Fiscal Note

Fiscal Services Division

HF 375 – Newborn Metabolic Screening (LSB1263YH)
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Fiscal Note Version – New

Description

House File 375 requires the Department of Public Health (DPH) to expand the newborn metabolic screening panel to include Mucopolysaccharidosis type 1 (MSP-1), Glycogen storage disease type II (Pompe), and spinal muscular atrophy (SMA) by January 1, 2020.

Background

The purpose of the Iowa Newborn Screening Program (INSP) is to screen for metabolic and congenital disorders in the newborn period to enable the early identification of, and intervention for, at-risk individuals in order to prevent or lessen adverse health consequences such as intellectual and physical disability, serious illness, and death, with the overall objective of improving the quality of life for Iowans. Newborn screening is required to screen for certain inherited conditions. Babies born in Iowa have small spots of blood collected 24 to 48 hours from birth to be tested. The INSP is a fee-operated program.

The Iowa Congenital and Inherited Disorders Advisory Committee (CIDAC) includes representatives from professional groups and agencies as well as legislators, consumers, and individuals with an interest in promoting genetic services. The Committee provides advice and recommendations for the design and implementation of genetic disorder programs within the DPH.

Assumptions

- There are approximately 39,000 babies born in Iowa each year.
- Medicaid pays for approximately 40.0% of births in Iowa.
- The State share of the Federal Medical Assistance Percentages (FMAP) rate is 39.12%.
- Screening for SMA requires tandem mass spectrometry (MS/MS) equipment and can be run with the test for severe combined immunodeficiency (SCID) currently being done on equipment at the lab.
- The INSP charges a fee for screenings to cover annual costs and will increase the fee based on the estimated budget.
- Lab technicians will be hired no earlier than halfway through FY 2020.
- Screening will begin in January 2020.
- Screening for Pompe and MSP-1 will require additional equipment and staff to handle the expanded screening demands and can be conducted on MS/MS or microfluidics equipment. The alternative assumptions associated with MS/MS and microfluidics equipment are as follows:

MS/MS

- The INSP would require three additional MS/MS devices to handle the increased capacity.
- Additional technical lab staff required for MS/MS is estimated at 2.0 full-time equivalent (FTE) positions.
- The consumables portion of the cost per test on MS/MS is estimated at $1.46.

Microfluidics

- The INSP could receive three microfluidics devices free of charge.
- Additional technical lab staff required for microfluidics to meet 24/7/365 capacity is estimated at 3.0 FTE positions.
- The consumables portion of the cost per test on microfluidics is estimated at $3.47.

Fiscal Impact

The estimated cost of adding SMA to the INSP is presented in **Table 1**.

Table 1 – Spinal Muscular Atrophy

	FY 2020	FY 2021 and Subsequent Years
Startup Costs		
Test Development and Validation	$ 315,000	
Education	14,000	
Information Technology	136,000	N/A
Quality Assurance	32,000	
Subtotal Startup Costs	$ 497,000	
Daily Testing Operational Costs		
Staffing (0.5 FTE Position)	$ 18,500	$ 37,000
Reagents/Consumables	55,000	110,000
Subtotal Daily Testing	$ 73,500	$ 147,000
Total	$ 570,500	$ 147,000
Cumulative Five-Year Cost		**$ 1,158,500**

N/A = Not Applicable

The cost estimates associated with the two alternative methodologies for testing MSP-1 and Pompe on MS/MS or microfluidics are presented in **Table 2**.

Table 2 – Pompe and MSP-1 Screening Options

	Tandem Mass Spectrometry		Microfluidics	
	FY 2020	**FY 2021**	**FY 2020**	**FY 2021**
Startup Costs				
Instrumentation (Three MS/MS)	$ 750,000		$ 0 *	
Facility Renovation	200,000		100,000	
Test Development and Validation	200,000	N/A	200,000	N/A
Education	28,000		28,000	
Information Technology	273,000		273,000	
Quality Assurance	65,000		65,000	
Subtotal Startup Costs	$ 1,516,000		$ 666,000	
Daily Testing Operational Costs				
Staffing ($66.5K Per Lab Tech)	$ 66,500	$ 133,000	$ 100,000	$ 200,000
Reagents/Consumables	28,500	57,000	67,500	135,000
Subtotal Daily Testing	$ 95,000	$ 190,000	$ 167,500	$ 335,000
Other Annual Costs				
Maintenance	N/A	$ 60,000	N/A	$ 0
Depreciation		75,000		0
Total	$ 1,611,000	$ 325,000	$ 833,500	$ 335,000
Cumulative Five-Year Cost		**$ 2,911,000**		**$ 2,173,500**

N/A = Not Applicable

*Note: This assumes the DPH receives three microfluidics devices free of charge.

The revised fee for the INSP will increase General Fund expenditures for the Medicaid program by an estimated $75,000 annually. Increased expenditures for the State of Iowa Group Health Insurance Plan will increase by an estimated $10,000. The total estimated impacts of HF 375 are presented in **Table 3** with the INSP impacts subtotaled between the two screening equipment options.

Table 3 – Estimated Total Expenditure Increases

	FY 2020	FY 2021 and Subsequent Years
General Fund		
Medicaid	$ 37,500	$ 75,000
Iowa Group Health Insurance	5,000	10,000
Total General Fund	$ 42,500	$ 85,000
Iowa Newborn Screening Program		
SMA	$ 570,500	$ 147,000
Pompe and MSP-1 on MS/MS	1,611,000	325,000
Pompe and MSP-1 on Microfulidics	833,500	335,000
Subtotal SMA and MS/MS Option	$ 2,181,500	$ 472,000
Subtotal SMA and Microfluidics Option	$ 1,404,000	$ 482,000

Sources

Department of Public Health
Department of Human Services
Sanofi US
Wellmark
LSA analysis and calculations

/s/ Holly M. Lyons

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The fiscal note for this Bill was prepared pursuant to Joint Rule 17 and the Iowa Code. Data used in developing this fiscal note is available from the Fiscal Services Division of the Legislative Services Agency upon request.