and to a lesser extent from Medicaid (11), Title V MCH Block Grant funding (7), and state general revenue funding (3). Twenty states reported no change in the level of Medicaid or Title V fiscal support, and 23 had no increase from state general revenues.

As stated, increases came largely from augmented fee levels. A typical example is Oklahoma, which raised additional revenues from higher fees and increases in Medicaid support. At the same time, the state saw the end of special project funding from Title V and no increase in state general revenue support. Other programs had different experiences. For example, Florida reported having less funding from fees but an increase in Medicaid revenues for the newborn screening program. The balance and blending of funds are often complex and change over time.

One continuing question related to newborn screening program finance regards how fees fit into state budgets (ie, whether fees go into the program's budget or into the state general fund). Among the 31 responding states that collect fees for newborn screening, 77% reported that these funds go directly into a budget line for newborn screening or genetics (ie, not into the state general fund).

California provides an example of how a dedicated funding approach can work. Hospitals pay \$1 per test form and later receive an invoice for \$59 per infant screened, to reach the \$60 fee level. The funds from fees go directly into a genetic disease testing fund, which is used only to support the newborn screening program. These funds pay for the program laboratory tests for initial diagnostic evaluation, as well as education, data collection, and quality improvement activities. No other state or federal funds are used as direct support for the program, although Medicaid pays the fee indirectly as part of hospital reimbursement for births.

In Mississippi, birthing facilities must pay a fee to the state for each newborn screened (ie, blood specimen submitted). When the number of mandated screening conditions increased from 5 to 40, the newborn screening fee charged by the state increased from \$35 to \$70. At this level, the fee covers the cost of the tests for all targeted disorders and supports the state's follow-up program. Although Title V MCH Block Grant monies were used in the past to finance follow-up activities, the fee level is now sufficient to provide full funding for the newborn screening program. Given high family poverty rates in Mississippi, a substantial proportion of births are financed through Medicaid and the federal matching rate is high, making Medicaid an important source of program dollars. The program budget now does not depend routinely on other (non-Medicaid) state or federal funding.

New York, unlike most other states, does not collect fees to finance newborn screening. State officials expect to continue financing newborn screening through direct appropriations from state general revenues, rather than fees. Current and past governors and the legislatures have generally made adequate funding available to sustain and to enhance this program.

Virtually every state has changed its newborn screening program policies in recent years. The case studies of 7 states indicated that in some instances the process of change was triggered by state officials; in other instances, outside advocates were the driving force behind change. On the basis of this case study finding, surveyed states were asked about who led in advancing newborn screening program and policy reforms (eg, changing fees or adding tests). In 22 states, public health department staff members (eg, the newborn screening program director or director of health) were identified as the active leaders. Genetic or newborn screening advisory groups provided leadership in approximately one half of the states reporting. In one quarter of the states, the governor and/or legislature (senior state officials) initiated change, and advocates (eg, parent groups, March of Dimes, disease-specific organizations, and celebrities with affected children) were among the important change agents.

Funding Uses

Generally, states are focusing on a system of services, not just a screening test. As reported by the National Newborn Screening and Genetics Resource Center, GAO, March of Dimes, and others, a variety of program activities are supported by the fees and other sources of funding for newborn screening programs. With new technology, more conditions, and increased public interest, activities such as quality assurance, data collection, and follow-up services have become more important to program functioning.

All of the responding states that collect fees ($n = 31$)

use these funds to support laboratory expenses (directly or through contracts). Most (70%) finance short-term follow-up services from screening to diagnosis, as well as program administration or management (eg, data management and materials). Fewer states use newborn screening fee dollars for other program expenses. However, nearly one half (47%) finance longer-term follow-up services, case management, or family support beyond diagnosis. Other states (43%) reported purposes including genetic or nutritional counseling and subsidies for formula foods or treatment.

Evidence from the case studies suggests that certain public health agencies are reconsidering the balance between spending on laboratory services and spending on follow-up activities. Some states are increasing and broadening public health capacity and infrastructure for follow-up services (eg, California, Maryland, Mississippi, and Oklahoma). Others are adopting follow-up approaches that give greater emphasis to linkages with pediatric primary care providers (eg, Minnesota, New York, and Oregon). Two examples, Mississippi and Minnesota, exemplify such approaches.

In Mississippi, state law now requires provision of “comprehensive” newborn screening, and the panel of tests has grown from 5 to 40 conditions. State officials recognized that the number of staff members available for follow-up services would need to grow, given this increase in testing. Before the program redesign in 2002 to 2003, each of the state’s 9 public health districts had 1 staff person to coordinate newborn screening follow-up activities conducted by county public health nurses. Today, each public health district has a team composed of a nurse, a social worker, and a clerk, who are responsible for notifying families about screening results, providing counseling, repeating tests, arranging appointments for diagnostic services, and assisting families in finding treatment referrals and resources. These teams are supported through newborn screening program funds generated through increased fee levels and a carefully negotiated contract with a private screening laboratory.

Minnesota’s case study illustrates one newer approach, which emphasizes linkages to pediatric primary care providers. State officials reported that their newborn screening program had long had inadequate follow-up services and limited emphasis on communication with and linkages to pediatric health care providers. Before 2002, the Minnesota Department of Health had only 1 part-time nurse practitioner, whose effort was dedicated to follow-up contacts for positive screens. This was minimal staff capacity, given that Minnesota screens ~70 000 Minnesota infants each year. State officials thought that families were not connected consistently to available diagnostic and treatment services, because of gaps in the follow-up approach. With the new approach, the state notifies the child’s primary care provider about

positive screening results and helps the provider to connect with specialists for consultation. The primary care provider is encouraged to develop care plans in consultation with the family and relevant specialists. This approach places a share of the responsibility for follow-up care outside the health department. In addition, greater efficiencies with new technology mean that fewer false-positive results occur and fewer infants need follow-up contacts.

DISCUSSION

Regardless of where the funding stream comes from, all available evidence indicates that states are committed to maintaining their programs and securing the necessary financing. Unlike other programs, such as the SCHIP, the Supplemental Nutrition Program for Women, Infants, and Children, and programs for children with special health care needs, state newborn screening programs do not create waiting lists in lean budget times. Instead, states take action to secure necessary funding. This is highly consistent with the goal of newborn screening, ie, to identify serious inheritable disorders within days (for metabolic and endocrine disorders) or weeks (as with newborn hearing screening) after the birth of a child. Public support helps to remove financial barriers to the screening and diagnosis necessary to carry out this goal. Notably, this commitment is focused primarily on the initial screening activity, including clearly defined costs for laboratory tests and reporting results, as opposed to family support or treatment.

One major misconception is that tax dollars are the primary source of funds for newborn screening. When state public health officials go to legislatures and executive branches to seek additional funds for newborn screening, they are often confronted with concerns about budget constraints. However, in the states that fund their programs primarily with fees, most funding does not come from state or federal general revenues. This may change if states increase Medicaid direct billing and/or reimbursement levels significantly.

Although newborn screening programs were traditionally concerned with a few inherited disorders for which early identification and prompt treatment are critical, today’s programs address a much broader scope, including a wider array of genetic conditions, from hearing disorders and infectious diseases to heart problems. New technology, particularly MS/MS,³⁹ has changed the effectiveness, efficiency, and cost-effectiveness of newborn screening significantly, by giving states the capacity to test for dozens of conditions with a single blood specimen. With these changes, states have had to adapt their financing, through adjustments to program budgets and fee levels or allocation of program funding; most have increased fees.

Four additional factors will likely affect the future of newborn screening programs. First, state officials report

that adding MS/MS capacity in the laboratory is simple, compared with the fiscal, ethical, and system-of-care decisions that must be made when a newborn screening program is expanded. Increased follow-up efforts are only one topic with fiscal implications.

Second, state officials and others have acknowledged that newborn screening programs follow in the wake of advances in genetic science, and they fully expect additional changes to occur in the near future. What is unknown is how parents and state officials will respond, in terms of what the public will accept and what it is willing to pay for, as testing becomes possible for an increasing number of conditions.

Third, introducing profit into newborn screening programs has changed the environment for the programs and for state public health agencies. States face particular challenges when a private laboratory secures funding for newborn screening but does not assume the public health roles for follow-up services and related activities. As when managed care organizations secured contracts with Medicaid agencies, these new public-private ventures will require ongoing oversight by state senior officials and, in some cases, adoption of state legal and regulatory structures to ensure that programs remain “universal.”

A fourth set of contemporary political pressures is related to financing for any health care service, including newborn screening. Across our country, political pressure is against increasing health care costs. Will legislators say that they cannot afford to expand newborn screening? In a sense, they already had this response in states where fees were raised but general fund appropriations have not increased. Other legislators respond by recommending that the executive branch and its public health agency should carry out an expansion of newborn screening without additional funding. In addition, health care providers and birthing facilities may reach a tipping point, after which they refuse to absorb newborn fee increases that come out of global payments for care at the time of birth. Health insurance plans may say that higher fees for newborn screening will drive up premium costs. Such pressure against rising health care costs would be an additional disincentive to legislative approval of newborn screening fee increases and possibly additional expansion of state newborn screening panels.

Many have observed that states need a reliable base of funding to build a high-quality, equitably distributed, national newborn screening system. Title XXVI of the Children’s Health Act of 2000 provides one opportunity to improve and to assist state newborn screening programs. The MCHB has provided some indirect support for development of data capacity and infrastructure. However, no federal funds are designated specifically as direct grants to state newborn screening programs. Other federal proposals have been introduced that

would alter the federal-state partnership for funding newborn screening. In 1999, US Senator Edward Kennedy (D-MA) introduced legislation (that was never approved) to create a federal-state partnership to share the burden of developing and maintaining newborn screening services, modeled on the existing Title V MCH program. In 2003, Senators Christopher Dodd (D-CT) and Michael DeWine (R-OH) introduced the Newborn Screening Saves Lives Act⁴⁰ for the purpose of establishing grant programs to provide for education and outreach, as well as coordinated follow-up care.

Title XXVI of the Children’s Health Act also created a Federal Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children. This committee, which was chartered in 2003 and launched in 2004, is charged with making recommendations to the Secretary of Health and Human Services regarding the most appropriate application of universal newborn screening tests, technologies, policies, and programs to reduce the morbidity and mortality rates for newborns and children with or at risk for heritable disorders. Currently, the committee is reviewing available evidence to recommend a uniform panel of conditions for which all states should screen. If a federal or even national recommendation for a uniform newborn screening panel is created, then pressure to provide dedicated federal funding would likely increase.

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