



# BUDGET DEEP-DIVE INTO NEWBORN SCREENING PROGRAMS

SOCIAL SERVICES APPROPRIATIONS SUBCOMMITTEE  
STAFF: RUSSELL FRANSDEN

ISSUE BRIEF

## SUMMARY

In recent efforts the State of Utah performed 150,997 screenings to test approximately 52,000 newborns for 42 diseases/disorders. The testing resulted in 1,012 positive, confirmed test results which required follow up. The number of screenings unintentionally missed for newborns was 3,828. The Legislature may want to consider taking additional action steps.

## LEGISLATIVE ACTION

1. The fiscal analyst recommends that the Department of Health do the following prior to submitting its proposed fee for the newborn screening kits for FY 2019:
  - a. Determine if the newborn screening programs are covering their share of indirect costs.
  - b. Establish a consistent cost allocation formula for laboratory costs (and any other identified indirect costs) shared by the newborn screening programs.
  - c. Propose a fee that covers the program's share of both direct and indirect costs.
  - d. **Agency Response:** "UDOH agrees with this recommendation. We regularly assess the kit fee amount to ensure it is complete and accurate. Regarding 1.a., UDOH indirect costs will be applied to state funds starting in SFY18. For recommendation 1.b., the heelstick program is the only one that uses the State Laboratory to process samples collected, therefore there are no "shared" laboratory costs among the programs." Regarding 1.c, we will propose a kit fee that covers all anticipated costs during the normal budget process and after considering all expenses."
2. Provide additional authorization for the role of the Newborn Screening Advisory Committee by doing one of the following:
  - a. The Social Services Appropriations Subcommittee intends that the Department of Health create rules authorizing and organizing the membership, governance, powers, and functions of the Newborn Screening Advisory Committee by June 30, 2018 and report to the Office of the Legislative Fiscal Analyst by August 15, 2018 on the implementation status.
  - b. Open a bill file to authorize and organize the membership, governance, powers, and functions of the Newborn Screening Advisory Committee.
  - c. **Agency Response:** "UDOH is neutral to this recommendation. We feel the Newborn Screening Program Advisory Committee has currently been operating well, but if directed, UDOH is willing to consider formalization of the Newborn Screening Committee in rule. We would like to ensure the rule allows for flexibility in membership so UDOH can quickly adjust needed subject matter expertise in response to the screening types the Committee is considering without the need to change the rule on a frequent basis or require legislative action to change a statute."

**DISCUSSION AND ANALYSIS**

The discussion regarding newborn screening programs has the following sections below. Each section has a brief discussion of the question.

1. What are we attempting to accomplish?
2. How do we know if we are successful?
3. How are we organized?
4. What are we buying and how are we paying for it?
5. What non-governmental sources are involved?
6. What are other states doing for newborn screening?

***What are we Attempting to Accomplish?***

Utah law in [UCA 26-10-6](#) directs the Department of Health to do the following regarding newborn screening:

- “(1) Except in the case where parents object on the grounds that they are members of a specified, well-recognized religious organization whose teachings are contrary to the tests required by this section, a newborn infant shall be tested for:”
  - “(a) phenylketonuria (PKU);”
  - “(b) other heritable disorders which may result in an intellectual or physical disability or death and for which:
    - (i) a preventive measure or treatment is available; and
    - (ii) there exists a reliable laboratory diagnostic test method;”
  - “(c) ...hearing loss...”
  - “(d) critical congenital heart defects using pulse oximetry.”
- “(2) In accordance with Section [26-1-6](#), the department may charge fees for
  - (a) materials supplied...
  - (b) tests required...
  - (c) laboratory analyses...
  - (d) the administrative cost of follow-up contacts with the parents or guardians of tested infants.”
- “(4) Results of tests for hearing loss described in Subsection [\(1\)](#) shall be reported.”

The Department of Health decides which heritable disorders are included for newborn testing. The federal government’s [Department of Health and Human Services Advisory Committee on Heritable Disorders in Newborns and Children](#) provides recommendations for disorders to be tested. As of May 2017, the federal committee recommends screening for 34 core disorders (disorders that should be included in every Newborn Screening Program) and 26 secondary disorders (disorders that can be detected in the differential diagnosis of a core disorder) for a total of 60. Utah currently screens for 42 disorders, 33 core disorders and nine secondary disorders. Utah’s Newborn Screening Advisory Committee, which is made up of clinical experts, health care providers, and community representatives, advises the Department of Health on which disorders to add to the newborn screening. The Utah committee was created in 1990 and the Department of Health has accepted 100% of the committee’s recommendations regarding disorders to be included on the heelstick disorder screening panel.

The Newborn Screening Advisory Committee plays an important role in helping to decide which disorders will be included in the newborn heelstick testing. The committee is not authorized in rule or statute. Because of this the fiscal analyst recommends one of two possible actions steps.

- 1) *The Social Services Appropriations Subcommittee intends that the Department of Health create rules authorizing and organizing the membership, governance, powers, and functions of the Newborn Screening Advisory Committee by June 30, 2018 and report to the Office of the Legislative Fiscal Analyst by August 15, 2018 on the implementation status.*
- 2) *Open a bill file to authorize and organize the membership, governance, powers, and functions of the Newborn Screening Advisory Committee.*

Alternatively, the Legislature could choose to put the disorders to be tested in state statute, as is done in some other states. This would require a law change for any new disorders to be included in future testing.

The Newborn Screening Advisory Committee is currently considering four disorders for possible inclusion into the newborn heelstick screening. The Department of Health believes that the committee may have a recommendation by October 2017. The four disorders and their likely annual frequency of positive results as well as tentative start dates if approved are listed below:

- 1) Spinal Muscular Atrophy (SMA) – approximately 5 infants in Utah might be diagnosed beginning July 2018
- 2) Mucopolysaccharidosis Type I (MPSI) – approximately 1 infants in Utah might be diagnosed beginning July 2019
- 3) X-Linked Adrenoleukodystrophy – approximately 3 infants in Utah might be diagnosed beginning July 2019
- 4) Glycogen Storage Disease Type II (Pompe) – approximately 2 infants in Utah might be diagnosed beginning July 2019

Newborn Screening	Total Screenings	Problems Identified	% With Problems	False Positives	Missed Screen	Missed Problems (est.)	Parents Declined	Missed Problems (est.)
Heelstick and Follow-up (2016)	51,348	678	1%	35	140	1.8	44	0.6
Critical Congenital Heart Disease (2016)	48,043	92	0%	unknown	3,490	6.7	N/A	N/A
Hearing (2014)	51,606	242	0%	262	198	0.9	134	0.6
<b>Total</b>	<b>150,997</b>	<b>1,012</b>	<b>1%</b>	<b>297</b>	<b>3,828</b>	<b>9.5</b>	<b>178</b>	<b>1.2</b>

**How do we Know if we are Successful?**

The discussion of how we know if we are successful has the following sections:

- 1) Overview of All Newborn Screening Efforts
- 2) Heelstick Program – this is the prick of a baby’s heel that is used to gather blood samples on a paper card which is sent to laboratories to test for 40 disorders.
- 3) Hearing Screening – machines check a newborn’s ears’ and/or brain’s response to soft sounds.
- 4) Critical Congenital Heart Defect Screening – pulse oximetry checks the amount of oxygen in the blood via a machine that passes light through the skin.

**Overview of All Newborn Screening Efforts**

What have been the recent results of newborn screening?

1. The Department of Health has completed over 151,000 screenings.
2. Screenings resulted in the identification of 1,012 disorders in newborns.
3. A total of 3,828 or 3% additional screenings of eligible newborns could have taken place but were not. Using the positive test results for other newborns, there may have been approximately nine disorders not identified among the newborns not screened.
4. A total of 178 or 0.1% of screenings of newborns did not take place due to parental refusal. The only statutorily-allowed reason for parental refusal is based on religious objections. Using the positive test results for other newborns, there may have been one disorder not identified among the newborns whose parents refused screening.

**Heelstick Program**

The Department of Health tracks a number of performance measures for the heelstick program some of which are listed below with results for 2016:

<b>Newborn Heelstick Screening Performance Measure</b>	<b>2016 Results</b>		<b>Target</b>
Eligible newborns screened	99.6%	51,348	100%
Newborns with a confirmed positive medical diagnosis.	1%	678	N/A
Newborns without final medical diagnosis of positive test results.	0%	4	0%
Eligible newborns not receiving a screening.	0%	140	0%
Newborns not tested due to parental refusal	0%	44	N/A
Newborns with specimens that could never be tested.	0%	21	0%
Results not reported within seven days of life.	14%	7,132	0%
<b>Other Information</b>			
Total births (2016)	51,533		

The Department of Health provides each hospital with a monthly report card on newborn sample quality and the timeliness of submission. Additionally, department staff visit each hospital yearly to discuss options for process improvement. Further, the Department of Health hopes to have a real-time performance measures available to the public by the end of 2017.

What has been the recent trend over time of important performance measures?

Newborn Heelstick Screening Performance Measure	2013 Results		2014 Results		2015 Results		2016 Results	
Total screenings	99%	51,491	99%	51,768	99%	51,487	99.6%	51,348
Newborns with a confirmed positive medical diagnosis.	1%	304	1%	361	1%	402	1%	678
Results not reported within seven days of life.							14%	7,132
Eligible newborns not receiving a screening.							0%	140
Newborns with specimens that could never be tested.							0%	21
Newborns not tested due to parental refusal							0%	44
<b>Other Information</b>								
Total births		51,872		52,171		51,749		51,533

Part of the reason for the increase in newborns with a confirmed positive diagnosis is because beginning in 2016 the program began, after consultation with a hemoglobin specialist, following up on all hemoglobin variant tests that had an “unknown” result. The heelstick testing previously only followed up on positive results for the specific disorders being tested. Previously unknown variants were reported as “normal.”

Newborn Hearing Screening Performance Measure	2014 Results		Target
Total screenings	99%	51,606	>95%
Eligible newborns not receiving a screening before one month old.	2%	1,006	<5%
Newborns not tested due to parental refusal	0%	134	N/A
Not passing initial screening	1%	504	<4%
Not passing screening, who are diagnosed before three months old.	59%	297	>90%
Not passing screening, eligible for early intervention who are enrolled before six months old.	59%	57	>90%
Not passing screening lost to follow up.	14%	70	<15%
<b>Other Information</b>			
Total births		52,171	

### Hearing Screening

What has been the recent trend over time of important performance measures? The table below show the trend in performance measures from 2011 through 2014. One trend of note is the reduction in the number of newborns who did not pass the initial hearing screening that are lost due to follow up. The number lost to follow up was 425 in 2011 and 381 in 2012, but has now been lower in recent years at 153 in 2013 and 70 in 2014. The Department of Health explains the improvement in this trend with the use of federal funds

to hire a follow-up coordinator who worked with corporate compliance officers for those programs who were under-performing. The coordinator also provided report cards to providers.

Newborn Hearing Screening Performance Measure	2011 Results		2012 Results		2013 Results		2014 Results	
Total screenings	99%	51,661	99%	51,880	99%	51,288	99%	51,606
Newborns with a confirmed positive medical diagnosis.	0%	104	0%	100	0%	121	0%	104
Not passing screening lost to follow up.	1%	425	1%	381	0%	153	0%	70
Eligible newborns missing screening	0%	256	0%	191	1%	287	0%	198
Newborns not tested due to parental refusal	0%	57	0%	95	0%	49	0%	134
<b>Other Information</b>								
Total births		52,342		52,518		51,872		52,171

**Critical Congenital Heart Defect Screening**

The Utah Critical Congenital Heart Defect Screening refers to pulse oximetry screening. There may be incorrect reporting currently for the number of newborns not screened. The screening results are reported on the newborn’s birth certificate. With 8-9% of Utah newborns ending up in the neonatal intensive care unit (NICU), sometimes the birth certificate is issued prior to the completion of screening (even though screening may take place later). Health: “An echocardiogram may also be completed and a “not screened” result reported. In addition, there are several other reasons a “not screened” result may be reported such as “prenatal diagnosis of a heart defect”, “refused (for medical reason)” such as hospice care and death within 1-2 days of life.” The Department of Health receives actual pulse oximetry data on newborns from 2 hospitals directly so birth certificate data can be corrected to more accurately reflect the screened vs. not screened rate. The Department of Health hopes to have a data connection established with all health care providers statewide by July 2018. Additionally, the Department of Health plans to have report cards for health care providers screening results by June 2018. The Department of Health contacts health care providers who are routinely out of compliance with screening.

What has been the recent trend over time of important performance measures?

Critical Congenital Heart Defect Screening Performance Measure	2014 Results (Oct.-Dec.)		2015 Results		2016 Results	
Total screenings	92%	11,510	92%	47,824	93%	48,043
Newborns with a positive test result.	0%	17	0%	96	0%	92
Eligible newborns not receiving a screening.	8%	1,003	8%	3,930	7%	3,490
<b>Other Information</b>						
Total births		12,513		51,754		51,533

**How are we Organized?**

Medical personnel collect the blood samples for the heelstick blood screen send samples to the Department of Health Laboratory for testing. Medical personnel also administer the hearing and congenital heart disease tests before the baby leaves the hospital and report the results back to the department. The most common locations for these tests to take place are in hospitals, pediatrician offices, birthing centers, and in homes for at-home births. Of the 9 testing platforms that cover the 40 disorders tested via the heelstick blood screen, the state laboratory runs seven platforms, and contracted providers run two platforms.

Staff with the Department of Health also follow up on positive test results for the heelstick blood screen and hearing test, as well as following up on if providers followed proper protocols for positive results from the congenital heart disease test. The Department of Health has about a \$100,000 contract with the Metabolic Genetics Clinic at the University of Utah to connect some newborns with certain positive test results to immediate care with a metabolic specialist. If the State of Utah began doing more follow up on newborns who do not receive the congenital heart disease test, then the Department of Health estimates a need for 1 FTE and database enhancements.

**What Are we Buying and How Are we Paying for it?**

The Department of Health bought the following in FY 2016 to carryout newborn screening programs:

Newborn Screening (FY 2016)	Total	% Total	Heelstick and Follow-up	Critical Congenital Heart Disease	Hearing
Contractual	\$ 2,413,500	45%	\$ 2,325,300	\$ -	\$ 88,200
Personnel	\$ 1,710,300	32%	\$ 1,155,800	\$ 50,500	\$ 504,000
Lab Supplies & Current Expenses	\$ 857,200	16%	\$ 815,800	\$ 700	\$ 40,700
Department of Technology Services	\$ 166,600	3%	\$ 153,600	\$ -	\$ 13,000
Capital Equipment	\$ 70,400	1%	\$ 70,400	\$ -	\$ -
Lab Admin. Overhead - Portion of Labwide Costs	\$ 179,000	3%	\$ 179,000	\$ -	\$ -
Travel	\$ 17,200	0%	\$ 10,100	\$ -	\$ 7,100
<b>Total Expenses</b>	<b>\$ 5,414,200</b>	<b>100%</b>	<b>\$ 4,710,000</b>	<b>\$ 51,200</b>	<b>\$ 653,000</b>
FTEs	19.0		12.6	0.5	5.9
Surplus/(Deficit)	\$ 251,100	105%	\$ 250,900	\$ -	\$ 200
<b>Total Revenues</b>	<b>\$ 5,665,300</b>		<b>\$ 4,960,900</b>	<b>\$ 51,200</b>	<b>\$ 653,200</b>
Kit Fees	\$ 5,319,800	94%	\$ 4,960,900	\$ 51,200	\$ 307,700
Federal Funds	\$ 345,500	6%	\$ -	\$ -	\$ 345,500

Newborn screening kit fees provided 94% or \$5,162,600 of newborn screening revenues. Hospitals and other providers pay the fee directly to the Department of Health and then charge the consumer to recoup their costs. In calendar year 2016 Medicaid covered 15,279 or 30% of all the State’s 51,533 births. This

means that the State paid indirectly via Medicaid for probably about \$1,580,000 total funds (\$470,000 General Fund and \$1,110,000 federal funds) of the newborn kit fee revenue.

Federal funds supported 6% or \$345,500 of all newborn screening costs in 2016, but were only available for the hearing screenings. If the federal funds supporting newborn screening programs were to end and the State wanted to maintain the prior funding level for the services provided with those funds, this would represent an increase of \$6.75 per kit.

Newborn Screening	FY 2013 Total	FY 2014 Total	FY 2015 Total	FY 2016 Total
Contractual	\$ 2,109,600	\$ 2,356,600	\$ 2,229,200	\$ 2,413,500
Personnel	\$ 1,510,400	\$ 1,503,000	\$ 1,719,900	\$ 1,710,300
Lab Supplies & Current Expenses	\$ 855,200	\$ 845,700	\$ 987,200	\$ 857,200
Department of Technology Services	\$ 296,200	\$ 186,600	\$ 158,300	\$ 166,600
Capital Equipment	\$ 14,400	\$ -	\$ 168,800	\$ 70,400
Lab Admin Overhead - Portion of Labwide Costs	\$ 192,600	\$ 216,500	\$ 210,800	\$ 179,000
Travel	\$ 11,500	\$ 8,700	\$ 15,100	\$ 17,200
<b>Total Expenses</b>	<b>\$ 4,989,900</b>	<b>\$ 5,117,100</b>	<b>\$ 5,489,300</b>	<b>\$ 5,414,200</b>
FTEs	17.6	17.9	18.4	19.0
Surplus/(Deficit)	\$ 700,100	\$ 453,200	\$ 100,000	\$ 251,100
<b>Total Revenues</b>	<b>\$ 5,690,000</b>	<b>\$ 5,570,300</b>	<b>\$ 5,589,200</b>	<b>\$ 5,665,300</b>
Kit Fees	\$ 5,246,600	\$ 5,252,000	\$ 5,258,200	\$ 5,319,800
Federal Funds	\$ 443,400	\$ 318,300	\$ 331,000	\$ 345,500
<b>Kit Fee</b>	<b>\$ 95.61</b>	<b>\$ 102.99</b>	<b>\$ 103.79</b>	<b>\$ 103.79</b>
<b>Kits Sold</b>	<b>54,875</b>	<b>50,995</b>	<b>50,662</b>	<b>51,255</b>

What has been the recent trend over time in expenditures and revenues? The table above details the expenditures and revenues for newborn screening from 2013 through 2016. One trend of note, the laboratory administration overhead charge to the newborn screening programs has not been consistent over the years. The charge from 2013 through 2016 has ranged from a low of \$179,000 2016 to a high of \$216,500 in 2014. The Department of Health explains the change in overhead charges by noting that how the overhead costs are allocated has changed over time to hopefully better reflect actual costs. Going forward starting with FY 2017 the Department of Health believes the cost allocation will be more stable. Currently, the indirect costs charged to newborn screening do not include any department-wide costs.

What should be covered by fee revenue? UCA [63J-1-504](#) states: “(2) Each fee agency shall adopt a schedule of fees...that are reasonable, fair, and reflect the cost of services provided.” Finance’s “Revenues – Cost Formula for Fees” (revised May, 1, 2010), Finance Accounting Policies and Procedures 07-10.00, states “agencies should include direct and indirect costs in their formula.”

*The fiscal analyst recommends that the Department of Health do the following prior to submitting its proposed fee for the newborn screening kits for FY 2019:*

1. *Determine if the newborn screening programs are covering their share of indirect costs.*
2. *Establish a consistent cost allocation formula for laboratory costs (and any other identified indirect costs) shared by the newborn screening programs.*
3. *Propose a fee that covers the program's share of both direct and indirect costs.*

### **What Non-governmental Sources Are Involved?**

There are several private entities that can handle the laboratory testing portion of the heelstick screening; however, no other entity provides comprehensive follow-up for all positive test results. The Department of Health has decided to do most of the testing at the state laboratory to lower costs and have faster results.

### **What are Other States Doing for Newborn Screening?**

The State of Utah currently charges \$112.16 for newborn screening. The Department of Health reports that fees charged by the other 50 states range from \$0 in four states (Florida, Kansas, New York, and Pennsylvania) to \$162.98 in Rhode Island. Half of all states charge less than \$90.69 per kit and the other half of states charge more than \$90.69 per kit. The average of Utah's neighboring states is \$97, ranging from a low of \$77 in Wyoming to a high of \$138 in New Mexico.

Utah is a two-screen state, which means that newborns receive two heelstick tests for disorders that may take a few days to manifest in the newborn's blood sample. Overall 37 of 50 or 74% of states do one rather than two screens. Because some states use other funds to offset their newborn screening programs or do not include follow up costs in the fee charged, it is difficult to estimate a reduction in costs from going to a one screen. In general, one screen states charge 3% less for heelstick kits. If that 3% were to be realized in Utah from the change to a one screen, then that would be a reduction of \$150,000 based on 2016 kit fee revenues for the heelstick program. The Department of Health recommends that Utah continue to be a two-screen state because some disorders may not show up until a newborn's metabolism has been functioning for two weeks. The first screen includes 40 of 40 disorders and the second screen tests for 36 of 40 disorders.

How does Utah's testing compare to neighboring states and similar states that test for more disorders? The number of disorders listed in this paragraph come from <http://www.newsteps.org/> and differ from Utah's 42 disorders mentioned previously due to subvariants of disorders being included. Maryland and Mississippi have somewhat similar annual number of births compared to Utah and were mentioned by the National Conference of State Legislatures as states that almost screen for 60 disorders. Both Mississippi and Maryland do more universal tests for disorders than Utah's 52 at 59 and 55 respectively; however, Utah tests for a total of 60 disorders when you include disorders likely to be discovered via other test results. These 60 disorders tested make Utah's screening the highest number of disorders tested amongst our neighboring states as well as Maryland and Mississippi. The number of disorders for Utah's neighboring states ranges from 42 disorders in Arizona to 56 disorders in Nevada. If Utah were to add all the tests done by Mississippi and Maryland as well as neighboring states but not currently done in Utah, it would likely identify an additional two disorders in newborns annually. These additional six disorders tested in other states fall into the following federal categories: (1) 0 core disorders, (2) four secondary disorders, and (3) two other disorders with no current federal recommendation for inclusion. If Utah were to perform only the tests done in its neighboring states as well as Maryland and Mississippi, then Utah

would likely identify three to fifteen less disorders annually in newborns. Utah and 30 other states test for 31 federally-recommended core disorders. Eleven states test for less than 31 recommended disorders. Two states, New Hampshire and Massachusetts, test for the lowest number of disorders at 28. Eight states test for more than 31 disorders with one state Pennsylvania testing for all 34 federally-recommended disorders.

State	Utah	Idaho	Wyoming	Colorado	Nevada	Arizona	New Mexico	Mississippi	Maryland
Screening Fee	\$112.16	\$100	\$ 77.00	\$ 92.00	\$ 81.00	\$ 95.00	\$138.00	\$ 110.00	\$ 106.00
Disorder Tests (Universal)	52	48	51	45	42	30	43	59	55
Disorders Likely Detected From Other Test Results	8	-	-	-	14	12	6	-	-
Annual Births (2014)	51,000	23,000	8,000	66,000	36,000	87,000	26,000	39,000	74,000
More/(Less) Births vs Utah	-	(28,000)	(43,000)	15,000	(15,000)	36,000	(25,000)	(12,000)	23,000
Expected Positive Test Results Based on Disorders Tested and Utah births	179	164	166	173	176	173	175	176	176
More/(Less) Results Than Utah's Tests	0	(15)	(13)	(6)	(3)	(6)	(4)	(3)	(3)
Source:	<a href="http://www.newsteps.org/">http://www.newsteps.org/</a>								

**Additional Information**

- Attachment A - Utah Department of Health Newborn Screening Services Budget Deep Dive
- Attachment B - LegisBrief from the National Conference of State Legislatures entitled "State Newborn Health Screening Policies"
- <http://www.newsteps.org/>
- <https://www.newsteps.org/news-and-education/news/newborn-screening-program-receives-governor%E2%80%99s-award>
- <https://www.cdc.gov/ncbddd/hearingloss/ehdi-data2014.html>

# Utah Department of Health Newborn Screening Services Budget Deep Dive

Within the Utah Department of Health, the two Divisions, Disease Control and Prevention (DCP) and Family Health and Preparedness (FHP), work together to support Newborn Screening services. Newborn screening is a critical public health service, identifying conditions that can affect a child's long-term health, cognitive or physical development, or survival. The early detection, diagnosis, and interventions facilitated by newborn screening and follow-up services can prevent death or disability and assist children to reach their full potential.

The Newborn Screening services consist of three components:

1. Newborn Heelstick Screening and Follow-up (Disease Control and Prevention)
2. Newborn Critical Congenital Heart Disease Screening (Family Health and Preparedness)
3. Newborn Hearing Screening (Family Health and Preparedness)

The Newborn Screening Kit fee covers all costs for the Newborn Heelstick Screening and follow-up program. The fee also covers the costs for Critical Congenital Heart Disease Screening and a portion of the costs for the Newborn Hearing Screening.

The following pages describe the three components of Newborn Screening Services in detail.

## Component I: Newborn Heelstick Screening and Follow-up

### Purpose:

The purpose of the Newborn Screening Program-Heelstick (NSP-H) is to establish a statewide system for early identification and referral of newborns with a congenital disorder. The program screens for disorders that are detectable by a laboratory-based screening method which allows for early treatment to prevent mortality and/or reduce morbidity, and allow each child to reach their maximum potential.

### Detailed Questions:

#### What We Are Attempting to Accomplish

**1. *What authorizes delivery/provision of function (statute, intent, rule)?***

The NSP-H is established under Section 26-10-6, Utah State Code, annotated, and Rule 398-1, Newborn Screening.

**2. *What other activities are undertaken without explicit authority?***

None

**3. *What alternative government and non-government resources exist to achieve these outcomes? Why is state involved?***

Newborn Screening was mandated in Utah in 1965 and administration of the testing was established at each hospital. In 1979, the Utah Department of Health (UDOH) began the oversight of newborn screening program to ensure consistent testing and timely follow-up are provided for every newborn.

It is universally accepted that state-run NSPs level the playing field across geographic and socio-economic boundaries to ensure standard implementation of protocols.

There are no non-governmental entities that handle an entire NSP-H end-to-end. However, several private and not-for profit entities can handle the laboratory testing portion of the screening. Such entities include PerkinElmer Genetics, which can handle all laboratory testing components, or ARUP, which can handle testing for amino acid and acylcarnitine disorders. However, neither provides the critical and required follow-up for abnormal test results.

#### How We Are Organized

**4. *What organizations are associated with this function?***

The Newborn Screening Program-Heelstick is located within the Utah Public Health Laboratory and is part of the Division of Disease Control and Prevention, Utah Department of Health.

The NSP-H is guided by an advisory committee, comprised of clinical experts, health care providers, Utah Department of Health representatives, the Utah Hospital Association, various foundations (such as the March of Dimes), and community/patient representatives. The NSP-H provides quarterly performance updates to the committee including testing and follow-up turn-around-times and the number of

disorders identified. The advisory committee provides their expertise in disease specific areas including studies/reviews of new disorders in order to make recommendations to the Executive Director of UDOH regarding which diseases should be included in the Utah specific screening panel. Utah currently screens for 40 disorders and 4 disorders are under consideration for addition to the panel. Disorders are chosen based on evidence that supports the benefit of screening for affected individuals as well as for the population overall, the availability of a screening test for the disorder, the ability of the Utah Public Health Laboratory to provide the screening test and follow-up services, and the availability of effective treatments.

The NSP-H closely observes policy recommendations and follows guidance provided by the Department of Health and Human Services Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC). The ACHDNC provides advice, recommendations, and technical information about all aspects of heritable disorders and newborn/childhood screening to the Secretary of Health and Human Services (HHS). HHS provides policies and prioritizes which diseases should be part of the screening panel to enhance the ability of State and local health agencies to provide for screening, counseling, and health care services for newborns and children having, or at risk for, heritable disorders. The Secretary of HHS maintains the Recommended Universal Screening Panel (RUSP). The RUSP is the list of disorders that HHS recommends are screening at birth. However, each State decides which disorders are part of the state specific panel. Utah currently screens for 31 of the 34 core conditions and nine of 26 secondary conditions. Attachment 1 Kit Fee and Service Comparison shows the number of core conditions currently screened for by each state.

**5. *What are the missions of the organizations associated with that function?***

Our mission is the early identification (prior to disease onset) and treatment of newborns with a congenital disorder detectable by a laboratory-based screening method. Attaining this goal reduces morbidity and mortality and allows a child the opportunity to reach their full potential. Included in this mission is the drive to provide the best and most timely service to all babies in Utah irrespective of a family's geographic location or economic status.

**6. *What outcomes are achieved by the organization associated with this function?***

The outcomes we strive to achieve are to facilitate early detection, prompt referral, early treatment, and prevention of disability and/or death. This reduces the burden on the health care system and other social systems.

**7. *What data is collected/reported to document/demonstrate progress toward the outcomes?***

The Newborn Screening Program tracks monthly:

- number of tests completed
- turn-around-time for testing
- number of 'out of range' results
- number of unsatisfactory specimens
- time from diagnosis to treatment
- number of infants identified with a disorder

We further analyze all clinical test data to ensure cut-off levels are accurate and to minimize unnecessary repeat screening thereby minimizing costs and maximizing turn-around time.

**8. How are appropriations structured to accomplish this function?**

The Newborn Screening Program is funded through kit fees. Hospitals and individuals (for home births) purchase the newborn screening kits (collection device) from the Utah Public Health Laboratory. The hospitals or individuals (mid-wives) pay UPHL directly and usually pass the cost of kits on to parents through the costs associated with the birth of the child. Therefore, if the parents have coverage, insurance or Medicaid indirectly pay for the kits.

The kit is a two part kit that contains the filter paper for the blood collected via the heel stick. Utah is a two-screen state meaning that babies are screening for disorders at 24-48 hours of birth and again between 7 and 28 days. The kit fee covers 100% of the costs of laboratory testing and heelstick follow-up services. The kit fee also supports in part, Critical Congenital Heart Disease Screening and Newborn Hearing Screening programs, which are point of care tests performed in the hospital prior to discharge and administered by the Division of Family Health and Preparedness.

Some state programs are funded solely from a kit fee (like Utah), while others are funded partially or completely through general funds, Medicaid and/or federal Title V funds. Therefore, the published fee that a state charges for services cannot be directly compared. For example, Alaska and Rhode Island kit fees have reached over \$160 and New Jersey just increased its kit fee to \$150. On the other end of the spectrum are states like New York that do not charge a kit fee, yet provides one of the most comprehensive screening panels.

Likewise, elements of service of the most relevant component in a NSP-H, follow-up services, are not specified in kit fee disclosures. This portion of the program has the biggest impact over life and death of an infant.

**9. In what units of measure are outputs reported, how and why have those outputs changed over time?**

The overall output of NSP-H is the number of screens performed and the numbers of babies identified with a disorder. The output changes as population size expands or contracts, or when the number of disorders added to the screening panel increases. Operationally, success for these outcomes is measured utilizing timeliness and quality indicators. A meaningful output must provide meaningful clinical conclusions and must be timely; an inconclusive screening result does not allow clinical action and late results no longer allow avoidance of catastrophic consequences.

As clinical and scientific data matures regarding genetic disorders, the number of conditions on the panel will continue to expand. This expansion is a function of increased clinical understanding, expanded economic knowledge of screening benefits, the development of suitable screening tests, and the availability of treatment.

Clinically, outcomes are defined by specific disease incidence on a population basis.

In financial terms, the output measure is cost per screen.

**10. Are performance measures meaningful and how is management assuring such?**

Yes, the measures chosen for tracking are specific for NSP-H. The measures outlined in Question 7 and 12, monitor the entire process beginning with the baby (birth) and ending with the baby (reported results/follow-up) to ensure customer value. Customers are defined as all babies and families in Utah, primary care providers, and specialty care providers. Such an expanded focus takes external and internal processes into account.

In an effort to maintain quality customer service, annual visits with all birthing hospitals have provided overwhelming positive performance and process development. (See Attachment 2: Customer Statements and Attachment 3: NSP-H Hospital Report Card Example).

**11. What kind of external variables impact the organization/function and what is the current status of those variables?**

External variables that affect the NSP-H are:

1. Difficult and inefficient IT environment
2. Dependence on the United States Postal Service for the transportation of NBS specimens between the pediatrician and the laboratory
3. A lack of brand perception and a notion of “no news is good news” with older care providers
4. Constantly expanding screening panels
5. Economic uncertainty regarding coverage (Medicaid and insurance) of expensive treatment costs
6. Disorder subtypes that are identified during the screen but will not present until later in life

The current status of these variables are:

1. Bi-weekly or weekly meetings with DTS staff to discuss ways to enhance our ability to control our data.
2. Exploring the options of using a courier service for these samples. The laboratory already has a very well established courier service.
3. Continuing to work with other organizations such as NORD (National Organization for Rare Diseases)
4. Continuing to work with medical experts to assess the feasibility of adding new tests
5. Continue to monitor the outcomes of federal and state decisions regarding insurance coverage
6. Continue to work with the advisory committee and others on how to address this issue

**12. Are there standards (industry, national, other states, etc.) for output or output per unit of input? How do they compare to this?**

The following provides a snapshot of clinical indicators expected of all newborn screening programs and how Utah compares:

Quality Indicator	NSP-H Status						
Presumptive positive results for time-critical conditions should be communicated immediately to the child’s healthcare provider but no later than the fifth day of life	Meets this requirement						
All presumptive positive results for all other conditions should be communicated to the child’s healthcare provider as soon as possible but no later than seven (7) days of life.	Meets this requirement						
All Newborn Screening (NBS) results should be reported within seven (7) days of life.	<p>For 2016 – 86.11% reported within 7 days of life</p> <p>For 2017 – 94.18% we reported within 7 days of life</p> <p><b>Average age of newborn when results are available</b></p> <p>2016 – 5.64</p> <p>2017 – 5.04</p>						
Quality Indicator 1: Percent of dried blood spot specimens that were unacceptable due to improper collection and/or transport.	<table border="1" data-bbox="597 1167 1185 1276"> <thead> <tr> <th>Total First Unsatisfactory Screens</th> <th>CY201</th> <th>CY2017(to date)</th> </tr> </thead> <tbody> <tr> <td></td> <td>6 1.35%</td> <td>1.76%</td> </tr> </tbody> </table> <p>Baseline would be 0%</p>	Total First Unsatisfactory Screens	CY201	CY2017(to date)		6 1.35%	1.76%
Total First Unsatisfactory Screens	CY201	CY2017(to date)					
	6 1.35%	1.76%					
Quality Indicator 2: Percent of dried blood spot specimens with at least one missing state-defined essential data field upon receipt at the lab.	The current laboratory information system is unable to provide a percentage for this indicator, however the laboratory constantly monitors information as samples are received and any missing information is collected within one business day.						
Quality Indicator 3: Percent of eligible newborns not receiving a newborn screen, reported by dried blood spot or point of care screen(s).	<p>The NSP-H only has this data completed for 2013 and 2014. We are waiting on Vital Records to complete data for 2015 and 2016.</p> <table border="1" data-bbox="597 1717 1291 1791"> <thead> <tr> <th>Percent <u>Not</u> Screened</th> <th>CY2013</th> <th>CY2014</th> </tr> </thead> <tbody> <tr> <td></td> <td>1.03%</td> <td>1.12%</td> </tr> </tbody> </table> <p>Baseline would be 0%</p>	Percent <u>Not</u> Screened	CY2013	CY2014		1.03%	1.12%
Percent <u>Not</u> Screened	CY2013	CY2014					
	1.03%	1.12%					

<p><b>Quality Indicator 4: Percent of infants that have no recorded final resolution (confirmed diagnosis or diagnosis ruled out by an appropriate medical professional) within the newborn screening program.</b></p>	<table border="1"> <thead> <tr> <th>Number of Births Screened</th> <th>CY2013</th> <th>CY2014</th> <th>CY2015</th> <th>CY2016</th> </tr> </thead> <tbody> <tr> <td>Number of Births Screened</td> <td>51,491</td> <td>51,768</td> <td>51,487</td> <td>51,348</td> </tr> <tr> <td>Cases Pending Final Resolution</td> <td>0</td> <td>0</td> <td>0</td> <td>4</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td>SCID: 2 cases Acyl: 2 cases; open cases are closely followed by subspecialists, as of 05/2017 no final diagnosis</td> </tr> </tbody> </table>	Number of Births Screened	CY2013	CY2014	CY2015	CY2016	Number of Births Screened	51,491	51,768	51,487	51,348	Cases Pending Final Resolution	0	0	0	4					SCID: 2 cases Acyl: 2 cases; open cases are closely followed by subspecialists, as of 05/2017 no final diagnosis															
Number of Births Screened	CY2013	CY2014	CY2015	CY2016																																
Number of Births Screened	51,491	51,768	51,487	51,348																																
Cases Pending Final Resolution	0	0	0	4																																
				SCID: 2 cases Acyl: 2 cases; open cases are closely followed by subspecialists, as of 05/2017 no final diagnosis																																
<p><b>Quality Indicator 5: Timeliness of Newborn Screening Activities.</b></p>	<table border="1"> <thead> <tr> <th>Total Transit Time (hospital to laboratory) for First Screens</th> <th>CY2016 Less than 48h 85.4%</th> <th>CY2016 3-4 days 13.3 %</th> <th>CY2017 Less than 48h 86.98%</th> <th>CY2017 7 3-4 days 11.88%</th> </tr> </thead> <tbody> <tr> <td colspan="5" style="text-align: center;">Average time between birth and sample collection</td> </tr> <tr> <td colspan="5" style="text-align: center;">2016 – 1.46 days</td> </tr> <tr> <td colspan="5" style="text-align: center;">2017 – 1.45 days</td> </tr> <tr> <td colspan="5" style="text-align: center;">Average time between sample receipt at laboratory and final report issued</td> </tr> <tr> <td colspan="5" style="text-align: center;">2016 – 2.46 days</td> </tr> <tr> <td colspan="5" style="text-align: center;">2017 – 1.93 days</td> </tr> </tbody> </table>	Total Transit Time (hospital to laboratory) for First Screens	CY2016 Less than 48h 85.4%	CY2016 3-4 days 13.3 %	CY2017 Less than 48h 86.98%	CY2017 7 3-4 days 11.88%	Average time between birth and sample collection					2016 – 1.46 days					2017 – 1.45 days					Average time between sample receipt at laboratory and final report issued					2016 – 2.46 days					2017 – 1.93 days				
Total Transit Time (hospital to laboratory) for First Screens	CY2016 Less than 48h 85.4%	CY2016 3-4 days 13.3 %	CY2017 Less than 48h 86.98%	CY2017 7 3-4 days 11.88%																																
Average time between birth and sample collection																																				
2016 – 1.46 days																																				
2017 – 1.45 days																																				
Average time between sample receipt at laboratory and final report issued																																				
2016 – 2.46 days																																				
2017 – 1.93 days																																				
<p><b>Quality Indicator 6: Percent of infants with an out-of-range newborn screen result requiring clinical diagnostic workup (A) by an appropriate medical professional, reported by disorder category (B).</b></p>	<p>A)</p> <table border="1"> <thead> <tr> <th>Number of Birth Screened</th> <th>CY2013</th> <th>CY2014</th> <th>CY2015</th> <th>CY2016</th> </tr> </thead> <tbody> <tr> <td>Number of Birth Screened</td> <td>51,491</td> <td>51,768</td> <td>51,487</td> <td>51,348</td> </tr> <tr> <td>Total Dx tests</td> <td>369</td> <td>420</td> <td>467</td> <td>713 (*)</td> </tr> <tr> <td>Percent</td> <td><b>0.72</b></td> <td><b>0.81</b></td> <td><b>0.91</b></td> <td><b>1.39 (*)</b></td> </tr> </tbody> </table> <p>(*) Starting in 2016 “UNKNOWN” hemoglobin variants no longer reported as “NORMAL”</p>	Number of Birth Screened	CY2013	CY2014	CY2015	CY2016	Number of Birth Screened	51,491	51,768	51,487	51,348	Total Dx tests	369	420	467	713 (*)	Percent	<b>0.72</b>	<b>0.81</b>	<b>0.91</b>	<b>1.39 (*)</b>															
Number of Birth Screened	CY2013	CY2014	CY2015	CY2016																																
Number of Birth Screened	51,491	51,768	51,487	51,348																																
Total Dx tests	369	420	467	713 (*)																																
Percent	<b>0.72</b>	<b>0.81</b>	<b>0.91</b>	<b>1.39 (*)</b>																																

	<p>B)</p> <table border="1"> <thead> <tr> <th>Number of Birth Screened</th> <th>CY2013</th> <th>CY2014</th> <th>CY2015</th> <th>CY2016</th> </tr> </thead> <tbody> <tr> <td></td> <td>51,491</td> <td>51,768</td> <td>51,487</td> <td>51,348</td> </tr> <tr> <td>AMINO</td> <td>21</td> <td>15</td> <td>14</td> <td>17</td> </tr> <tr> <td>ACYL</td> <td>48</td> <td>44</td> <td>51</td> <td>40</td> </tr> <tr> <td>BIOT</td> <td>4</td> <td>11</td> <td>15</td> <td>9</td> </tr> <tr> <td>CAH</td> <td>9</td> <td>6</td> <td>9</td> <td>5</td> </tr> <tr> <td>CF</td> <td>21</td> <td>26</td> <td>27</td> <td>25</td> </tr> <tr> <td>CHYP</td> <td>32</td> <td>34</td> <td>30</td> <td>30</td> </tr> <tr> <td>GALT</td> <td>7</td> <td>2</td> <td>1</td> <td>1</td> </tr> <tr> <td>HB (**)</td> <td>215</td> <td>264</td> <td>298</td> <td>573</td> </tr> <tr> <td>SCID (*)</td> <td>12</td> <td>18</td> <td>22</td> <td>13</td> </tr> <tr> <td><b>Total</b></td> <td><b>369</b></td> <td><b>420</b></td> <td><b>467</b></td> <td><b>713</b></td> </tr> </tbody> </table> <p>(*) Screening started 2013  (**) Starting in 2016 "UNKNOWN" hemoglobin variants no longer reported as "NORMAL"  Presented as totals not percentages.</p>	Number of Birth Screened	CY2013	CY2014	CY2015	CY2016		51,491	51,768	51,487	51,348	AMINO	21	15	14	17	ACYL	48	44	51	40	BIOT	4	11	15	9	CAH	9	6	9	5	CF	21	26	27	25	CHYP	32	34	30	30	GALT	7	2	1	1	HB (**)	215	264	298	573	SCID (*)	12	18	22	13	<b>Total</b>	<b>369</b>	<b>420</b>	<b>467</b>	<b>713</b>
Number of Birth Screened	CY2013	CY2014	CY2015	CY2016																																																									
	51,491	51,768	51,487	51,348																																																									
AMINO	21	15	14	17																																																									
ACYL	48	44	51	40																																																									
BIOT	4	11	15	9																																																									
CAH	9	6	9	5																																																									
CF	21	26	27	25																																																									
CHYP	32	34	30	30																																																									
GALT	7	2	1	1																																																									
HB (**)	215	264	298	573																																																									
SCID (*)	12	18	22	13																																																									
<b>Total</b>	<b>369</b>	<b>420</b>	<b>467</b>	<b>713</b>																																																									
<p><b>Quality Indicator 7: Percent of disorders detected by newborn screening with a confirmed diagnosis by an appropriate medical professional.</b></p>	<table border="1"> <thead> <tr> <th>Number of Birth Screened</th> <th>CY2013</th> <th>CY2014</th> <th>CY2015</th> <th>CY2016</th> </tr> </thead> <tbody> <tr> <td></td> <td>51,491</td> <td>51,768</td> <td>51,487</td> <td>51,348</td> </tr> <tr> <td>AMINO</td> <td>7</td> <td>6</td> <td>7</td> <td>6</td> </tr> <tr> <td>ACYL</td> <td>19</td> <td>19</td> <td>16</td> <td>12</td> </tr> <tr> <td>BIOT</td> <td>4</td> <td>5</td> <td>11</td> <td>11</td> </tr> <tr> <td>CAH</td> <td>4</td> <td>5</td> <td>3</td> <td>3</td> </tr> <tr> <td>CF</td> <td>25</td> <td>22</td> <td>31</td> <td>21</td> </tr> <tr> <td>CHYP</td> <td>22</td> <td>26</td> <td>25</td> <td>17</td> </tr> <tr> <td>GALT</td> <td>3</td> <td>2</td> <td>1</td> <td>0</td> </tr> <tr> <td>HB (**)</td> <td>215</td> <td>264</td> <td>298</td> <td>603</td> </tr> <tr> <td>SCID (*)</td> <td>5</td> <td>12</td> <td>10</td> <td>5</td> </tr> <tr> <td><b>Total</b></td> <td><b>304</b></td> <td><b>361</b></td> <td><b>402</b></td> <td><b>678</b></td> </tr> </tbody> </table> <p>(*) Screening started 2013  (**) Starting in 2016 "UNKNOWN" hemoglobin variants no longer reported as "NORMAL"  Presented as totals not percentages.</p>	Number of Birth Screened	CY2013	CY2014	CY2015	CY2016		51,491	51,768	51,487	51,348	AMINO	7	6	7	6	ACYL	19	19	16	12	BIOT	4	5	11	11	CAH	4	5	3	3	CF	25	22	31	21	CHYP	22	26	25	17	GALT	3	2	1	0	HB (**)	215	264	298	603	SCID (*)	5	12	10	5	<b>Total</b>	<b>304</b>	<b>361</b>	<b>402</b>	<b>678</b>
Number of Birth Screened	CY2013	CY2014	CY2015	CY2016																																																									
	51,491	51,768	51,487	51,348																																																									
AMINO	7	6	7	6																																																									
ACYL	19	19	16	12																																																									
BIOT	4	5	11	11																																																									
CAH	4	5	3	3																																																									
CF	25	22	31	21																																																									
CHYP	22	26	25	17																																																									
GALT	3	2	1	0																																																									
HB (**)	215	264	298	603																																																									
SCID (*)	5	12	10	5																																																									
<b>Total</b>	<b>304</b>	<b>361</b>	<b>402</b>	<b>678</b>																																																									
<p><b>Quality Indicator 8: Percent of missed cases, reported by disorder.</b></p>	<p>To our knowledge, of the babies the program has screened, we have missed zero cases.</p>																																																												

Based on the indicators above, Utah has one of the fastest NSP-Hs with average turn-around-times below the critical window that allows for clinical interventions. Turn-around time performance equally

depends on performance of the screening program and follow-up service, but also on a functioning logistics system to ensure fast delivery of all samples to the laboratory.

For our focus on performance, we have received local and national attention and recognition. We are in the process of implementing a real-time performance dashboard that will be available to the public, Utah parents, and hospitals that will display relevant performance measures.

However, service/cost metrics are difficult to compare (see Attachment 1 Kit Fee and Service Comparison). For example, our neighboring states disclose only part of their NSP-H fees without precise monetary amounts being specified. Yet, New York State's NSP-H charges no fee and screens for the largest number of disorders and provides the most comprehensive clinical testing among all US programs.

Likewise, elements of service of the most relevant component in a NSP-H, follow-up services, are not specified. This portion of the program has the biggest impact over life and death of an infant. If, for example, insurance preauthorization is required for a clinical confirmation test that is not covered by a NBS kit fee, this delay can have deadly consequences.

While performance indicators provide numerical pass/fail scores, they do not necessarily capture utility for medical experts, general practitioners or families. Attachment 2 provide high level feedback from our customers (see Attachment 2 – Customer Statements)

Our performance is also reflected in local and national news coverage. Please see the provided links:

<http://www.deseretnews.com/article/865656079/Newborn-screening-saves-lives-in-Utah.html>

<http://archive.jsonline.com/watchdog/watchdogreports/days-after-newborn-screening-reform-a-babys-life-is-saved-b99381386z1-282047501.html>

For quality and timeliness efforts, NSP-H was awarded the Governor's Award of Excellence in 2015.

<https://www.newsteps.org/news-and-education/news/newborn-screening-program-receives-governor%E2%80%99s-award>

### **13. To whom is performance data reported?**

Performance data is reported to all participants of the program:

- Hospitals receive a performance report which provides data on sample quality and timeliness. A copy of such a report card is attached (see attachment 3). Hospitals receive these report cards monthly. Annual performance records are also shared with hospital leadership (CEO). All birthing hospitals are visited annually and the performance report is reviewed with staff to allow for process improvement.
- The advisory committee receives operational performance data, including total number of babies screened, number of cases identified, numbers of unsatisfactory samples, and total turn-around time (from birth to diagnosis).
- Specific test information is shared with clinical specialists to help guide screening performance. This allows for the adjustment of cut-offs to accommodate Utah specific population data and to lower specific cut-offs to reduce inconclusive results and/or confirmatory testing needs.

**14. What decisions are based on reporting data?**

Essentially all decisions regarding process changes or process maintenance are based on data.

The following highlights an example of how this interaction occurs.

The laboratory set a goal to improve the timeliness of services. We assessed all program components from the birth of the baby to delivery of test results to the medical provider. We identified bottlenecks and inefficiencies, prioritized, and implemented improvement steps. A sequential look at each step of the process significantly improved turn-around time for all babies by resulting in 7-day operations, and one of the fastest follow-up turn-around-times to initiate clinical care.

A perfect example of these improvements in action is the story of Baby Juniper. Below is an excerpt from Juniper’s story that was highlighted in a national investigative report:

“Juniper has a genetic disorder called MCAD deficiency, a condition where the body cannot properly convert some fats to energy. A newborn with MCAD deficiency can appear perfectly healthy while fatty acids are building up in the body, soon plunging the child into metabolic crisis. A baby who takes a nap and goes too long without eating can suddenly die or end up brain damaged. If the disorder is detected early, however, parents know to feed the child every two hours. That’s often all it takes for a baby with the condition to grow up and lead a normal, healthy life. Juniper was born on Sunday, in a rural Utah hospital. Just three days earlier, Uintah Basin Medical Center had started using FedEx to ship newborn screening samples overnight to Utah’s state lab. The hospital previously relied on regular mail service to send the blood samples, which meant about half of babies’ tests took five or more days to get to the state lab. A wait like that could have killed Juniper. “

This story further provides insights about the interconnectedness of the program and the advantages of a state-mandated program:

“Luckily [Andreas or ‘Andy’] Rohrwasser had spent the previous months figuring out how to make Utah’s newborn screening program more efficient. His goal was to identify and eliminate bottlenecks throughout the process without increasing costs, which would require more funding from the state legislature.....Rohrwasser said it was a team effort with help from the Utah Hospital Association as well as staff from individual hospitals. He rejiggered the newborn screening program’s budget to fund the \$7-per-test FedEx fee for hospitals that didn’t already have couriers and has been re-evaluating positions and shifts within the lab so it can operate on Saturdays.”

Family impact:

“Juniper’s mom didn’t know newborn screening was so important and wasn’t aware that the samples needed to be sent quickly for testing. She has since been spreading the word, insisting that parents need to be advocates for their children.”

**15. How might you recommend the authorization, mission, or performance measurement change?**

The Newborn Screening Program – Heelstick does not see any need to change/improve on our authorization or mission. In an effort to help with further process improvement and better track data for performance measures, unrestricted access to our data and the ability to manage our local IT infrastructure would allow for almost real time accountability and performance insight for the entire process.

## **What We Are Buying**

### **16. What is the largest category of expenditure for an organization and how big is it?**

See Graph 1 below.

### **17. How does this expenditure support the above justification/authorization?**

Program expenditures appropriately support the Newborn Screening Program-Heelstick laboratory and follow-up programs. Expenditures support the purchase of lab supplies necessary for testing, contractual costs for testing done at ARUP, equipment maintenance, administrative overhead, DTS telecommunication charges, and other overhead expenditures necessary for operation such as photocopy expense, office supplies, insurance, etc. The personnel services expenses pay for 7 laboratory staff and 6 follow-up staff. The Data Processing Current Expense supports the program with network connectivity, hosting services, application maintenance, software maintenance (LIMS), and various other hardware and software products. These expenses are critical to running the program effectively and efficiently. Contractual payments are made to the University of Utah and ARUP for Cystic Fibrosis genetic counseling and metabolic program support. Capital expenditures support infrastructure investments to eliminate bottle necks, upgrade aging equipment, improve screening logic, and to streamline the workflow.

### **18. What is that category of expenditure buying (how many/cost per unit)?**

See Graphs 1 & 2 below and Question 17 above.

### **19. How does the above relate to units of output?**

Over time, the units of output (number of babies born that need to be screened) have remained relatively constant. The FTE count for the NSP-H has remained relatively constant as well. What has changed, however, is the way that employees have been used. There was a huge need for turnaround times to improve. This was accomplished by increasing the number of testing days from 5 to 6 days a week without increasing FTEs. Also, instead of rehiring a position that wasn't as needed, the Chief hired a Health Informaticist to aid in bringing on laboratory and data management programs. In addition, the follow-up program increased its hours of availability to 24 hours a day, seven days a week without increasing FTEs.

In 2017, NSP-H began implementation of a new LIMS (SpecimenGate & Footsteps) system which will automate timeliness, eliminate data entry, and automate reporting.

In 2015, the NSP-H made investments in high throughput sample preparation technology reduce high personnel requirements in the sample preparation step.

In 2016, NSP-H added instrumentation to introduce Severe Combined Immunodeficiency (SCID) testing in-house to address a major bottleneck in one of the testing steps.

In 2017, NSP-H replaced failing equipment and replaced manual methods with automation.

20. How has the expenditure changed over five years relative to the units of output?

See Graphs 1 & 2 below.

21. Are there any outliers/anomalies in current or budgeted spending in this category?

No.

22. Does the amount of expenditure for a category change significantly in accounting period 12 or 13? Why?

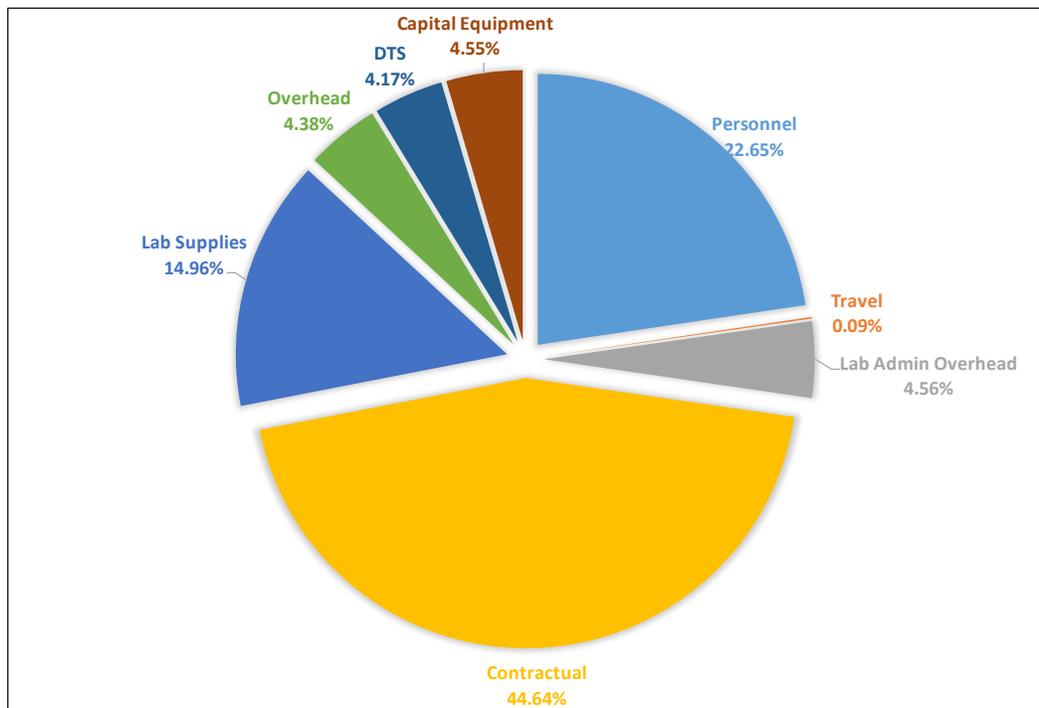
No.

23. How might you recommend this expenditure category change based on the above?

We have no recommendations for change at this time.

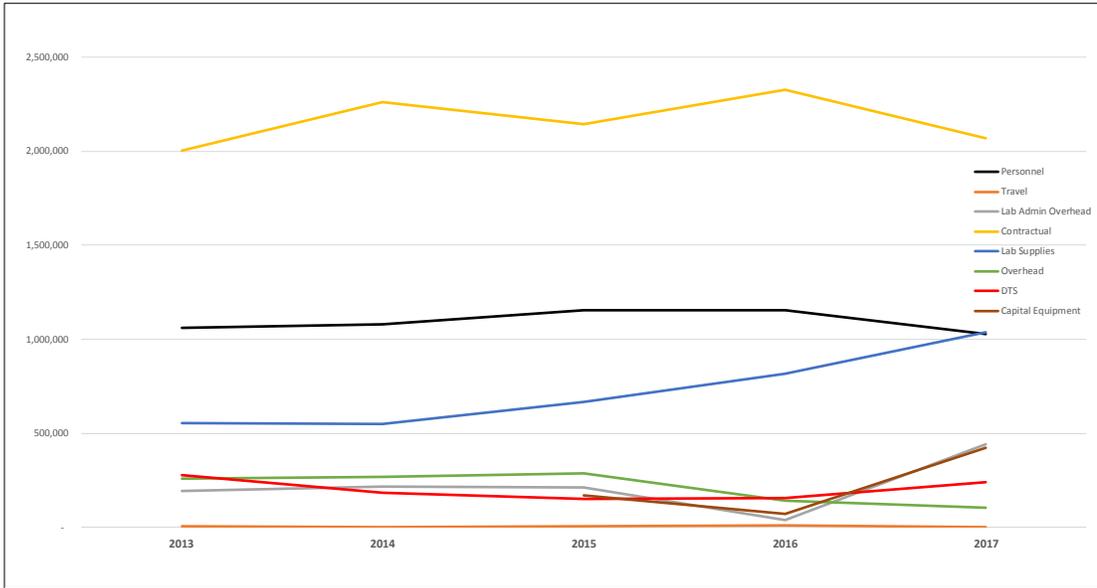
Graph 1: Newborn Screening Kit Fee Breakdown, 5 year average

Graph 1: This graph represents a percentage of the whole that each expense type encumbers. It covers an average of each type of expense for years 2013 - 2017. Because 2017 is still in progress, the 2017 number contains the actual amount of expense through period 10, with an anticipated amount for periods 11,12, and 13.



**Graph 2: Newborn Screening & Follow-Up Program Spending Trends**

Graph 2: This graph represents the trend in spending (by category) from 2013 to 2017. Because 2017 is still in progress, the 2017 numbers contain the actual amount of expense through period 10, with an anticipated amount for periods 11, 12, and 13.



	2013	2014	2015	2016	2017	5 Yr Avg	5 Year Avg %
Personnel	1,058,872	1,078,226	1,155,798	1,155,844	1,029,098	1,095,568	22.65%
Travel	5,372	619	6,048	10,109	464	4,522	0.09%
Lab Admin Overhead	192,611	216,517	210,796	38,231	443,649	220,361	4.56%
Contractual	2,000,612	2,261,589	2,142,310	2,325,345	2,066,256	2,159,222	44.64%
Lab Supplies	552,682	549,989	664,457	815,822	1,035,808	723,752	14.96%
Overhead	258,483	270,211	288,080	140,776	102,165	211,943	4.38%
DTS	278,478	181,716	152,932	153,631	241,085	201,568	4.17%
Capital Equipment	4,347,109	4,558,868	168,777	70,400	421,748	220,308	4.55%
	4,347,109	4,558,868	4,789,197	4,710,158	5,340,273	4,837,244	

**How We Are Paying For It**

**24. What is the largest fund or account from which resources are drawn to support the above expenditures and how big is it?**

Newborn Screening Kit Fee

	2013	2014	2015	2016	2017
Kit Fee	95.61	102.99	103.79	103.79	112.16
Revenue/Yr	5,246,600	5,252,000	5,258,200	5,319,800	5,812,200

**25. What are the revenue sources for that fund or account and what are their relative shares**

The NSP-H is funded entirely by the Newborn Screening Kit Fee.

**26. Is the source one-time or ongoing and do ongoing sources match or exceed ongoing expenditures?**

Source is on-going and match ongoing expenditures.

**27. How has the source changed over time relative to expenditures and units of output?**

	2013	2014	2015	2016	2017
Revenue applicable only to NBS and Follow-Up	5,020,139	5,012,089	4,889,172	4,804,864	5,187,208
Total Revenue/# of Tests	97.69	99.15	97.95	95.72	106.11
Total Expense/# of Tests	84.59	90.19	95.95	93.84	109.24
Difference	13.10	8.97	2.00	1.89	-3.13

Efforts have taken place over the last few years to better reflect actual expenditures related to the NSP and Follow-Up programs and track them as such; therefore a reduction between the difference in revenues and expenditures is noted.

**28. Are there any outliers/anomalies in current or budgeted periods for this source?**

The only outliers in the amount of revenue for this program come from (1) needing to raise the fee to expand the testing panel, and (2) hospitals ordering more kits in a fiscal year when they know the kit fee is going to go up in the next fiscal year as it did in 2014, 2015, and 2017. The amount of increased orders is fairly nominal.

**29. Does source have unencumbered balances that relate directly to this function/organization? How have those balances changed over time?**

No.

**30. What is a reasonable balance and Why?**

A reasonable balance is the current non-lapsing authority, which is \$250,000. Non-Lapsing funds are critical for one-time expenditures such as replacing outdated equipment, costly method development, and bringing in new technologies that facilitate expanded testing and improve communication with hospitals and birthing centers. Because necessary equipment upgrades are so costly and the program has to pay for the equipment and recognize the entire expense in full at the time of purchase, the non-

lapsing authority is vital to program improvement, maintenance, and sustainability. The administration of the NSP has improved greatly over time to better reflect actual expenditures.

**31. Is the availability of sources (grants or previous "building blocks"), rather than mission or objective, driving expenditures?**

Overall, the mission of the program is what drives expenditures. Historically, when the program needed to implement some form of process improvement, they have been able to fund it through an increased kit fee or a reduction in expense as a result of making operations more efficient.

**32. Are other sources available to support the same expenditure?**

No, there are no other sources that fund the NSP-H.

**33. How might you recommend this revenue category change based on the above?**

Not applicable.

**Do We Balance?**

**34. What are total expenditures and total sources? Do they equal one another?**

See table below in Question 35.

**35. Have all appropriated or authorized resources been expended at year-end?**

See table below.

	2013	2014	2015	2016	2017
Total Expenditures	4,347,109	4,558,868	4,789,197	4,710,158	5,340,273
Total Revenue	5,020,139	5,012,089	4,889,172	4,960,864	5,437,208
Surplus/(Deficit)	673,030	453,221	99,975	250,706	96,935

No - as you can see in question 27 above, there has been a varying surplus each year. The administration of the Newborn Screening program has improved greatly over time to better reflect actual expenditures that are related to the NSP and Follow-Up programs. Non-lapsing balances are essential for keeping NPS lab equipment up-to-date.

\*2017 expenditures are projected through June 30, 2017

**36. How have nonlapsing appropriation balances (if any) changed over time?**

FY17 is the first year with non-lapsing authority

**37. Are fees or taxes supporting a function and are those fees or taxes reasonable?**

Yes, the Newborn Screening Kit Fee supports the Newborn Screening Program-Heelstick.

**38. Are there significant risk associated with this organization/function, if so, are there proper controls in place?**

Financial risks are minimal. Fees have been carefully calculated to cover costs. Expenditures are monitored carefully.

**Contact Information:**

Robyn M Atkinson-Dunn, PhD HCLD/PHLD

Director

Utah Public Health Laboratory

4431 S. Constitution Blvd.

Taylorsville UT 84129

Main number: (801) 965-2525

Direct number: (801) 965-2424

[rmatkinson@utah.gov](mailto:rmatkinson@utah.gov)

## Component II: Utah Critical Congenital Heart Defect (CCHD) Screening

### Purpose:

The purpose of the Utah CCHD Screening is to establish a statewide system to educate health care providers, improve the screening process, and create a statewide CCHD screening and data collection system. Through CCHD point-of-care screening, the Utah CCHD Screening Program promotes early detection of asymptomatic CCHD.

### Detailed Questions:

#### What We Are Attempting to Accomplish

**1. *What authorizes delivery/provision of function (statute, intent, rule)?***

Newborn Screening Statute 26-10-6 (<https://le.utah.gov/xcode/Title26/Chapter10/26-10-S6.html>) and Birth Defect Reporting Rule R398-5 (<https://rules.utah.gov/publicat/code/r398/r398-005.htm>).

**2. *What other activities are undertaken without explicit authority?***

None.

**3. *What alternative government and non-government resources exist that perform similar functions? Why is the state involved?***

On September 21, 2011, Secretary Sebelius, Department of Health and Human Services, endorsed CCHD screening and added CCHD screening to the recommended uniform screening panel. Since that endorsement, the American Academy of Pediatrics, American Hospital Association, American College of Cardiology, and the March of Dimes have all endorsed CCHD screening. During the 2013 legislative session, Representative Paul Ray implemented legislation mandating CCHD screening using pulse oximetry for all babies born in Utah. There is no other agency ensuring all infants are universally screened using pulse oximetry in the state of Utah.

#### How We Are Organized

**4. *What organizations are associated with this function?***

The Utah Birth Defect Network (UBDN)/CCHD program is located in the Division of Family Health and Preparedness within the Bureau of Children with Special Health Care Needs, Utah Department of Health.

The National Birth Defects Prevention Network (NBDPN) in collaboration with Centers for Disease Control and Prevention (CDC) provide support for issues surrounding birth defects surveillance, research, and prevention and is a national network of state and population-based birth defects programs. Members include public health professionals, epidemiologists, academics, parents, and others committed to understanding factors that may lead to birth defects, identifying strategies for

reducing birth defects, and working to prevent potential secondary disabilities through earlier detection and optimal care.

**5. What are the missions of the organizations associated with that function?**

The goal of the Utah CCHD Screening Program is to create a safety net for all babies born in Utah by educating health care providers, improving the screening process, and creating a statewide CCHD screening and data collection system. Through CCHD point-of-care screening, the Utah CCHD Screening Program promotes early detection of asymptomatic CCHD.

**6. What outcomes are achieved by the organization associated with this function?**

Through CCHD screening, early detection of asymptomatic CCHD means earlier treatment and identification of life threatening heart defects.

- a. Increase the number of infants screened for CCHD with pulse oximetry.
- b. The results of the pulse oximetry screening will be reported on the birth certificate.
- c. Infants failing their CCHD screen should receive a complete clinical evaluation by their provider, which may include a cardiac echocardiogram.

**7. What data is collected/reported to document/demonstrate progress toward the outcomes?**

The Utah Birth Certificate captures CCHD status: Pass, Failed, and Not Screened. Reports demonstrate compliance by health care providers. If a health care provider is routinely failing to screen their births for CCHD, the program contacts the provider to ascertain deficiencies in procedures, training issues, or reason for non-compliance. The chart below shows the screening results for the state over the last three years. Each year the Not Screened rate has declined demonstrating improvements in universally screening all Utah infants using pulse oximetry.

	Pass	%	Fail	%	Not Screened	%	Total
<b>2014*</b>	11,493	91.9%	17	0.1%	1,003	8.0%	12,513
<b>2015</b>	47,728	92.2%	96	0.2%	3,930	7.6%	51,754
<b>2016</b>	47,951	93.0%	92	0.2%	3,490	6.8%	51,533
<b>Total</b>	107,172	92.5%	205	0.2%	8,423	7.3%	115,800

\* 2014 data is reported October 1, 2014 through December 31, 2014

**8. How are appropriations structured to accomplish this function?**

The Division of Family Health and Preparedness, Bureau of Children with Special Health Care Needs has an agreement in the amount of \$50,000 with Division of Disease Control and Prevention, Utah Public Health Laboratories to provide newborn CCHD screening which is a portion of the newborn kit fee collections.

**9. *In what units of measure are outputs reported, how and why have those outputs changed over time?***

Reports are run monthly from the Birth Certificate records. Cases failing CCHD are reviewed to determine if infant received appropriate intervention and protocols were followed. Data is compared from other reporting sources, per the Utah Birth Defect Network reporting rule, to ensure Fails and Not Screened are reported accurately. Through this process if deficiencies in procedures are identified training is provided to health care providers. See trends above in question 7.

**10. *Are performance measures meaningful and how is management assuring such?***

Screening results from the birth certificate, specifically, Not Screened and Fails are the primary areas of review currently. The program also reviews discrepant data and updates the birth certificate utilizing the UBDN data received. Analysis of the data on the Utah Birth Certificate and reporting of CCHD screens is the primary way to measure goals and objectives. Data is collected from health care providers per the UBDN reporting rule R-398-5.

Performance measures are meaningful and specific to CCHD screening. The UBDN has begun reporting CCHD compliance to providers in 2017 and is working to link their data to the birth certificate data to ensure accurate reporting and make modifications to the birth certificate as necessary.

**11. *What kind of external variables impact the organization/function and what is the current status of those variables?***

Using birth certificate data and data reported under UBDN reporting rule allows ascertainment of compliance with the statute. As areas of deficiency are identified, the UBDN works with the various health care providers to remediate areas of non-compliance. One challenge identified with using the birth certificate to receive data is that infants who are transferred to the NICU may not have a CCHD screen completed prior to the birth certificate clerk submitting the birth certificate resulting in a Not Screened result on the birth certificate. This accounts for approximately 8-9% of the births in Utah. Receiving the actual pulse oximetry results will allow the network to verify results and correct the birth certificate. Expanding the reasons for Not Screened (by pulse oximetry) and identifying the reason CCHD screening did not occur (cardiac echocardiogram) will help identify true Not Screened infants.

**12. *Are there standards (industry, national, other states, etc.) for output or output per unit of input? How do they compare to this?***

There currently is not a national standard. Most states have implemented CCHD screening but standardization of data collection has not been fully established. The availability for comparisons between states is currently not available since implementation nationally occurred within the last 3-4 years. However, UBDN is working with National organizations (i.e. HRSA, Association of Public Health Laboratories and CDC) in an effort to establish a national standard allowing CCHD screening data availability nationally.

Our current process of collecting the final CCHD screening result is very similar to other states and includes:

- a. Percent of eligible newborns not receiving a CCHD screen (see data in Question 7).
- b. Number of newborns detected by CCHD Screening (preliminary data only).
- c. Number of newborns missed by CCHD screen (preliminary data only).

**13. *To whom is performance data reported?***

- a. Health care providers report CCHD screening results on the Birth Certificate.
- b. Hospitals report pulse oximetry results to the UBDN.
- c. Report cards for Health Care providers are under development.
- d. Internal monthly performance reports.
- e. Annual performance reports for Health Care Providers are under development.
- f. IBIS Indicator.
- g. Public Health Outcome Measures Report for the Governor and Legislature.

**14. *What decisions are based on reporting data?***

The Utah Birth Certificate captures CCHD status: Failed, Not Screened, and Passed. Reports are run documenting compliance by health care providers. If a health care provider is routinely failing to screen their births for CCHD, the program contacts the provider to ascertain deficiencies in procedures, training issues, or reason for non-compliance. As this is a point-of-care screen all immediate decision about the treatment of the infant are made by the health care provider at the or near the time of screening.

**15. *How might you recommend the authorization, mission, or performance measurement change?***

This program focuses on quality improvement and currently does not complete any direct family follow-up. This screening is a point-of-care screening meaning that if a Failed screen occurs, immediate evaluation by the health care provider is necessary. Other states do complete follow up services to ensure that children diagnosed with CCHD received the necessary services at the time of diagnosis and if necessary referred to Early Intervention for services. If such follow-up was implemented in Utah it would require additional funding of a 1.0 FTE to ensure proper follow-up and enhancements to the current database.

**What We Are Buying**

**16. *What is the largest category of expenditure for an organization and how big is it?***

The majority of CCHD screening program budget is in the personnel category with the only other category being current expense. See Graph 1 below.

**17. *How does this expenditure support the above justification/authorization?***

The Utah Birth Defect Network program manager oversees this project and has a Master of Public Health degree as well as an undergraduate degree in Health Promotion. The program manager was a part of the pilot project, which looked at high altitude and the screening protocol and works directly

with the health care providers to improve compliance and identify areas for quality improvement. The data analyst is a RN (BSN) with experience with numerous programs including Newborn Screening (Heelstick) program. Proficiency with MS Access and data extraction from both Vital Records (Birth Certificate) and the XIX Data Warehouse is required.

**18. What is that category of expenditure buying (how many/cost per unit)?**

The personnel expenditure supports 0.5 FTE and the current expense includes Operating and Maintenance charges and medical equipment.

**19. How does the above relate to units of output?**

The UBDN program manager and the UBDN data analyst both provide services to support the CCHD screening program. This is completed through report generation and education for health care providers about CCHD screening.

**20. How has the expenditure changed over five years relative to the units of output?**

The mandate for this program was approved during the 2013 legislative session and went into effect on October 1, 2014 directly following the pilot project. Therefore only 3 years of expenditures for this program are available. See Graph 2 below.

**21. Are there any outliers/anomalies in current or budgeted spending in this category?**

No.

**22. Does the amount of expenditure for a category change significantly in accounting period 12 or 13? Why?**

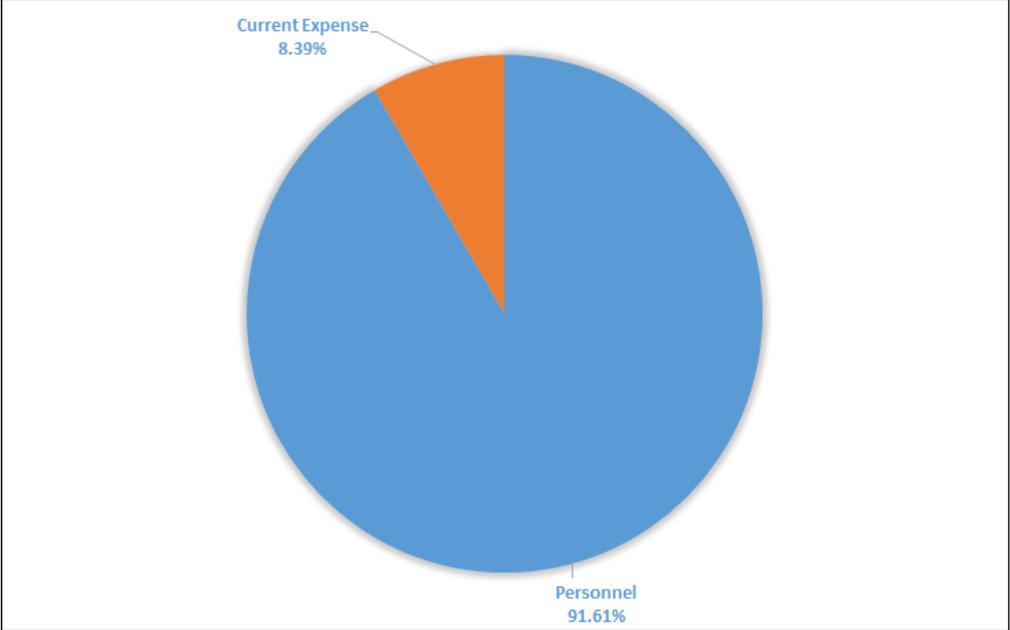
In FY 2015, most of the Operating and Maintenance charges came during this time period, but this is not expected to be an ongoing issue.

**23. How might you recommend this expenditure category change based on the above?**

Currently this only covers a 0.5 FTE. If it were decided that additional follow-up services should be provided additional funding would be need to support this effort. At this time, "not screened" cases are only reviewed if identified by the Utah Birth Defect Network (UBDN) as diagnosed with a reportable congenital heart defect.

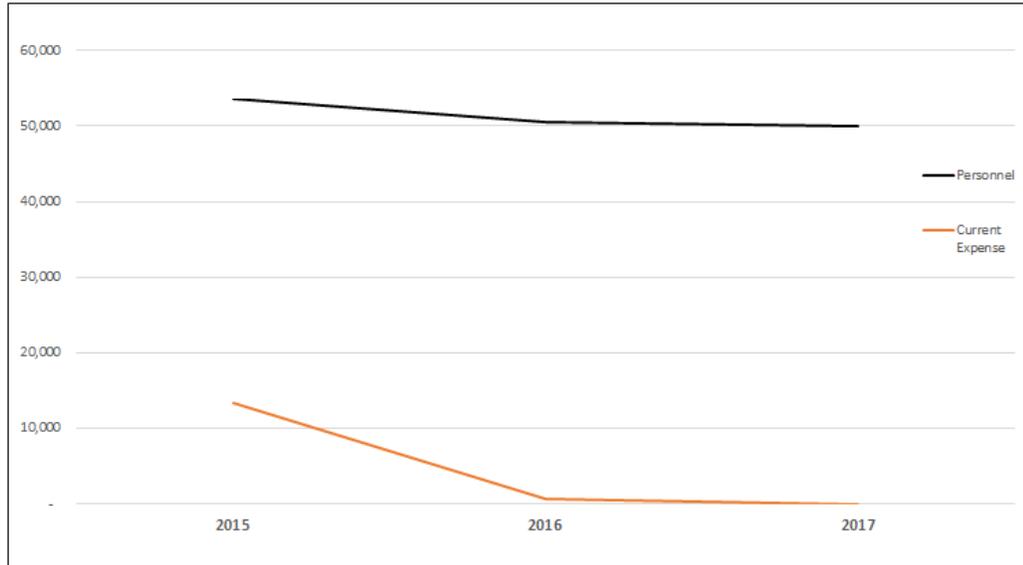
**Graph 1: Critical Congenital Heart Defect Kit Fee Breakdown, 3 year average**

Graph 1: This graph represents a percentage of the whole that each expense type encumbers. It covers an average of each type of expense for years 2015 - 2017. Because 2017 is still in progress, the 2017 number contains the estimated year end.



**Graph 2: Critical Congenital Heart Defect Program Spending Trends**

Graph 2: This graph represents the trend in spending (by category) from 2015 to 2017. Because 2017 is still in progress, the 2017 number contains the estimated year end.



	2015	2016	2017	Average Totals	CCHD Fee Breakdown, 3 Year Average
Personnel	53,637	50,522	50,000	51,386	91.61%
Current Expense	13,444	670	-	4,705	8.39%
<b>Totals</b>	<b>67,081</b>	<b>51,192</b>	<b>50,000</b>	<b>56,091</b>	<b>100.00%</b>

**How We Are Paying For It**

**24. What is the largest fund or account from which resources are drawn to support the above expenditures and how big is it?**

The NBS Revenue Agreement funds this effort which is currently at \$50,000.

**25. What are the revenue sources for that fund or account and what are their relative shares?**

CCHD Kit Fee.

**26. Is the source one-time or ongoing and do ongoing sources match or exceed ongoing expenditures?**

Ongoing funding.

**27. How has the source changed over time relative to expenditures and units of output?**

In previous years the funding source for this program was a portion of the kit fees purchased. Since the NBS Follow-up program moved to the Utah State Laboratory (FY17) and a revenue agreement established, it was lowered to a flat \$50,000 for the program each year.

**28. Are there any outliers/anomalies in current or budgeted periods for this source?**

No

**29. Does source have unencumbered balances that relate directly to this function/organization? How have those balances changed over time?**

No

**30. What is a reasonable balance and Why?**

N/A

**31. Is the availability of sources (grants or previous "building blocks"), rather than mission or objective, driving expenditures?**

No

**32. Are other sources available to support the same expenditure?**

No

**33. How might you recommend this revenue category change based on the above?**

The current funding level of \$50,000 for CCHD screening does not provide for any type of follow-up service.

**Do We Balance?**

**34. What are total expenditures and total sources? Do they equal one another?**

Yes, see expenditures above. In previous years the allocation for this program was a portion of the kit fees purchased. Since the NBS Follow-up program moved to the Utah State Laboratory (FY17) and a revenue agreement was established, it was lowered to a flat \$50,000 for the program each year.

**35. Have all appropriated or authorized resources been expended at year-end?**

Yes

**36. How have nonlapsing appropriation balances (if any) changed over time?**

N/A

**37. Are fees or taxes supporting a function and are those fees or taxes reasonable?**

Yes, the Newborn Screening fee supports the CCHD Screening program for quality improvement and education efforts to health care providers.

**38. Are there significant risk associated with this organization/function, if so, are there proper controls in place?**

The program has no perceived risks besides normal program operational issues.

The CCHD screening itself is completed using pulse oximetry. Pulse oximetry itself presents no risk to a newborn. However, screening will not catch all heart defects in every infant tested. There is a chance that a heart defect missed by the screening will cause symptoms later. This screening will produce some false positive results. This means that some newborns with healthy hearts will not pass the screening and then may undergo additional testing.

**Program Contact Information**

Amy Nance, MPH  
Program Manager  
Utah Birth Defect Network  
44 N. Mario Capecchi Dr  
Salt Lake City, UT 84114  
Direct number: (801) 883-4661  
Email: aenance@utah.gov

## Component III: Utah Newborn Hearing Screening

### Purpose:

Hearing loss is one of the most common birth defects, occurring at a rate of 1 in 300 babies. The first months and years of life are a critical period for brain development, including speech and language skills, social and emotional development, and academic success. Early identification of hearing loss and appropriate intervention help ensure a child will have the opportunity to reach their maximum potential.

The Early Hearing Detection and Intervention (EHDI) program's purpose is to facilitate early screening, identification, management and early intervention for deaf or hard-of-hearing children statewide. The program maintains a comprehensive EHDI database on every infant born and contacts providers and families to assist with follow-up. The EHDI program supports each family by arranging parent-to-parent support, care coordination with their medical home, access to hearing aids for families that qualify, and enrollment into early intervention services.

### Detailed Questions:

#### What Are We Attempting to Accomplish

**1. *What authorizes delivery/provision of function (statute, intent, rule)?***

- a. UCA 26-10-6 Testing of Newborn Infants  
(<https://le.utah.gov/xcode/Title26/Chapter10/26-10-S6.html>)
- b. Utah Administrative Rule R398-2 Newborn Hearing Screening  
(<https://rules.utah.gov/publicat/code/r398/r398-002.htm>)

**2. *What other activities are undertaken without explicit authority?***

None.

**3. *What alternative government and non-government resources exist to achieve these outcomes? Why is state involved?***

None; there are no other agencies ensuring all infants are universally screened and tracked through the completion of the EHDI process in Utah.

For state fiscal year 2010 the newborn kit fee was increased by \$3.40 to support newborn hearing screening and its associated follow-up. Beginning fiscal year 2016 this funding is provided through a revenue agreement between the Bureau of Children with Special Health Care Needs and the Utah Public Health Laboratories (UPHL). There are no other agencies or persons ensuring that all infants in Utah are universally screened and provided follow-up for hearing loss.

## How We Are Organized

### **4. What organizations are associated with this function?**

The EHDI program within the Children with Special Healthcare Needs (CSHCN) bureau, Division of Family Health and Preparedness, Utah Department of Health.

### **5. What are the missions of the organizations associated with that function?**

Utah's EHDI program provides newborn hearing screening oversight to assure all infants born in Utah have access to early screening, identification and intervention for hearing loss in order to maximize linguistic competence and literacy development for children who are deaf or hard of hearing.

### **6. What outcomes are achieved by the organization associated with this function?**

As determined by the Joint Committee on Infant Hearing Position Statement (2007), the National EHDI goals and reportable state outcomes are the "1-3-6" milestones:

- a. All infants should have access to hearing screening using a physiologic measure at no later than 1 month of age.
- b. All infants who do not pass the initial hearing screening and the subsequent rescreening should have appropriate audiological and medical evaluations to confirm the presence of hearing loss at no later than 3 months of age.
- c. All infants with confirmed permanent hearing loss should receive early intervention services as soon as possible after diagnosis but no later than 6 months of age.

In order to comply with additional state mandates, additional goals and reportable outcomes specific to Utah EHDI are the following:

- a. All newborns receive hearing screening before hospital discharge or before 10 days of age if born out of hospital.
- b. For infants that do not pass, repeat the hearing screening no later than 14 days of age.
- c. If infants do not pass the second hearing screening:
  - i. Test for congenital Cytomegalovirus infection before 21 days of age.
  - ii. Complete a diagnostic hearing evaluation by a pediatric audiologist before 3 months of age.
- d. If infants are diagnosed with hearing loss, they are to be enrolled into early intervention services before 6 months of age.

Utah EHDI outcome data is reported in question #12.

### **7. What data is collected/reported to document/demonstrate progress toward the outcomes?**

Comprehensive EHDI data collected, reported and analyzed include:

- a. Total occurrent births represented in HiTrack (the Utah EHDI database system) and the percent of those matching total occurrent births in Vital Records
- b. Percent of newborns with documented hearing screening
  - i. Percent of newborns screened excluding infant deaths and parent refusals
  - ii. Percent of newborns screened before 1 month of age
- c. Percent of newborns not passing final / most recent screening  
Percent not passing inpatient screen and not receiving an outpatient screen

- d. Percent of newborns of infants not passing with a documented diagnosis
  - i. Percent with no hearing loss
  - ii. Percent with hearing loss
  - iii. Percent diagnosed before 3 months of age
  - iv. Prevalence of hearing loss
- e. No documented diagnosis
  - i. Percent in process
  - ii. Percent infant died or parents declined
  - iii. Percent non-resident / moved
  - iv. Overall Percent Loss to Follow-up (LFU) / Loss to Documentation (LTD) for Diagnosis
    - A. Percent LFU / LTD (= Number of Parents/Family Contacted but Unresponsive + Number Unable to Contact + Unknown)
    - B. Percent LFU / LTD for Diagnosis: Due to Unable to Contact and Unknown
    - C. Percent Unresponsive for Diagnosis: Due to Parents/Family Contacted but Unresponsive
- f. Other cases of hearing loss
  - i. Number of additional cases (e.g. late-onset hearing loss & infants not screened at birth)
  - ii. Number of cases of non-permanent / transient hearing loss
- g. Documented Referral to Early Intervention (EI)
  - i. Percent referred to Part C EI (of those with hearing loss)
  - ii. Percent eligible for Part C EI (of those referred)
  - iii. Percent not referred to Part C and Unknown (of those with hearing loss)
- h. Documented Enrollment in EI
  - i. Percent Receiving EI = Number in Part C EI and Number in Non-Part C EI
  - ii. Percent Receiving EI before 6 months of age (Part C and Non-Part C)
- i. No Documented Enrollment in EI
  - i. Percent with hearing loss receiving No EI services
    - A. Percent infant died / parents declined
    - B. Percent non-resident / moved
    - C. Percent not eligible for Part C EI
    - D. Percent LFU / LTD for Intervention
      - LFU / LTD = Number of Parents / Family Contacted but Unresponsive + Number Unable to Contact + Number Unknown

All of the above data is reported to the CDC on an annual basis. The next data to be submitted will be that of 2015.

In addition to the data submitted to the CDC, Utah EHDI also collects and analyzes the following aggregate and individual facility/midwife data. Individual information is compiled into an "EHDI Report Card" that is distributed on a semi-annual basis to each birthing facility and homebirth hearing project midwife in the state.

- a. Percent of out-of-hospital births' EHDI milestones attainment (screening, diagnosis, EI)
- b. Percent of primary care physician (PCP) notifications of failed initial screening documented in HiTrack
- c. Percent of CMV testing referrals documented in HiTrack

- d. Percent of eligible infants completing CMV testing; both before and after 21 days
- e. Percent inpatient referral rate
- f. Percent inpatient missed screening
- g. Percent outpatient screened or re-screened
- h. Percent diagnostic evaluation completion
- i. Percent EI referrals made
- j. Percent lost to follow-up
- k. Percent transfer babies screened
- l. Percent data submitted weekly
- m. Number of incorrect heel stick numbers entered
- n. Number of missing babies
- o. Number of blank gender
- p. Number of incorrect date of birth
- q. Number of blank primary contact last name

Report cards are utilized for program improvement and Quality Improvement and Quality Assurance initiatives.

**8. *How are appropriations structured to accomplish this function?***

The Division of Family Health and Preparedness, Bureau of Children with Special Healthcare Needs has an agreement with the Division of Disease Control and Prevention, Utah Public Health Laboratories to provide newborn hearing screening and its associated follow-up, which is a portion of the newborn kit fee collections.

**9. *In what units of measure are outputs reported, how and why have those outputs changed over time?***

See #7. Outputs have increased based on increased database/reporting/tracking program capabilities and increased federal EHDI requirements. The Utah EHDI program outputs have shown significant improvement over the last five years, as is evidenced in nationally published data (<https://www.cdc.gov/ncbddd/hearingloss/ehdi-data.html>)

**10. *Are performance measures meaningful and how is management assuring such?***

Yes, performance measures are very meaningful and based on national and state standards. Management assures that the program data collection and reporting mechanisms are such that standard attainment and program performance can be appropriately measured and reported at least annually.

**11. *What kind of external variables impact the organization/function and what is the current status of those variables?***

Over the past five years, on average federal grants represented 56% of the EHDI program’s funding (MCHB, HRSA, and CDC). This funding has been for the specific purposes of EHDI data integration and reducing loss to follow-up with quality improvement methodology. With the federal landscape as it is, this funding is at considerable risk. A new grant project began for HRSA on 4/1/17 with a 43% reduction from the applied funding to the actual award received. The current grant project for the CDC ends on

6/30/17. Although the EHDI program applied for a new CDC grant, it is unknown at this time if a) it will be awarded and b) if so, in what amount. It is anticipated that if funding is received, it will be substantially reduced. In addition, in the President’s proposed federal budget, the Universal Newborn Hearing Screening program is one that is slated to be eliminated. MCHB block grant funding is also uncertain at this time.

**12. Are there standards (industry, national, etc.) for output or output per unit of input? How do they compare to this?**

Every state and territory is required to submit comprehensive data to the Centers for Disease Control and Prevention (CDC) Hearing Screening and Follow-up Survey (HSFS).

This data is published annually with the most recent data available at:  
<https://www.cdc.gov/ncbddd/hearingloss/ehdi-data2014.html>

Utah EHDI performs better than the national average in every reportable category.

CDC 2014 Published Data	National Average	Utah EHDI
Percent screened < 1 month	96.1%	98.1%
Percent diagnosed < 3 months	71.3%	81.1%
Percent EI enrollment < 6 months	67.9%	77.0%
Percent LTFU/LTD	34.4%	13.9%
Percent LTFU/LTD minus Contacted but Unresponsive	25.5%	3.4%

**13. To whom is performance data reported?**

- a. The CDC is responsible for collecting and analyzing EHDI data from across the United States and its territories; data is reported to them annually.
- b. Data is reported to HRSA per grant requirements.
- c. Data is reported for the annual MCH Block Grant.
- d. EHDI data is reported annually to Utah’s Public Health Indicator Based Information System (IBIS).

**14. What decisions are based on reporting data?**

Staffing needs; quality assurance and improvement projects; program goals, objectives, and activities.

**15. How might you recommend the authorization, mission, or performance measurement change?**

N/A.

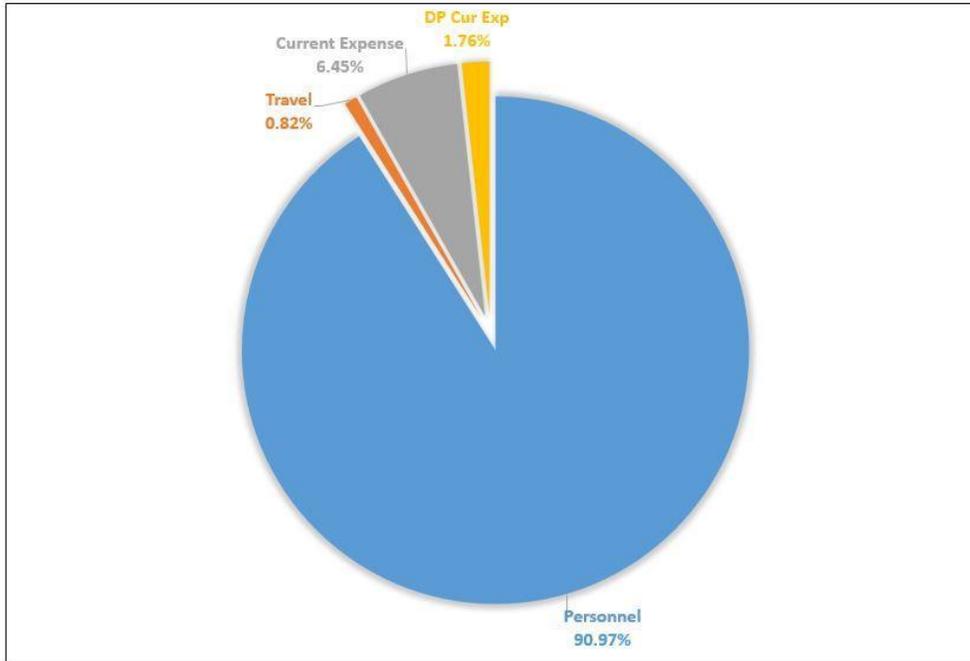
## What We Are Buying

### 16. What is the largest category of expenditure for an organization and how big is it?

The largest category of expenditure is personnel. See below broken down by funding source: Kit Fee only (91.07%) and Federal Grants only (61.51%).

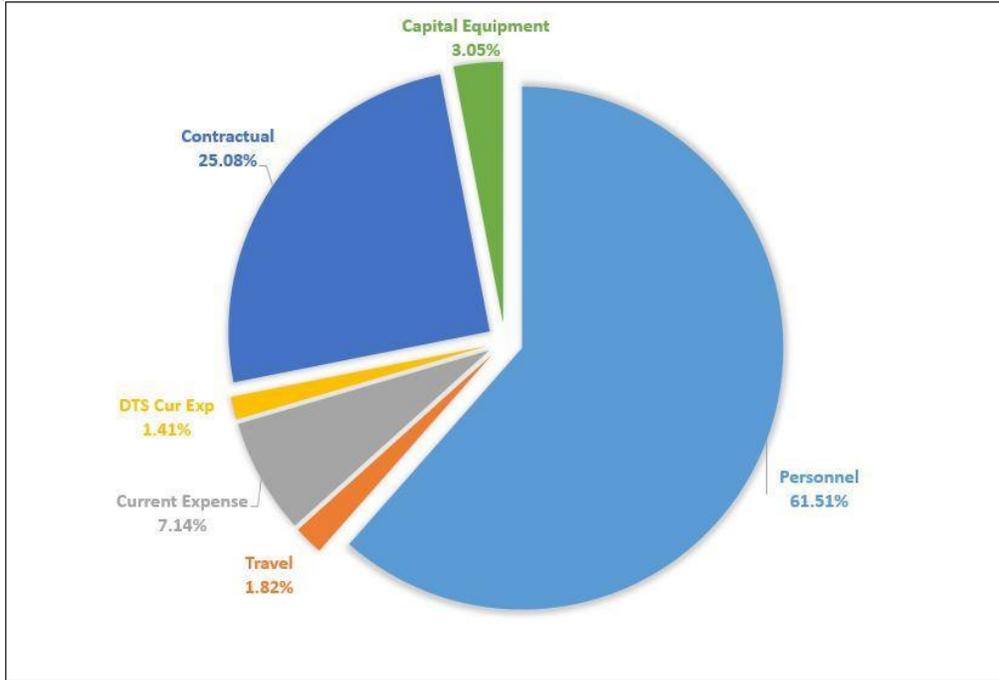
Graph 1: Newborn Hearing Screening Kit Fee Breakdown, 5 year average

Graph 1: This graph represents a percentage of the whole that each expense type encumbers. It covers an average of each type of expense for years 2013 - 2017. Because 2017 is still in progress, the 2017 number contains the actual amount of expense through period 10, with anticipated amounts for periods 11,12, and 13.



**Graph 1: EHDl Grant Funding Breakdown, 5 year average**

Graph 1: This graph represents a percentage of the whole that each expense type encumbers. It covers an average of each type of expense for years 2013 - 2017. Because 2017 is still in progress, the 2017 numbers are estimated year end amounts.



**17. How does this expenditure support the above justification/authorization?**

Personnel are essential to not only maintaining, but improving, program performance, which directly correlates with the percentage of infants completing the EHDl process in a timely manner.

**18. What is that category of expenditure buying (how many/cost per unit)?**

The Kit Fee funds supports 3.07 FTE, and Federal Grants support 2.83 FTE.

**19. How does the above relate to units of output?**

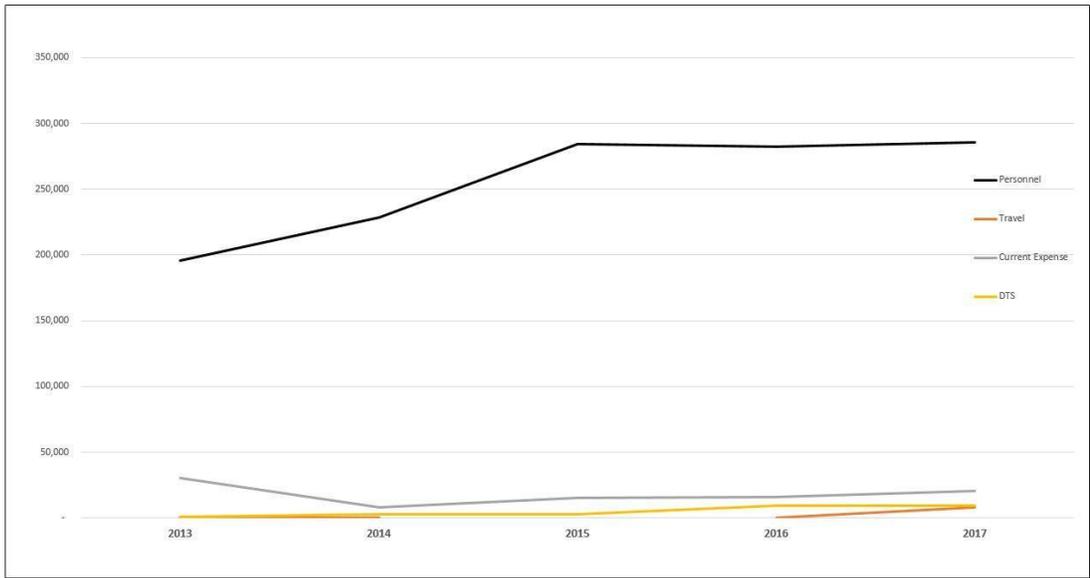
These personnel are necessary for performing essential program functions including compliance, data collection and analysis, quality assurance and quality improvement.

**20. How has the expenditure changed over five years relative to the units of output?**

Due to the increase in newborn hearing screening and follow-up requirements as required by additional testing and reporting demands, personnel needs and activities have increased. See below for Five Year Spending Trends for the Kit Fee and EHDl Federal Grants.

**Graph 2: Newborn Hearing Screening & Follow-Up Program Spending Trends**

Graph 2: This graph represents the trend in spending (by category) from 2013 to 2017. Because 2017 is still in progress, the 2017 numbers contain the actual amount of expense through period 10, with an anticipated amount for periods 11, 12, and 13.

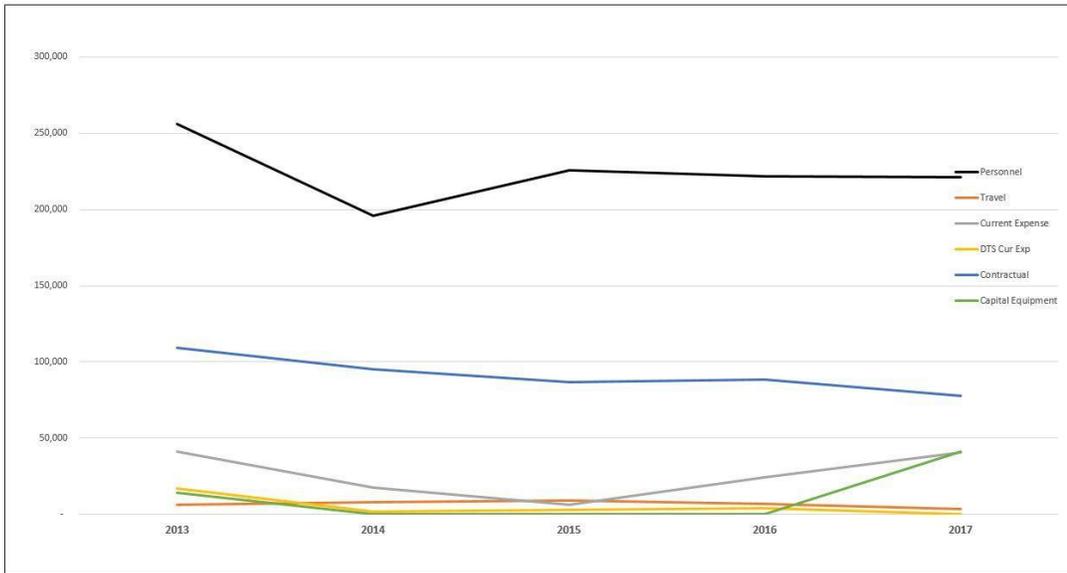


	2013	2014	2015	2016	2017	Newborn Hearing Screening Fee Breakdown, 5 Year Average	
Personnel	195,503	228,848	284,612	282,150	285,740	255,371	91.07%
Travel	6	197		324	8,210	2,184	0.78%
Current Expense	30,111	7,894	14,901	16,172	20,204	17,856	6.37%
DP Cur Exp	867	3,006	2,453	9,100	9,608	5,007	1.79%
Totals	226,487	239,945	301,966	307,746	323,762	280,418	100.00%

\* 2017 estimated year end expenditures

**Graph 2: EHD Grant Program Spending Trends**

Graph 2: This graph represents the trend in spending (by category) from 2013 to 2017. Because 2017 is still in progress, the 2017 numbers are estimated year end amounts.



**HRSA, CDC, MCH Grant Breakdown, 5 Year**

	2013	2014	2015	2016	2017		Average
Personnel	256,053	195,934	225,807	221,878	221,219	224,178	61.51%
Travel	6,131	7,868	9,063	6,780	3,300	6,628	1.82%
Current Expense	40,978	17,589	6,301	24,480	40,825	26,035	7.14%
DTS Cur Exp	16,864	1,904	2,903	3,945	-	5,123	1.41%
Contractual	108,996	94,983	86,897	88,201	77,937	91,403	25.08%
Capital Equipment	14,380	-	-	-	41,200	11,116	3.05%
	443,402	318,278	330,971	345,284	364,481	364,483	100.00%

**21. Are there any outliers/anomalies in current or budgeted spending in this category?**

No.

**22. Does the amount of expenditure for a category change significantly in accounting period 12 or 13? Why?**

No.

**23. How might you recommend this expenditure category change based on the above?**

N/A.

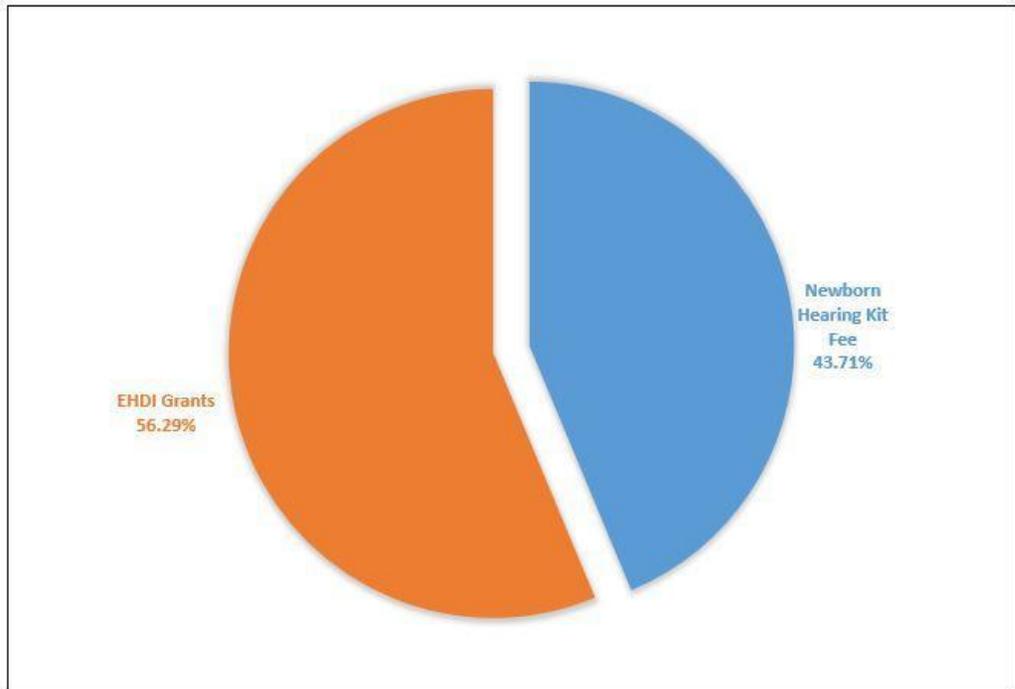
## How We Are Paying For It

**24. What is the largest fund or account from which resources are drawn to support the above expenditures and how big is it?**

The agreement between UPHL and CSHCN provides a revenue transfer of \$325,000 to support the Newborn Hearing Screening activities, which is the largest single source. See graph below to see Kit Fee vs Federal Grants (all 3 grants combined: HRSA, CDC, MCH).

Graph 1: EHDl Program Funding Breakdown, 5 year average

Graph 1: This graph represents a percentage of the whole that each expense type encumbers. It covers an average of each type of expense for years 2013 - 2017. Because 2017 is still in progress, the 2017 numbers are estimated year end amounts.



**25. What are the revenue sources for that fund or account and what are their relative shares?**

See Graph above. The revenue source of the Kit Fee fund is the money collected from the newborn screening kit fees.

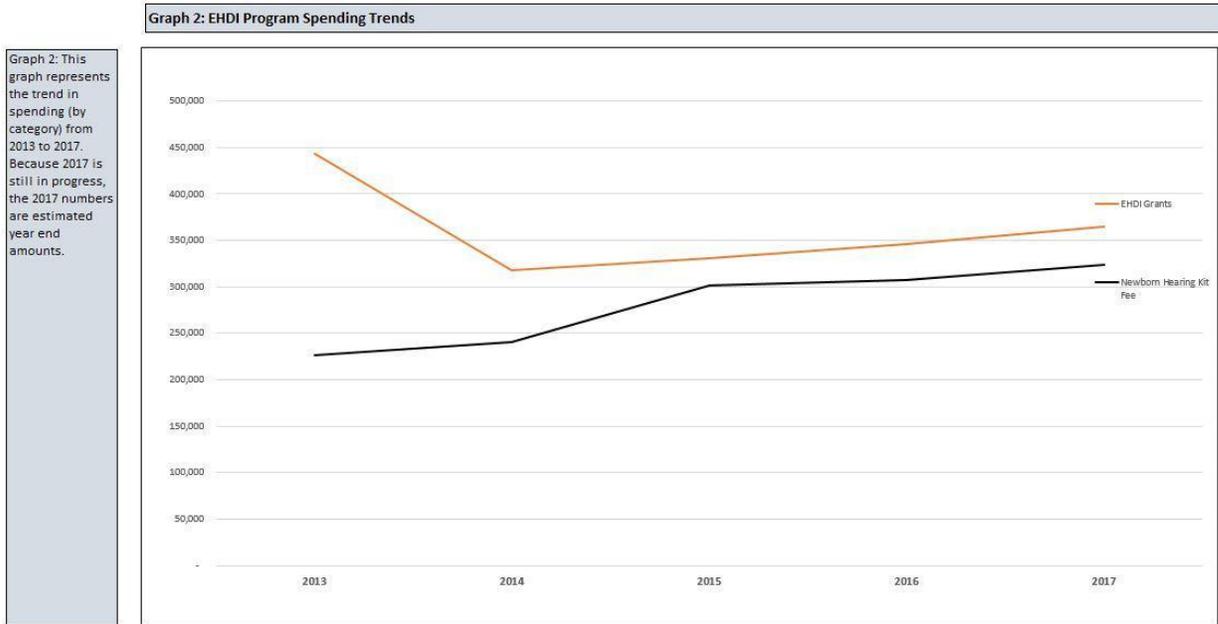
**26. Is the source one-time or ongoing and do ongoing sources match or exceed ongoing expenditures?**

This is an ongoing source of funding.

**27. How has the source changed over time relative to expenditures and units of output?**

See graphs below and in question #20. Increased Kit Fee funding has supported EHDl personnel in the improvement of program outputs; directly improving the timeliness of newborn hearing screening process completion and EHDl milestone attainment for Utah infants.

See below for combined five-year graph of Kit Fee and Federal Grant source funding.



	2013	2014	2015	2016	2017	HRSA, CDC, MCH, Kit Fee Grant Breakdown, 5 Year Average	
Newborn Hearing Kit Fee	226,487	239,945	301,966	307,746	323,762	279,981	43.71%
EHDI Grants	443,402	318,278	330,971	345,481	364,481	360,523	56.29%
<b>TOTAL</b>	<b>669,889</b>	<b>558,223</b>	<b>632,937</b>	<b>653,227</b>	<b>688,243</b>	<b>640,504</b>	<b>100.00%</b>

**28. Are there any outliers/anomalies in current or budgeted periods for this source?**

No.

**29. Does source have unencumbered balances that relate directly to this function/organization? How have those balances changed over time?**

No.

**30. What is a reasonable balance and Why?**

N/A.

**31. *Is the availability of sources (grants or previous "building blocks"), rather than mission or objective, driving expenditures?***

Our mission remains; what we can achieve is dependent on funding to support the necessary personnel to achieve the program objectives.

**32. *Are other sources available to support the same expenditure?***

No.

**33. *How might you recommend this revenue category change based on the above?***

Federal funding is precarious at best and it is anticipated that the EHDl program will require an increase in state funding to support the statewide newborn hearing screening and follow-up program and to maintain its current success.

**Do We Balance?**

**34. *What are total expenditures and total sources? Do they equal one another?***

See graphs above. Yes.

**35. *Have all appropriated or authorized resources been expended at year-end?***

Yes.

**36. *How have nonlapsing appropriation balances (if any) changed over time?***

N/A.

**37. *Are fees or taxes supporting a function and are those fees or taxes reasonable?***

Yes

**38. *Are there significant risks associated with this organization/function; if so, are there proper controls in place?***

N/A.

**Program Contact Information**

Stephanie McVicar, Au.D. CCC-A  
Program Manager  
Early Hearing Detection & Intervention Programs  
44 N. Mario Capocchi Drive  
Salt Lake City, UT 84114  
Direct number: (801) 584-8218  
Email: [smcvicar@utah.gov](mailto:smcvicar@utah.gov)

Appendix 1. Kit fee and service comparison

State/NBS Program	#Births	1 or 2 screen State	Screening fee	Additional screening fees	RUSP conditions (out of 34)	Fee/Funding
Alabama	60,000	1	\$150.00	NA	30	NBS Fee and General funds
Alaska	11,300	2	\$159.50	Included in the initial fee	31	
Arizona	85,400	2	\$30.00	\$65.00	30	
Arkansas	11,500	1	\$121.00	Included in the initial fee	31	
California	492,000	1	\$129.25	Included in the initial fee	32	
Colorado	66,300	2	\$92.00	Included in the initial fee	31	"Colorado NBS is in a financial crisis" Karen Trierweiler
Connecticut	35,800	1	\$98.00	Included in the initial fee	32	money collected goes into general funds
Delaware	11,500	2	\$135.00	Included in the initial fee	31	NBS Fee, General Funds, Federal Funds
District of Columbia	9,600	1	\$0.00	Included in the initial fee	30	federal funds
Florida	224,300	1	\$0.00	\$0.00	31	NBS Fee , Bill insurance and Medicaid; grants for EHDI
Georgia	131,400	1	\$63.00	\$63.00	31	General Funds
Hawaii	18,500	1	\$55.00	Included in the initial fee	31	NBS fee
Idaho	22,900	2	\$51.00	\$49.00	30	NBS Fee and Federal Funds
Illinois	158,200	1	\$118.00	\$118.00	33	NBS fee
Indiana	84,100	1	\$90.00	Included in the initial fee	30	NBS fee
Iowa	39,685	1	\$122.00	Included in the initial fee	31	NBS fee
Kansas	39,200	1	\$0.00	Not Provided	30	not provided
Kentucky	56,000	1	\$99.00	Included in the initial fee	33	NBS Fee and General Funds
Louisiana	65,100	1	\$30.00	Not Provided	30	General Funds , Medicaid
Maine	71,500	1	\$110.00	Included in the initial fee	31	NBS Fee
Maryland	73,700	2	\$106.00	Included in the initial fee	31	not provided
Massachusetts	71,500	1	\$98.45	Included in the initial fee	28	NBS Fee
Michigan	113,400	1	\$125.16	\$117.11	31	NBS Fee
Minnesota	70,000	1	\$150.00	\$150.00	32	NBS fee
Mississippi	38,400	1	\$110.00	\$110.00	31	NBS Fee
Missouri	75,100	1	\$85.00	\$85.00	33	NBS Fee and Federal funds
Montana	12,600	1	\$112.25	\$112.25	31	NBS Fee
Nebraska	26,700	1	\$45.50	Included in the initial fee	31	NBS Fee and Federal funds
Nevada	36,300	2	\$81.00	Included in the initial fee	30	NBS Fee
New Hampshire	12,500	1	\$71.00	\$71.00	28	NBS Fee
New Jersey	103,200	1	\$90.00	Included in the initial fee	31	NBS Fee and Federal funds
New Mexico	26,000	2	\$138.00	Included in the initial fee	31	NBS Fee
New York	237,300	1	\$0.00	Not Provided	33	General Funds
North Carolina	120,900	1	\$44.00	Included in the initial fee	31	not provided
North Dakota	12,000	1	\$75.00	Included in the initial fee	31	NBS Fee, General Funds, Federal Funds
Ohio	139,300	1	\$74.61	\$74.61	31	NBS Fee
Oklahoma	53,200	1	\$137.28	Not Provided	31	NBS Fee
Oregon	45,700	2	\$64.00	Included in the initial fee	31	NBS Fee
Pennsylvania	141,100	1	\$0.00	Included in the initial fee	34	State and Federal funds
Puerto Rico	31,200	1	\$78.00	Included in the initial fee	31	not provided
Rhode Island	11,000	1	\$162.98	Not Provided	31	NBS fee
South Carolina	58,200	1	\$81.78	Included in the initial fee	31	NBS fee and federal funds
South Dakota	12,400	1	\$75.00	Included in the initial fee	31	NBS Fee
Tennessee	81,700	1	\$125.00	Included in the initial fee	31	NBS Fee
Texas	403,700	2	\$55.24	\$55.24	31	NBS fee and general funds
Utah	52,000	2	\$112.16	Included in the initial fee	31	NBS Fee
Vermont	6,000	1	\$125.00	Included in the initial fee	31	NBS Fee
Virginia	103,300	1	\$78.00	Included in the initial fee	31	not provided
Washington	89,000	2	\$76.10	Included in the initial fee	30	not provided
West Virginia	19,900	1	\$91.37	Not Provided	31	NBS Fee and Federal Funds
Wisconsin	67,100	1	\$109.00	Not Provided	31	NBS fee
Wyoming	8,000	2	\$77.00	Included in the initial fee	30	Kit fee and general funds; Colorado completes testing

## Appendix 2: Reflections from NBS Customers

The Newborn Screening Program is a vital part of the care we provide to infants and their families in Utah. This program has been a mainstay of accurate and prompt information that impacts how infants are managed. The system does an excellent job of educating providers promptly on an abnormal screen so that the provider can maintain the medical home model with the family. The Utah Newborn Screening Program also links both providers and the families with the subspecialists that are required to manage these rare diseases in a very timely manner. The infants who are diagnosed before symptoms emerge benefit greatly from medical care that can help prevent some of the sequelae of the disease processes. As a pediatrician on the Wasatch front, I am very satisfied with the program.

Kim Gehle, MD  
Mountain View Pediatrics  
9720 S 1300 E Ste E100  
Sandy UT 84094

The newborn screening program for Cystic Fibrosis has redefined the expected outcomes of the disease. Due to earlier diagnosis (and earlier interventions) survival for patients with disease exceeds 40 years now. We are also observing improved nutrition and lung function. The timeliness of the UT NBS for CF meets national guidelines. Our center is very satisfied with the services provided (testing and genetic counselling). We are also very happy with the high level of collaboration and communication with the NBS team.

Please let me know if you have any questions.

Yours,

Fadi Asfour, M.D.  
Medical Director, The Pediatric Intermountain Cystic Fibrosis Center  
Assistant Professor, Pediatric Pulmonology  
University of Utah, School of Medicine

The newborn screening program in Utah provides services that are invaluable to the families of babies who have a positive screening test. It's an overwhelming and frightening time for parents. The experience and knowledge of the newborn screening program staff helps provide information, resources, and, more importantly, comfort at a time when it is needed most.

It is critical that the testing and notification services provided by the Utah newborn screening program are done in a timely manner so that the devastating consequences of these disorders can be prevented. The Utah newborn screening program does an excellent job in making sure that the babies are identified and the clinicians and families are notified in the fastest time possible.

As an advocate for newborn screening disorders, I have seen circumstances where babies and families have suffered the consequences of a poorly run newborn screening program. Families in Utah are lucky to have one of the premier programs in the country.

Amy Oliver,  
Parent of a child with PKU

To whom it may concern:

Pediatric endocrinology has 2 tests on the newborn screen. Both are important for protection of the infant from "silent" conditions that can be easily treated and in which treatment results in significant improvement in the child's health and wellbeing.

[..]

The state program is doing an excellent job. When I moved to UT 15 years ago, I thought the program was very much behind the standards I was used to in other states. Over the time I have lived in UT and worked with the program, I've been very impressed. In the last few years, the program has substantially improved their time line for reporting results. They are extremely helpful in trouble shooting test results. They critically evaluate their data and their processes. I've been involved in numerous discussions about how to control costs and still provide extremely high quality results. When I have been in a position to compare the quality of testing and the support given to providers with that provided by other state programs, I find the program in the state of Utah to be very competitive with other states.

In summary, I find the program to be of very high quality and to be very supportive to families and clinicians.

If you have any questions, please feel free to contact me.

Sincerely,

Mary Murray MD, FAAP  
Chief, Pediatric Endocrinology and Diabetes  
University of Utah School of Medicine



## State Newborn Health Screening Policies

BY TAHRA JOHNSON AND MARGARET WILE

State public health programs screen an estimated 4 million infants annually for genetic and metabolic disorders. States screen newborns because early detection can prevent severe cognitive and physical disabilities, and even death. Screening newborns can also save states and families money by avoiding expensive medical treatments later.

One example of how early detection can prevent cognitive and physical disabilities is the screening for cystic fibrosis, which affects the lungs and digestive system. Newborns with cystic fibrosis detected through screening can receive treatment early, which slows the condition's progression and allows for a better quality of life.

Currently, there are three types of newborn screening tests: a hearing screen, a [heel stick](#) (collecting a small blood sample) and a [pulse oximetry](#) (evaluating the amount of oxygen in the blood). If a child tests positive for a disorder, additional work must be done to confirm the diagnosis and treat the condition to help ensure that children with potentially life-threatening conditions receive early intervention and care.

Factors such as the condition's prevalence and severity, treatment availability and effectiveness, and cost may help determine whether a state screens for a particular disorder. Recent advances in technology enable states to use existing laboratory techniques to add a substantial number of conditions to their newborn screening list (known as a panel) in a relatively short timeframe.

Each state decides which conditions to include in its newborn screening program and most include those on the federal [Recommended Uniform Screening Panel \(RUSP\)](#). In some states, the panel is set in state statute, while in others, the state health department or other entity has the authority to alter the panel.



### Federal Action

The [Advisory Committee on Heritable Disorders in Newborns and Children](#), established under the Public Health Service Act, advises the U.S. Department of Health and Human Services secretary on universal newborn screening test guidelines, standards and technology. Together, the advisory committee and secretary decide on the Recommended Uniform Screening Panel, which provides guidance, but not a mandate, to states. The panel

B-1

### Did You Know?

- Every year, newborn screening tests identify more than 5,000 babies with rare conditions.
- The national Recommended Uniform Screening Panel includes 34 core conditions and 26 secondary conditions for all newborn screening programs.
- Most states charge a fee for newborn screenings, which can range from \$15 to \$100 and is generally covered by private health insurance, Medicaid or the Children's Health Insurance Program (CHIP).

currently includes 34 core conditions for which specific tests and treatments exist. In addition, 26 [secondary conditions](#) have been identified that may be detected through screenings for core conditions. In other words, no additional tests are required to identify a secondary condition. Three core conditions were added to the national recommended panel in 2016, including Pompe disease, a serious muscular disorder. As the science evolves, other conditions may be added to the RUSP.

To qualify as a core condition in the panel, it must, at a minimum, [meet three qualifications](#): “It can be identified at a time (24-48 hours after birth) at which it would not ordinarily be detected clinically; a test with appropriate sensitivity and specificity is available for it; and there are demonstrated benefits of early detection, timely intervention, and efficacious treatment of the condition.” Additionally, rigorous clinical evidence review is performed by the advisory committee before a condition is added to the RUSP.

## State Action

Prior to the three conditions added in 2016, 42 state screening panels matched or exceeded the federal recommendations. Several states, including California, Illinois, Maryland, Mississippi, Missouri, New York and Tennessee, [screen for almost 60 core conditions](#).

The process for adding new diseases or disorders to a state’s newborn screening panel differs among states. Some states consult advisory panels to assist in making recommendations, some states require legislation to enact a change and in certain states, the state health department has the authority to revise the newborn screening panel by regulation.

[Tennessee](#) added the lysosomal storage disorders (such as Krabbe and Pompe) to its state screening panel in 2015. A work group was formed to plan the implementation and these diseases will be instituted into the screening panel by July 2017. California in 2016 enacted [legislation](#) requiring its newborn screening panel to include any disease that is detectable in blood samples within two years of its inclusion in the federal recommendations. In January 2017, Nebraska introduced a [bill](#) that specifically adds the three new conditions to the state’s newborn screening panel, enabling the state to be current with the

**The process for adding new diseases or disorders to a state’s newborn screening panel differs among states. Some states consult advisory panels, some require legislation and some give the authority to the state health department.**

RUSP recommendations.

[Maryland](#) created an expert advisory group to recommend best practices for screening for [congenital heart disease](#). The state is implementing the recommendations for screening and following up with families after diagnosis.

Illinois was ahead of the curve on screening for Pompe disease, which, when treated early with a special diet that prevents serious cognitive impairment, can extend life. The [bill](#) required the Department of Public Health to establish screening for Pompe. A pilot program completed in 2014 helped determine how to optimize and ensure effectiveness of the screening, which is now used for all newborns.

In some states statutes or regulations address payment for newborn screening services and other related issues. These include treating disorders, such as requiring insurers to cover special medical foods, and regulating storage, use and disposal of blood samples. The laws and regulations also address issues such as privacy and confidentiality, parent education about newborn screening, contracting services and laboratory standards.

Screening lab capabilities and capacity also vary among states. Most states have an in-state laboratory, but some send their tests to a regional laboratory or contract with a commercial laboratory. Regional laboratories may be more affordable for less-populated states, but if those labs have limited capabilities, it could make it more difficult for a state to add new conditions to its screening panel. Currently, four labs across the country collectively test for 12 or more states.

## Additional Resources

[NCSL webpage, Newborn Hearing Screening Laws](#)

[Newborn Screening Clearinghouse—Baby’s First Test](#)

[Centers for Disease Control and Prevention, State Legislation, Regulations and Hospital Guidelines for Newborn Screening for Critical Congenital Heart Defects](#)

## NCSL Contacts

[Tahra Johnson](#)  
(303) 856-1389

[Margaret Wile](#)  
303-856-1459