

**GOVERNOR'S Child Health  
Advisory COMMITTEE**

**COPY**

November 20, 2006

Secretary Roderick Bremby  
Kansas Department of Health and Environment  
Curtis State Office Building  
1000 SW Jackson  
Topeka, KS 66612

Dear Secretary Bremby:

On behalf of the Governor's Child Health Advisory Committee, it is my pleasure to submit the Committee's recommendations related to expanded newborn screening. These are presented in partial fulfillment of the Committee's mandate to "advise the Governor and the Secretary of Kansas Department of Health and Environment on various issues involving children, including: obesity, newborn screening, immunizations and education."

The Committee considered the attached draft along with information from the National Newborn Screening and Genetics Resource Center. The draft proposal was adopted with the noted exceptions and comments.

We urge the expeditious implementation of expanded newborn screening, which is in the best interests of Kansas children and will bring our State in line with the medical standard of care. Please let us know if you need additional information.

Sincerely,



Dennis Cooley, MD  
Chair, Governor's Child Health Advisory Committee

C: Jennifer Crow, Office of the Governor  
Howard Rodenberg, MD, Director of Health

Enclosure

**GOVERNOR'S Child Health  
Advisory Committee**

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**Expanded Newborn Screening Recommendations**

The purpose of the Child Health Advisory Committee, appointed January, 2006, is to “advise the Governor and the Secretary of Kansas Department of Health and Environment (KDHE) on various issues involving children, including: obesity, newborn screening, immunizations and education.”

The attached draft was adopted by the Governor’s Child Health Advisory Committee on November 2, 2006, with the noted exceptions and comments:

**Exceptions to Draft Proposal:**

1. Implement a staged approach to cover all 49 (or more) identified newborn screening conditions. Start with an expanded newborn screening program for the core group of 29 conditions the first year and move towards coverage of all 49-plus conditions the following year. The additional 20 or more tests will cost approximately \$1 more per newborn for laboratory costs. While an estimate of the laboratory costs are known for the additional 20-plus conditions (for a total of 49 or more), treatment and follow-up costs for these additional tests are not yet known.
2. On page 1, line 24, add a note stating, “This list of conditions is in conformance with the American College of Medical Genetics (ACMG) Uniform Screening Panel.”
3. Although the Committee understands the repeat screenings are and will continue to be part of the process, text should be added in the proposal to specifically indicate repeat screening is included.
4. On page 4, to clarify the text, replace lines 159-165 with the following paragraph:

Annually, treatment for children diagnosed with conditions new to the screening panel is estimated to cost \$191,000 SGF. This will be in addition to the nearly \$450,000 expended from the 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 will double from the number currently being identified on the current testing panel.

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**Abbreviations and Typographical Edits to Draft Proposal:**

1. On page 1, line 21, change "TMS" abbreviation to "MS/MS" to be consistent with national literature. Define "MS/MS" on first use as "tandem mass spectrometry {MS/MS}".
2. On page 3, line 110, change "\$1,170.000" to "\$1,170,000".
3. On page 3, line 110, change text to define "SGF": "State General Fund (SGF)".

**Additional Comments:**

1. One committee member suggested the testing fee be raised from \$30 to \$35 to raise the additional \$191,000 needed. KDHE explained that this was considered by the financing group, but the \$30 fee was recommended for new laboratory and follow-up costs. State general funds of \$191,000 were recommended for treatment costs not covered by public or private insurance.
2. A concern was raised by one committee member that a mechanism needs to be developed for the administrative tracking and billing of newborn screening at non-birth hospitals to which newborns have been transferred.
3. One committee member was concerned that start-up costs may be underestimated. KDHE explained that there will be close scrutiny of costs throughout the next year or two and estimates will be revised as needed. The program will continue to closely monitor costs over time.

**DRAFT**

**Proposal:**

**Expanded Newborn Screening in Kansas**

Report of the KDEH Newborn Screening Advisory Group  
Prepared by Aidan Loveland Koster  
August 16, 2006

# Expanded Newborn Screening in Kansas

## 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.

## Background

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 TMS 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. Conditions in **bold** represent Kansas' current screening mandate:

- |   |    |   |
|---|----|---|
| 1. <b>Phenylketonuria</b>                           | 45 | 15. Beta-Ketothiolase deficiency                      |
| 2. Maple Syrup Urine Disease                        | 46 | 16. Medium-chain acyl-CoA dehydrogenase deficiency    |
| 3. Homocystinuria                                   | 47 | 17. Very long-chain acyl-CoA dehydrogenase deficiency |
| 4. Citrullinemia                                    | 48 | 18. Long-chain 3-OH acyl-CoA dehydrogenase deficiency |
| 5. Argininosuccinic acidemia                        | 49 | 19. Trifunctional protein deficiency                  |
| 6. Tyrosinemia type I                               | 50 | 20. Carnitine uptake defect                           |
| 7. Isovaleric acidemia                              | 51 | <b>21. Sickle cell anemia</b>                         |
| 8. Gultaric academia type I                         | 52 | <b>22. Hb S/Beta-Thalassemia</b>                      |
| 9. Hydroxymethylglutaric aciduria/HMG-CoA lyase     | 54 | <b>23. Hb S/C disease</b>                             |
| 10. Multiple carboxylase deficiency                 | 55 | <b>24. Congenital hypothyroidism</b>                  |
| 11. Methylmalonic academia due to mutase deficiency | 57 | 25. Biotinidase deficiency                            |
| 12. Methylmalonic academia cblA and cblB forms      | 59 | 26. Congenital adrenal hyperplasia                    |
| 13. 3-Methyl crotonyl-CoA carboxylase deficiency    | 60 | <b>27. Classical galactosemia</b>                     |
| 14. Propionic academia                              | 61 | 28. Cystic fibrosis                                   |

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

72  
73 At the behest of the 2006 Kansas Legislature, the Division of Health convened an  
74 advisory group of concerned stakeholders to draft a plan for implementing XNBS in the  
75 state. Various parties were represented, including Medicaid, the Kansas Hospital  
76 Association, insurance trade groups, the Kansas Chapter of the American Academy of  
77 Pediatrics, and appropriate KDHE staff. Over the course of three meetings, the group  
78 became educated about XNBS implementation in neighboring states; the laboratory  
79 processes, follow-up protocol, and treatment requirements associated with the conditions  
80 on the recommended screening panel; funding schemes employed in states currently  
81 using the recommended panel; and, the proposed funding requirements for implementing  
82 an XNBS program in Kansas.

83  
84 The proposal is the result of this collaborative process and has been subject to the  
85 concurrence of these interested groups. Baseline cost analysis revealed that current  
86 newborn metabolic screening program costs in FY06 were \$952,634.49. Breakdown of  
87 new costs was estimated as follows:

88  
89 **New Laboratory Costs: \$996,366.03**

- 90 >Leasing Arrangement for Tandem Mass Spectrometry equipment, test kits,  
91 reagents, and training: \$450,000
- 92 >Laboratory equipment/supply costs for new non-TMS screening: \$335,000
- 93 >Other laboratory overhead and supplies: \$75,000
- 94 >Salaries and Benefits for 2 Senior Laboratory Scientists: \$136,366

95 **New Follow-Up Costs: \$107,776**

- 96 >Salaries and Benefits for 2 additional follow-up staff (Nurse III, Administrative  
97 Specialist): \$95,276
- 98 >Overhead/Supplies: \$12,500

99 **New Treatment Costs: \$191,000**

- 100 >Necessary treatment products (metabolic formula, medications, certain treatment  
101 services): \$160,000
- 102 >Medically Necessary Foods: \$6,000
- 103 >Contracts for Consultants: \$25,000

104  
105 **Total Cost: \$1,295,142.03**

106  
107 As noted above, implementing an XNBS program utilizing Tandem Mass Spectrometry  
108 (TMS) screening technology will require \$1,295,142.03 in new total annual funding. A  
109 fee of approximately \$30 per live birth would be assessed to fund the new laboratory and

110 follow-up costs, generating \$1,170,000 per year. An additional \$191,000 SGF is required  
111 to cover new treatment costs.

112

113 The following outline summarizes the proposal:

114

115 • Fee: \$30/LB

116 ○ Covers new laboratory costs and new follow-up costs.

117 ○ No treatment costs included.

118 • Billing:

119 ○ Medicaid would be billed directly by KDHE

120 ■ Estimated cost to Medicaid:  $40\% * 39,000 * \$50 = \$468,000$

121 ■ KHPA Staff have confirmed the ability of MCD to fund these costs

122 ○ Hospitals would be billed by KDHE for non-Medicaid births

123 ○ Hospitals and 3<sup>rd</sup> party payors will negotiate as per tradition

124 • Timeframe:

125 ○ Window for implementing expanded screening is Jan-July/2008

126 ■ Dependent on state budget/legislative process, hospital/insurance  
127 negotiations

128 • Start-Up Funding:

129 ○ Will be necessary for the required program staff to be hired, trained, and  
130 ready at the time of implementation

131 ○ KDHE program staff will investigate possible grants for start-up funds

132 ○ KDHE will include a \$191,000 enhancement for the FY 08 budget

133 • Educational Materials:

134 ○ State will continue provision of education materials per statutory  
135 requirement

136 ○ Costs for materials are already included in BCYF proposed costs

137

### 138 Legislative Implications

139 Legislative approval is needed to make the statutory changes required to expand Kansas'  
140 Newborn Metabolic Screening program. K.S.A. 65-180(b) states that newborn screening  
141 "services shall be performed without charge." This language must be removed and  
142 replaced with a statement granting the Secretary of Health and Environment the authority  
143 to establish a fee, per live birth, for the newborn metabolic screening program.

144

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

150

### 151 Impact on Other Agencies

152 The advisory group recommends that KDHE bill the Kansas Medicaid program directly  
153 for the per-live-birth fee included in the needed statutory changes. Therefore, KDHE and  
154 the Kansas Health Policy Authority will need to arrange an appropriate mechanism for

155 billing and payment. The Kansas Medicaid program is aware of these changes and will  
156 assist KDHE in organizing an appropriate protocol.

157

158 Fiscal Impact

159 An estimated \$191,000 SGF annually is required to fund treatment activities for children  
160 diagnosed with conditions new to the screening panel, and will be in addition to the  
161 nearly \$450,000 expended from SGF for treatment of the six currently tested conditions.

162 The conditions to be added to the screening panel are very rare. Though 23 conditions  
163 will be added to the panel, the number of children identified annually with these new  
164 conditions will likely be less than the number identified in a given year with conditions  
165 on the current testing panel.