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Every Newborn, Every State:

Funding to End Variability in Newborn Screening RUSP Implementation

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Overview

Started in the 1960's, newborn screening is widely regarded as one of the most successful public health initiatives. Thanks to these state-run programs, each of the nearly 3.6 million babies born in the U.S. is screened for certain serious and rare conditions at birth, allowing for early treatment of disease before the onset of preventable death or disability. The United States Department of Health and Human Services (HHS) maintains a comprehensive list of core and secondary conditions, referred to as the Recommended Uniform Screening Panel (RUSP), which serves as a guideline for state newborn screening panels. There are currently 40 core conditions, and 26 secondary conditions listed on the RUSP. Early detection and treatment of these conditions can greatly improve quality of life and reduce direct medical costs while also averting indirect costs (e.g., work productivity losses for caretakers).

Until 2025, the RUSP was formulated based on the recommendations of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC). The ACHDNC voted on whether to recommend to the HHS Secretary that a condition be added to the RUSP, by assessing whether screening for and diagnosis of the condition would offer substantial health benefits and whether there is a validated test and treatment.[1] Each state then has the authority to decide which conditions to include on the screening panel for that state.

State public health laboratories and their local partners play a vital role in protecting the nearly 4 million newborns screened each year.

They are responsible for accurate testing and timely follow-up, all while navigating the challenges and uncertainties of each state's annual budget cycle.

Objective

The objective of this paper is to estimate the cost of implementing newborn screening for conditions added to the RUSP in the last 10 years in the states that have not yet begun screening for such conditions.[2] The recently added conditions are: Pompe, X-ALD, MPS I, MPS II, GAMT, Infantile Krabbe Disease, DMD and MLD (see Exhibit 1). As part of the analysis, we also estimate the costs of two additional conditions that may be added to the RUSP in the next three to five years. This paper focuses on our existing newborn screening system, which is largely dried blood spot (DBS)-based biochemical testing with occasional additional confirmatory testing but does not address the feasibility or necessity of system modernization by wholesale incorporation of genetic sequencing tests, such as whole genome sequencing or targeted gene panel sequencing tests.

[1] In April 2025, the ACHDNC was disbanded and on December 16, 2025, HHS Secretary Kennedy exercised his authority to add two conditions to the RUSP (Duchenne Muscular Dystrophy (DMD) and Metachromatic Leukodystrophy (MLD)).

[2] The cost estimates presented in this paper are intended as a preliminary foundation to support discussion of implementation needs and do not represent any individual state's actual budget. To produce estimates that reflect operational realities, states will need to develop state-specific, detailed budgets with their newborn screening laboratories that incorporate implementation requirements, timelines, and available funding sources.

Modeling Methodology

Our cost model is based on the research and analysis of condition-specific estimates in the states that have implemented or are getting ready to implement newborn testing for these conditions. All the research described in this paper is based on data available as of January 2026.

To inform the analysis, we reviewed state legislation and publicly available newborn screening program reports, Health Resources & Services Administration (HRSA) and advocacy organization websites and peer review journals. We also connected with select state newborn screening programs to discuss notable trends, enablers and challenges associated with newborn screening.

We then used our state-specific research and interview findings to inform our modeling estimates across states. We collected cost estimates from a set of states where this information was publicly available and identified a range of potential estimates based on states' size, capabilities, and experience with similar testing methods. Based on this analysis, we grouped states into two tiers for modeling purposes. We defined Tier 1 as those states that are likely to have lower costs due to their capabilities or because they are already screening for conditions tested by similar methods. We define Tier 2 states as those with smaller populations and number of annual births (screening less than 90,000 newborn samples annually), that lack the size and resources of the larger states. States with highly developed newborn screening programs and infrastructure can leverage their resources to implement newer RUSP conditions across a larger number of newborns tested. Costs sustained in states with a fewer number of newborns, therefore, are generally higher than in the larger states. We then applied a uniform estimate for each of the tiers and arrived at an average estimate of cost per sample for each of the conditions, taking into account which states are not yet screening for these conditions.

We also conservatively assume that two additional conditions will be added to the RUSP in the next three to five years. Five conditions have been added to the RUSP between 2022-2025.

Research Findings

State lab capabilities and existing newborn screening processes vary widely, resulting in varying implementation and funding costs. Implementing newborn screening for new conditions can take several years given a labor-intensive and time-consuming implementation process, coupled with funding constraints and competing state budget priorities. The key research and interview findings we use to inform our estimates are listed below.

- States have been increasingly using advanced processes and new screening approaches to accelerate newborn screening implementation and reduce costs (e.g., using the same instrument for all lysosomal storage disorders).
- States' implementation costs of adding screening for new conditions may include modifying existing

lab space and systems, installing instruments and conducting assay validation, updating laboratory information management system, and hiring and training lab and care coordination personnel. Our research shows that states typically include these costs in their estimates, and they may also include the costs of second-tier screening (this is a small fraction of the cost per sample relative to other costs).

- In many instances, implementing a new type of RUSP condition typically requires the most investment; the next several conditions may be multiplexed with the first and screened by the same testing method, depending on the subsequent condition and testing approach. Some states add one condition at a time and others add two or three simultaneously spreading the costs across them.
- 12 states have partnered with larger states to leverage their lab infrastructure and personnel (see Exhibit 2). Most of these are smaller states where less than 25,000 newborns are being screened annually. Developing needed newborn screening capabilities in such states is often cost prohibitive.
- 12 states are two-screen states, which means that they screen their newborns twice (e.g., the first test soon after birth and the second within the first two weeks of birth). This approach helps catch the disorders that may be missed the first time due to physiological changes in the baby. The rest of the states are one-screen states (although they typically retest a share of samples to confirm results or in case of unsatisfactory samples).
- Fourteen states have enacted legislation that requires newborn screening for all conditions on the RUSP within a specific period after a condition is approved. Each of these states uses its own laboratories for testing and does not conduct testing on behalf of any other state. The only exception is Iowa, which also tests samples from Alaska, North Dakota, and South Dakota.

Modeling Assumptions

For each condition, we estimate average costs per newborn sample as a function of aggregate cost for states not screening for the condition and the number of samples across those states.

Estimating annual number of tested newborn samples: When estimating the number of newborn samples tested annually in states not currently screening for a specific condition, we start with the number of annual births in each of those states. We then take into account whether those states are one-screen or two-screen states. For one-screen states, we estimate that 15% of the births may need to submit a second sample (e.g., sample retesting to confirm a result or retest a failed sample run).

Estimating annual testing costs: Based on our findings above and a set of state-specific cost estimates that we collected in the research process, we group all states into two cost tiers for modeling purposes. Our cost estimates are comprehensive and consistent with the costs provided by states in their estimates (See types of costs described under Research Findings).

The below cost estimates were developed based on legislative research of data points provided by states. See Exhibit 3 for a summary of modeling assumptions.

Pompe, MPS I, MPS II, Krabbe, X-ALD, GAMT, DMD and MLD:

- **Tier 1** consists of states that have already developed the capabilities and infrastructure to add newer RUSP conditions at minimal cost. We define Tier 1 as the larger states (i.e., states screenings at least 90,000 newborn samples annually) that have already added one of the lysosomal storage disorders we discuss in this report (Pompe, MPS I, MPS II, or Krabbe). We assume modest per sample cost for Tier 1 states ($2.50 for each of the LSDs, $1.20 for GAMT and $1.30 for X-ALD), given states' ability to leverage existing testing processes and/or infrastructure for the newer RUSP conditions not yet added. Tier 1 costs for DMD and MLD are expected to be meaningfully higher at $7.50, as these are conditions were added to the RUSP most recently, with research showing estimated costs for DMD and MLD ranging between $7 and $11.
- **Tier 2.** We define Tier 2 as lower volume states (i.e., states screening less than 90,000 newborn samples annually either individually, or collaboratively if they are the states outsourcing to another state lab) or those that have not yet added newborn screening for any lysosomal storage disorders (LSDs).
    - We assume the per sample cost of $6.50 for LSDs, $6.30 for GAMT and $6.50 for X-ALD for Tier 2 states. These estimates are based on state-specific costs derived from our legislative research (See Modeling Methodology section for more details.)
    - Once a Tier 2 state adds their first LSD, we assume that the next condition can be added at the Tier 1 cost for that condition, given that the state has developed needed infrastructure while adding their first LSD.
    - Tier 2 costs for DMD and MLD are expected to be meaningfully higher - at $8.50, as these are conditions recently added to the RUSP (December 2025), with state-specific legislative research showing estimated costs for DMD and MLD ranging between $7 and $11.

Two RUSP Conditions to be Added over the next 3-5 years:

Our cost estimates assume the need to implement two additional conditions that could be added to the RUSP over the next 3-5 years. Our cost assumptions are described below for Tier 1 and Tier 2 states:

- **Tier 1:** We assume the cost of $7.50 for the 30 Tier 1 states, similar to DMD and MLD, as states may require additional investments, or states will eventually reach testing capacity and/or they will need to expand their testing capabilities and update or replace equipment.
- **Tier 2:** We assume a cost of $8.50 for each of the two conditions for 21 Tier 2 states, given their more limited capabilities and lower volumes.

See Exhibit 3 for a summary of modeling assumptions described above.

Modeling Results

If all states currently not testing for Lysosomal Storage Disorders (LSDs), Guanidinoacetate Methyltransferase (GAMT) Deficiency, X-linked adrenoleukodystrophy (X-ALD), Duchenne Muscular Dystrophy (DMD) and Metachromatic Leukodystrophy (MLD) were to implement testing for those conditions, we estimate the aggregate costs across those states to be ~$98 million, equating to $4.50 per sample or $6.07 per newborn (the difference comes from some states being two-screen states). Assuming two more conditions are added to the RUSP over the next three to five years, we estimate the aggregate costs of adding those future conditions to be $75M across states, equating to $7.67 per sample or $10.45 per newborn.

In aggregate, considering both current RUSP recommendations and potential future additions, we estimate an aggregate cost of $173M, equating to $5.14 per sample or $6.95 per newborn.

See Exhibit 4 for a summary of modeling results described above.

Looking Ahead

Over the past 20 years, laboratory advances have greatly improved identification of disorders at birth and have allowed for simultaneous high-volume testing of multiple disorders via approaches such as tandem mass spectrometry. At the same time, advances in treatments have made newborn screening increasingly relevant, since treatment outcomes largely depend on rapid disease identification and treatment start.

Yet, due to resource constraints, even beyond recently-added conditions, many of the states are not yet screening newborns for conditions added to the RUSP over the past 10 years often due to a high level of required investments and pressure on state budgets. While the initial investment to add one of the disorders described in this paper may be significant, the next condition to be added can in many cases use similar testing methods and the same infrastructure, resulting in meaningful savings. Moreover, numerous sources have documented that newborn screening is cost-effective.[3]

For some families, the scope of a state's newborn screening program can mean the difference between life and death for their children. The disparities among state newborn screening programs have prompted some advocates to describe the consequences of such disparities as "death by zip code," implying that the state of birth can influence whether a newborn receives critical screening and often life-changing healthcare. In states which delay implementation of newborn screening for RUSP conditions, many parents

[3] See, e.g., Rana, R., Keramat, S. A., & Ahmed, M. (2025, April 16). Cost-effectiveness of newborn screening for severe combined immunodeficiency: A systematic review. Clinical and Experimental Pediatrics, 68(9), 628–640. https://doi.org/10.3345/cep.2025.00052; Carroll, A. E., & Downs, S. M. (2006). Comprehensive cost-utility analysis of newborn screening strategies. Pediatrics, 117(Supplement 3), S287–S295. https://doi.org/10.1542/peds.2005-2633H; Tiwana, S. K., Rascati, K. L., & Park, H. (2012). Cost-effectiveness of expanded newborn screening in Texas. Value in Health, 15(5), 613–621. https://doi.org/10.1016/j.jval.2012.02.007.

experience a diagnostic odyssey which can take on average 5-7 years seeking a diagnosis that could have been identified shortly after birth if their state had included an already recommended condition in its testing panel.

Funding availability is one of the key challenges to increased implementation of newborn screening for RUSP conditions in the states. Congress has failed since 2019 to reauthorize the statute which provides existing federal support to the states, and the CDC and HRSA have drastically changed their state support grant processes leaving states with diminishing funding opportunities to implement RUSP conditions. As a result, despite the best and often heroic efforts of state laboratory personnel and their partners, too many babies are falling through the cracks in the system and this study validates the need for additional resources to support states' timely implementation of newborn screening for all RUSP conditions.

This is a critical moment for our nation's newborn screening system—one that demands strong leadership to address the growing uncertainty facing state programs each day. The goal remains clear: to identify and treat newborns as early as possible to prevent avoidable disability and death. This research demonstrates that timely implementation of newborn screening across states is achievable with additional support.

Exhibit 1: States Not Yet Screening for Recently Added RUSP Conditions

	Pompe	X-ALD	MPS I	MPS II	GAMT	Infantile Krabbe Disease	DMD	MLD
Added to RUSP	Mar 2015	Feb 2016	Feb 2016	Aug 2022	Jan 2023	Jul 2024	Dec 2025	Dec 2025
# of States Not Screening	43	3	5	33	37	36	49	51

Note: Spinal Muscular Atrophy (SMA) is another condition that has been added to the RUSP more recently (2018). Since all states have implemented newborn screening for SMA, we do not include it in the analysis.
Source: NewSteps, ALD Alliance, and Manatt Analysis

Exhibit 2: Screening Lab Utilization Across States

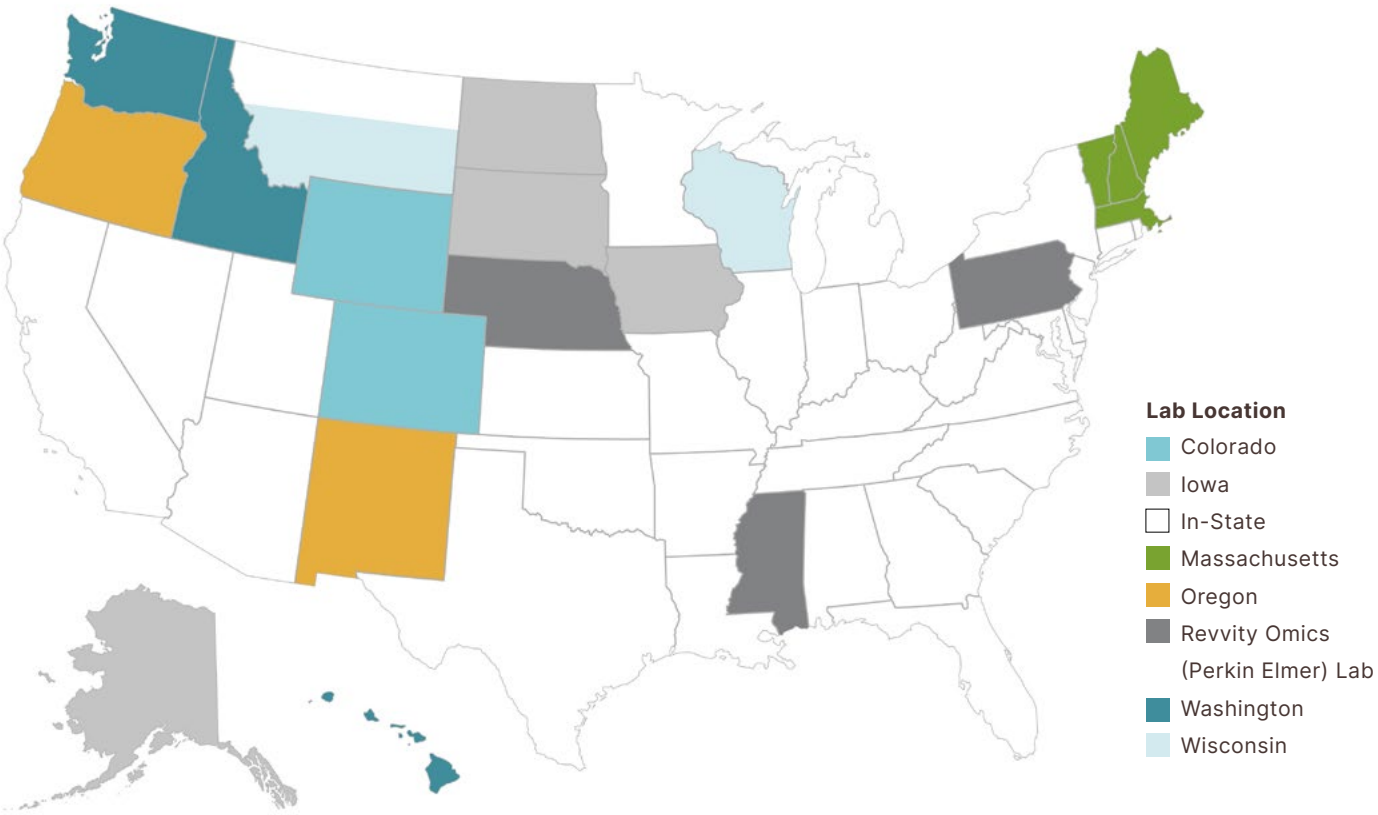

Exhibit 3: Modeling Assumptions – Costs Per Sample by Condition

Lysosomal Storage Disorders (LSDs)	Cost per Sample ($) Tier 1 States	Cost per Sample ($) Tier 2 States
Krabbe	$2.50	$6.50
MPS II	$2.50	$6.50
MPS I	$2.50	$6.50
Pompe	$2.50	$6.50

Notes:

1. Our research shows that all states needing to add MPS I and Pompe also need to add Krabbe and/or MPS II. Therefore, we assume that the costs for Tier 2 states to add MPS I and Pompe are $2.50 each because (1) these are the earlier conditions added to the RUSP (2016) and as a result states may have already made much of the needed investments, or (2) there will be synergies from having added the necessary infrastructure in preparation for Krabbe and/or MPS II.
2. Per sample cost of the 4 LSDs above is $10 for Tier 1 and $18 for Tier 2, consistent with our data findings for a sample of states we had reviewed.
3. Estimates above are based on a range of state-specific cost data points for each of the conditions. Cost data points vary based on state-specific capabilities and decisions.

Other Metabolic Disorders	Cost per Sample ($) Tier 1 States	Cost per Sample ($) Tier 2 States
GAMT	$1.20	$6.33
X-ALD	$1.32	$6.50
DMD	$7.50	$8.50
MLD	$7.50	$8.50

Notes:

1. Our research indicates that adding GAMT and X-ALD may be less expensive than adding the LSDs, because states can typically multiplex GAMT and X-ALD with a current assay.

2. All estimates above are based on a range of state-specific cost data points for each of the conditions.

Future RUSP Additions	Cost per Sample ($) Tier 1 States	Cost per Sample ($) Tier 2 States
Condition 1	$7.50	$8.50
Condition 2	$7.50	$8.50

Notes:
1. We assume two more conditions (Condition 1 and Condition 2) to be implemented across states in the next 3-5 years (either once added to the RUSP or state-specific decisions) and that none of the states are currently screening for these conditions. We assume the cost for each condition to be $7.50 per sample for Tier 1 states and $8.50 per sample for Tier 2 states.
2. We assume two future conditions will have costs comparable to DMD and MLD (as opposed to lower costs for the LSDs), as some states will need to expand their testing capacity and replace or update existing equipment. Preparation for implementation can also take 1-2 years, creating an inflation factor implicitly accounted for in this higher estimate.

Exhibit 4: Modeling Results – Costs to Implement Newborn Screening for States not Screening for Newer RUSP Conditions

Per Gap State	Average Cost per Sample ($)	Average Cost per Newborn ($)	**Aggregate Cost ($)**
Per current condition	$4.50	$6.07	$98,246,456
Per future condition	$7.67	$10.45	$75,140,860
Total	$5.14	$6.95	$173,387,316

Current conditions: Pompe, X-ALD, MPS I, MPS II, GAMT, Krabbe, DMD, MLD
Future conditions: Two future conditions

Appendix

Supporting Data and Study Limitations

The $173 million cost estimate reflects the aggregate **cost of one year of newborn screening, including**:

- Screening for RUSP-recommended conditions that states have not yet added to their panels - **Pompe, X-ALD, MPS I, MPS II, GAMT, Krabbe, DMD, MLD.**
- Projected one-year costs for **two additional conditions** that may be added to the RUSP in the next 3-5 years.

- This funding is intended to provide temporary support to help cover states' start up expenses and bridge the period during which they update newborn screening fee schedules to account for newly added conditions. After fee schedules are adjusted, ongoing screening costs are expected to be reimbursed by Medicaid and commercial insurers.
- The estimate is calculated using an estimated per-sample screening cost and each state's annual newborn screening volume. **The per-sample screening cost does not represent any individual state's actual budget**; rather, it is a generalized estimate informed by the limited publicly available cost projections shared by certain states.
- As outlined in the methodology section, estimated per-sample costs range from $1.20 to $8.50, depending on the condition, the state's approach to implementation (e.g., opportunities for multiplexing), and whether the state already has infrastructure that lowers the incremental cost of adopting newer RUSP conditions.
- **This estimate serves as an initial foundation to inform discussions about implementation needs and will need to be revised as states develop state-specific, detailed budgets** with their newborn screening laboratories that reflect operational requirements, timelines, and available funding sources.

State	Total Cost
Alabama	$4,189,151
Alaska	$671,798
Arizona	$5,076,240
Arkansas	$1,897,908
California	$14,954,037
Colorado	$4,452,412
Connecticut	$1,609,585
Delaware	$485,638
District of Columbia	$483,985
Florida	$8,275,199
Georgia	$4,849,313
Hawaii	$616,491
Idaho	$1,621,632
Illinois	$4,478,829
Indiana	$3,061,827
Iowa	$1,670,830
Kansas	$1,833,378
Kentucky	$2,032,574
Louisiana	$3,777,330
Maine	$484,059
Maryland	$3,935,640
Massachusetts	$2,507,601
Michigan	$3,989,741
Minnesota	$2,271,112
Mississippi	$2,112,164
Missouri	$3,110,815
Montana	$742,725
Nebraska	$1,477,884
Nevada	$3,707,180
New Hampshire	$496,923
New Jersey	$3,914,526
New Mexico	$1,516,936
New York	$7,609,999
North Carolina	$4,609,023
North Dakota	$663,424
Ohio	$3,823,668
Oklahoma	$2,936,582
Oregon	$2,772,928
Pennsylvania	$4,379,810
Rhode Island	$366,462
South Carolina	$3,106,975
South Dakota	$718,768
Tennessee	$3,217,670
Texas	$24,209,320
Utah	$3,151,330
Vermont	$210,868
Virginia	$4,283,376
Washington	$5,859,801
West Virginia	$893,735
Wisconsin	$3,834,414
Wyoming	$433,700
Total	**$173,387,316**