

**LEGISLATIVE SERVICES AGENCY
OFFICE OF FISCAL AND MANAGEMENT ANALYSIS**

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FISCAL IMPACT STATEMENT

LS 6479

BILL NUMBER: HB 1487

DATE PREPARED: Mar 1, 2001

BILL AMENDED: Feb 26, 2001

SUBJECT: Newborn Screening.

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**FUNDS AFFECTED: X GENERAL
X DEDICATED
X FEDERAL**

IMPACT: State & Local

Summary of Legislation: (Amended) This bill expands the Newborn Screening Program, which requires infants to be examined for certain disorders. The bill requires the State Department of Health to test for disorders that can be detected by tandem mass spectrometry if money is placed in the newborn screening fund to pay for the test. This bill also prohibits the State Department from assessing a fee for a test for disorders that can be detected by tandem mass spectrometry. The bill also allows the State Department of Health to develop criteria and procedures to determine if a laboratory should conduct tests using tandem mass spectrometry. The bill requires the State Department of Health to apply for a federal grant for newborn screening.

Effective Date: July 1, 2001.

Explanation of State Expenditures: (Revised) This bill expands the number of disorders that are required to for all infants under the provisions of the Newborn Screening Program. Two disorders, Congenital Adrenal Hyperplasia and Biotindinase Deficiency were recently added under the rule making authority of the Department of Health. The bill would include these disorders in the statute. The bill also adds disorders that are detectable by tandem mass spectrometry(MS/MS) if the technology is available and if certain payment conditions exist.

The bill requires that the tandem mass spectrometry testing is not required until there is sufficient funding available in the Newborn Screening Fund to pay for the cost of the tests performed by MS/MS. (The Newborn Screening Fund has never paid for the cost of any laboratory test in the past - this cost was assumed by public and private payers through the payment of hospital claims for services.) The bill further requires that the cost of all testing must be paid from money in the Newborn Screening Fund. It appears that any increase in the cost of newborn screening due to the implementation of tandem mass spectrometry testing would be required by this provision to have some outside source of funding - either public appropriations or grants or private grants for all infants born and tested in the state. If the laboratory test charges were to

increase by only \$5, the Newborn Screening Fund would require \$420,000 in additional funds to pay for the tests. (84,000 infants born annually x \$5 increase in the laboratory test charge.) If the fee increases to the \$25 charge for which other states provide this testing on a voluntary basis, (Tennessee, Mississippi, and Pennsylvania) the fund could require as much as \$2.1 million.

The provisions of the bill further prohibit the Department of Health from assessing the part of the fee that is attributable to tests that are performed by tandem mass spectrometry within the Newborn Screening Fee. The cost estimates given for the laboratory testing, do not include the costs associated with the ongoing medical treatment and nutritional therapy needed by affected individuals identified by the screening program nor does it include costs that may be avoided as a result of early identification of affected individuals. These provisions requiring payment to come from the Newborn Screening Fund eliminate any fiscal impact on the Medicaid Program and State employee insurance expenses.

Background: Current state law requires screening for: phenylketonuria, hypothyroidism, hemoglobinopathies, galactosemia, maple syrup urine disease, homocystinuria, and allows screening for other inborn errors of metabolism that result in mental retardation and that are designated by the State Department of Health. This bill permits the Department to expand newborn screening to include disorders that are detectable by tandem mass spectrometry. The bill also includes two additional conditions on the list of disorders required to be screened. Through its rule-making authority, the Department recently implemented screening for these two disorders, biotinidase deficiency and congenital adrenal hyperplasia. Some of the other additional disorders (permitted to be screened by the bill by tandem mass spectrometry) with early diagnosis and dietary adjustments can have significantly better outcomes; others can be detected and diagnosed but do not respond consistently to treatment.¹

The availability of new laboratory testing equipment is the impetus behind the expansion of the newborn screening program. Tandem mass spectrometry is a relatively new technology that permits rapid, sensitive, and accurate measurement of many different kinds of metabolites requiring minimal sample preparation. The computerized system has the capability to handle the large numbers of samples that are processed in universal newborn screening programs. Tandem mass spectrometry cannot currently replace all the tests used to screen for all of the currently required conditions. However, it is a more accurate and sensitive test for certain required screens (phenylketonuria, maple syrup urine disease, and homocystinuria) and permits the screening program to be expanded to include a number of disorders (approximately 30 total) that are not currently covered under the provisions of the statute. Some of these disorders are relatively common, difficult to detect before the onset of symptoms, and whose outcome is substantially improved by early treatment. The Department of Health currently has the ability to implement the use of tandem mass spectrometry. However, the bill allows the Department to report the results of the full range of screening available with this technology. The Department will still be required to define the conditions to be screened and reported through the rule-making process.

The Department of Health currently screens about 84,000 infants annually, or 99.6% of all births in the state, for eight conditions. The Newborn Screening Fee assessed by the Department is \$7 per infant. The laboratory charge for the screening test is about \$22.50. The laboratory charge is based on the cost necessary to screen all infants. Even if a repeat screen is necessary, there is no additional charge for the laboratory. This is significant since if the laboratory samples are collected too early, before sufficient metabolites are present in the infant's blood, the screens must be repeated. Repeat screens are performed on approximately 50% of the infants. Hospitals may have an additional associated phlebotomy charge for the collection of the specimen. It is not known at this time if the sensitivity of tandem mass spectrometry will allow for a reduction in the number of repeat screens that are currently required.

The Department also adds on a \$7 fee for administrative expenses associated with the Newborn Screening Program. This fee is the source of most of the revenue for the Newborn Screening Fund. This Fund pays for the registry that provides for tracking and follow-up of all newborns and individuals screened. It provides for a centralized program that helps families with affected children. The program helps with diagnosis and medical management as well as special foods for children and individuals with disorders identified in the statute. The Newborn screening fund helps to provide a statewide network of genetic evaluation and counseling services. It does not currently pay for any laboratory testing associated with the actual screening.

Allowing the expansion of the Newborn Screening Program to include conditions detectable by tandem mass spectrometry would not necessarily mean that the Department would automatically start using this technology. However, should the opportunity to convert selected existing testing protocols to the more accurate test arise, the Department could screen and report for disorders detectable under its expanded capacity. Indiana University currently is the contracted laboratory for the state newborn screening exams. IU does not currently have tandem mass spectrometry equipment capable of performing the screens for all newborns in the state. The system, if acquired, absent the provisions of this bill could be financed on the basis of an incremental increase in the laboratory screening fees charged for newborn screening. The literature indicates that tandem mass spectrometry “probably can be added to existing newborn screening systems for an incremental cost on the order of \$10 per sample”.¹

Without the provisions of this bill, the Department currently has the ability to add the technology and increase laboratory test charges as well as the newborn screening fee. The Department would not necessarily be allowed to increase the number of disorders they may screen and report without changes in the statute. This scenario would result in local hospitals covering the increased cost of the test within the current level of DRG payments until the increased cost is included in a rebased hospital DRG payment and managed care contracts are renegotiated by the Medicaid program.

The inclusion of additional disorders in the newborn screening menu could increase the number of patients identified with metabolic disorders each year. Many of these conditions result in significant medical complications or death if undetected. If treatable conditions are identified in a newborn screen, the medical resources necessary to provide for ongoing nutritional and medical needs will increase. However, there could be long term cost savings which will offset these expenses. The cost estimates above deal only with the cost of screening the general population; they do not include the additional expenses or cost savings associated with the identification of affected individuals.

Explanation of State Revenues:

Explanation of Local Expenditures:

Explanation of Local Revenues:

State Agencies Affected: All State Agencies; Department of Health, Newborn Screening and Children with Special Healthcare Needs; Family and Social Services Administration, Medicaid Division.

Local Agencies Affected:

Information Sources: Kathy Gifford, Assistant Secretary, Office of Medicaid Policy and Planning; Ed Blume, Newborn Screening Program, State Department of Health, 233-1252 and web page located at http://www.state.in.us/isdh/dataandstats/nat_intermpreg_marr/nat_1997/natalty.htm; Keith Beesley,

Department of Personnel, 232-3062; Ms. Jackie Bradford, Program Advocate, 684-3557.

¹ “Tandem Mass Spectrometry in Newborn Screening” American College of Medical Genetics / American Society of Human Genetics Test and Technology Transfer Committee Working Group, Genetics in Medicine, July/August 2000, Vol. 2, No. 4; “Newborn Screening,” Rhonda Gonzalez, NCSL Legisbrief, National Conference of State Legislatures, June/July 2000, Vol. 8, No. 27.