

Expanded Newborn Screening in Kansas

Report of the KDHE Newborn Screening Advisory Group

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Issue Definition

The Division of Health proposes instituting Expanded Newborn Screening (XNBS) in the state's mandatory newborn metabolic screening program. The current newborn metabolic screening program provides screening for all newborns; follow-up for newborns with abnormal results, until confirmatory diagnosis is made and specialty care is identified, if necessary; and necessary treatment products and certain medical care expenses for those with certain conditions who qualify financially. An expanded program will allow early diagnosis and treatment for a wide array of additional inborn errors of metabolism. Left undetected, these conditions can lead to chronic illness, mental retardation, and death.

Newborn Screening: Current Status

Kansas currently offers free screening for all newborns in Kansas for four sets of clinical conditions. These conditions are phenylketonuria, congenital hypothyroidism, galactosemia, and a set of hemoglobinopathies including both sickle cell disease and thalassemia. Testing is done by the Kansas State Health and Environmental Laboratory after acquisition of a blood spot on special paper has been obtained at the hospital. Tests are run seven days a week, and highly abnormal or 'presumptive' results are immediately called by KDHE to the referring physician. KDHE staff also facilitates follow-up for the affected individuals, and pays for treatment where such care is not covered by other third-party payors. The program has been in existence since 1965, when the mandate to screen infants for PKU was established; three additional mandates in 1977, 1984, and 1990 brought the range of tests to the current slate. In calendar year 2006, 41,601 newborns were screened. Over 5,000 repeat screenings were necessary due to confirmatory testing and sampling issues.

The KDHE NBS program refers newborns with abnormal results to medical specialty clinics for diagnosis. The Children with Special Health Care Needs Program (CSHCN) has contracts with one medical specialty clinic at KC and one at Wichita. After diagnosis, the family may submit an application to the CSHCN program. For those who apply and are eligible, CSHCN case management nurses help the family access ongoing medical, treatment and financial resources. In SFY 06, CSHCN enrollment was 117 individuals with PKU, Congenital Hypothyroidism, and Hemoglobinopathies. Enrollment was: 67 PKU (ages 0-55) of which 60 were receiving formula, Congenital Hypothyroidism 45 (ages 0-22), Hemoglobinopathies 5. Some of these were linked to medical specialty care, some helped to access public or private insurance coverage, and others got financial assistance primarily for medically necessary treatment products such as low-protein formula for PKU. Since the statute was changed in the 2006 session to eliminate free products and to require use of a sliding fee scale, Medicaid and some private insurers have started covering medically necessary treatment.

The program has been supported by state general fund revenue. Baseline cost analysis revealed that current newborn metabolic screening program costs in FY06 were \$1,088,063. Breakdown of current funding is as follows:

Laboratory Costs, SFY 06

	Salaries	Operating
SFY 06	\$329,948	\$ 245, 000

Salaries and Benefits for 6 positions: 1 Sr. Lab Scientist, 2 Microbiologists, 2 Laboratory Technologists, and 1 Chemist.

Operating cost: test kits, reagents, and training, plus laboratory equipment costs

Follow-up Costs, SFY 06

	Salaries	Operating
SFY 06	\$86,918	\$ 6,964

Salaries and Benefits for 2 positions: 1 Public Health Nurse, 1 Administrative Assistant

Operating Costs: communications (phone/postage), printing, supplies, travel

Treatment Costs (through CSHCN) SFY 06

	Diagnosis/FU	Treatment
SFY 06	\$149,630	\$269,096

Diagnosis and Followup through Developmental Disability Center at KUMC, Department of Pediatrics at KUMC, UKSM-Wichita, Via Christi in Wichita, and other Medical Specialists. Assistance with medically-prescribed treatment costs not covered by public/private insurance.

It is critical to note that as plans for XNBS programs are being established in Kansas, they do not in any way imply or infer any retraction of the state's current commitments. Adoption of an XNBS program adds an additional level of service over and above the current services. Screening for the conditions noted above will continue within an XNBS program, as will follow-up services and funding of needed treatment of affected children. The current fiscal commitment is maintained under the new proposal as well.

Expanded Newborn Screening

In recent years, scientific advances and technologic improvements have greatly expanded the number of inborn metabolic conditions for which newborns can be screened at birth. National experts and the March of Dimes recommend that all newborns now be screened at birth for 28 rare, but treatable, inborn metabolic conditions. The recommended list of conditions is limited to those for which both a reliable test and effective treatment are available. Identification of these conditions within the first days or weeks of life prevents the onset of the permanent disabilities, and sometimes death, which often manifest if these metabolic conditions remain untreated. The widespread availability and reasonable cost of Tandem Mass Spectrometry (MS/MS) has led to the implementation of XNBS in the majority of states' mandatory newborn screening programs.

The conditions included in the recommended panel are listed below. This list of conditions is in conformance with the American College of Medical Genetics (ACMG) Uniform Screening Panel.

1. Phenylketonuria
2. Maple Syrup Urine Disease
3. Homocystinuria
4. Citrullinemia

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| 5. Argininosuccinic acidemia | 16. Medium-chain acyl-CoA dehydrogenase deficiency |
| 6. Tyrosinemia type I | 17. Very long-chain acyl-CoA dehydrogenase deficiency |
| 7. Isovaleric acidemia | 18. Long-chain 3-OH acyl-CoA dehydrogenase deficiency |
| 8. Gultaric academia type I | 19. Trifunctional protein deficiency |
| 9. Hydroxymethylglutaric aciduria/HMG-CoS lyase | 20. Carnitine uptake defect |
| 10. Multiple carboxylase deficiency | 21. Sickle cell anemia |
| 11. Methylmalonic academia due to mutase deficiency | 22. Hb S/Beta-Thalassemia |
| 12. Methylmalonic academia cb1A and cb1B forms | 23. Hb S/C disease |
| 13. 3-Methyl crotonyl-CoA carboxylase deficiency | 24. Congenital hypothyroidism |
| 14. Propionic academia | 25. Biotinidase deficiency |
| 15. Beta-Ketothiolase deficiency | 26. Congenital adrenal hyperplasia |
| | 27. Classical galactosemia |
| | 28. Cystic fibrosis |

Conditions 1-20 are considered inborn errors of metabolism. Conditions 22-23 are subcategories of Condition 21; all three are referred to as "hemoglobinopathies" and are commonly counted as one test. Conditions 24-28 are grouped together as "others." MS/MS is used to screen for conditions 1-20. Various laboratory methods are employed for conditions 21-28. Of the conditions currently screened for in Kansas (see above), testing for all but Phenylketonuria (PKU) will continue according to current protocol. PKU can be reliably identified using MS/MS. Using MS/MS for PKU screening is the preferred method; therefore, the PKU screening protocol will be modified.

Implementing XNBS in Kansas: A Proposal

At the behest of the 2006 Kansas Legislature, the Division of Health convened an advisory group of concerned stakeholders to draft a plan for implementing XNBS in the state. Various parties were represented, including Medicaid, the Kansas Hospital Association, insurance trade groups, the Kansas Chapter of the American Academy of Pediatrics, and appropriate KDHE staff. Over the course of three meetings, the group became educated about XNBS implementation in neighboring states; the laboratory processes, follow-up protocol, and treatment requirements associated with the conditions on the recommended screening panel; funding schemes employed in states currently using the recommended panel; and, the proposed funding requirements for implementing an XNBS program in Kansas.

The proposal is the result of this collaborative process and has been subject to the concurrence of these interested groups. Baseline cost analysis revealed that current newborn metabolic screening program costs in FY06 were \$1,088,063. Breakdown of new costs was estimated as follows:

New Laboratory Costs: \$882,405

Leasing Arrangement for Tandem Mass Spectrometry equipment, test kits, reagents, and training: \$450,000

Other laboratory equipment costs for new non-MS/MS screening: \$223,598

Salaries and Benefits for 3 additional laboratory staff: \$208,807

New Follow-Up Costs: \$116,537

Salaries and Benefits for 2 additional follow-up staff (Nurse III, Administrative Specialist): \$95,276

Operating Costs/Supplies: \$21,261

New Treatment Costs: \$191,000

Necessary treatment products (metabolic formula, medications, certain treatment services): \$160,000

Medically Necessary Foods: \$6,000

Contracts for Consultants: \$25,000

Total Cost: \$1,189,942

As noted above, implementing an XNBS program utilizing MS/MS screening technology will require \$1,189,942 in new total annual funding. A fee of approximately \$30 per live birth would be assessed to fund the new laboratory and follow-up costs, generating \$1,170,000 per year. An additional \$191,000 in State General Fund (SGF) revenue will be required to cover new treatment costs.

Two important cost issues were reviewed in constructing the final proposal. One is the use of the State Laboratory versus outside contractors to conduct the screening process. Based upon the reviewed experiences of other states, the working group concurred that this testing be performed by the state laboratory. While private companies have historically provided low costs bids for these services, upon expiration of the initial contract period negotiations normally result in renewal at a significantly higher rate. In addition, once the capability to provide the service has been discontinued by the state laboratory in favor of outsourcing, the ability to re-establish the service is unlikely without a significant expenditure of funds and time required to recruit and train staff. This leaves the state in a position of negotiating with potential vendors without a viable option but to accept the most favorable proposal. Recent history in the State of Nebraska suggests this may not be a desirable option. The State of Texas recently compared the costs for outsourcing these services vs. costs for having the tests performed by the state laboratory. The result was continuation of the testing program in the state laboratory. Noting that 33 states currently perform newborn screening tests "in-house" provides further evidence that this approach is preferable.

A second concern related to the "per-live-birth" fee to be charged for newborn screening. This fee was calculated to be \$30.00 per live birth in Kansas. Our fee was constructed to cover reasonable costs expected with the XNBS program only, and not to supplement other funds or programs. In the other 50 states and the District of Columbia, the mean fee for newborn screening is \$45.77. When the five states and DC, which charge no fee for screening, are excluded from the calculation the Kansas proposed fee is far below the

mean of \$51.88. The proposed fee would rank 38th in the nation, including those states performing screening for free. The workgroup felt strongly about being good stewards of the public dollar, and the establishment of a "bare bones" fee reflects this orientation.

The following outline summarizes the proposal:

- Fee: \$30/live birth
 - Covers new laboratory costs, initial and repeat screenings, (confirmatory testing), and new follow-up costs.
 - No treatment costs included.
- Billing:
 - Medicaid would be billed directly by KDHE
 - Estimated cost to Medicaid: $(40\%)(39,000)(\$30) = \$468,000$
 - KHPA Staff have confirmed the ability of MCD to fund these costs
 - Hospitals would be billed by KDHE for non-Medicaid births
 - Hospitals and 3rd party payors will negotiate as per tradition
- Timeframe:
 - Window for implementing expanded screening is Jan-July/2008
 - Dependent on state budget/legislative process, hospital/insurance negotiations
- Start-Up Funding:
 - Will be necessary for the required program staff to be hired, trained, and ready at the time of implementation
 - KDHE program staff will investigate possible grants for start-up funds
 - KDHE will include a \$191,000 enhancement for the FY 08 budget
- Educational Materials:
 - State will continue provision of education materials per statutory requirement
 - Costs for materials are already included in BCYF proposed costs

Legislative Implications

Legislative approval is needed to make the statutory changes required to expand Kansas' Newborn Metabolic Screening program. K.S.A. 65-180(b) states that newborn screening "services shall be performed without charge." This language must be removed and replaced with a statement granting the Secretary of Health and Environment the authority to establish a fee, per live birth, for the newborn metabolic screening program. In order to allow enough "lead time" for KDHE laboratory staff to gain competence in MS/MS procedures and to permit hospitals to include the anticipated costs in annual negotiations with third party payors, the effective date of the legislation will be set as July 1, 2008. Legislation will include a "cap" on the fee to be assessed at \$30.00 per live birth.

Additional statutory language establishing an official Newborn Screening Advisory Committee, which will advise the Secretary of Health and Environment regarding issues related to genetics and heritable and congenital disorders, is necessary. Committee membership should include representatives from professional groups, affected trade groups, affected agencies, legislators, consumers, and interested members of the public.

The Committee's charge includes evaluating the operations of the program, determining the optimal staged approach to allow additional tests to be added to the screening profile, and assessing current fee structures and making recommendations for change.

Impact on Other Agencies

The advisory group recommends that KDHE bill the Kansas Medicaid program directly for the per-live-birth fee included in the needed statutory changes. Therefore, KDHE and the Kansas Health Policy Authority will need to arrange an appropriate mechanism for billing and payment. The Kansas Medicaid program is aware of these changes and will assist KDHE in organizing an appropriate protocol.

Fiscal Impact

Treatment for children diagnosed with conditions new to the screening panel is estimated to cost \$191,000 in SGF annually. This cost is in addition to the nearly \$450,000 expended from SGF for treatment of the six currently tested conditions. The conditions to be added to the screening panel are very rare. By adding 23 additional conditions to be tested, it is estimated that the number of children identified annually may potentially double from the number currently being identified on the current testing panel.