

REPORT TO THE THIRTY-THIRD LEGISLATURE

STATE OF HAWAI'I

2024

PURSUANT TO SECTION 321-291, HAWAI'I REVISED STATUTES

**REQUIRING THE DEPARTMENT OF HEALTH TO GIVE AN
ANNUAL REPORT FOR THE
NEWBORN METABOLIC SCREENING SPECIAL FUND**



**PREPARED BY:
STATE OF HAWAI'I
DEPARTMENT OF HEALTH
HEALTH RESOURCES ADMINISTRATION
FAMILY HEALTH SERVICES DIVISION
CHILDREN WITH SPECIAL HEALTH NEEDS BRANCH**

December 2023

**ANNUAL REPORT FOR THE
NEWBORN METABOLIC SCREENING SPECIAL FUND
FISCAL YEAR 2023**

PROGRAM MEASURE REPORT

Introduction

The Newborn Metabolic Screening Program (NBMSp) is administered by the Children with Special Health Needs Branch, Family Health Services Division, Hawai'i State Department of Health. NBMSp has statewide responsibilities for ensuring that all infants born in the State of Hawai'i are tested for phenylketonuria (PKU), congenital hypothyroidism, and other diseases that, if left untreated, could cause intellectual disabilities, developmental disorders, severe health problems, and even death. Currently, the program screens for 32 disorders. The program tracks and does follow-up on infants to ensure satisfactory testing and that infants with the specified diseases are detected and provided with appropriate and timely treatment and care. Newborn screening (NBS) has existed since 1963 and is a mandated public health activity in all 50 states. Parents in Hawai'i can opt out of screening only as a religious exemption.

The 1996 legislature established a Newborn Metabolic Screening user fee and a Newborn Metabolic Screening Special Fund (NMSSF), which is used for operating expenses. The Hawai'i Administrative Rules (HAR), Chapter 11-143, revised and adopted on May 27, 2017, pertains to NBMSp. Effective May 27, 2017, the newborn screening is \$99.00 per specimen kit. The fee covers staffing for the program; initial test; repeat testing (if necessary); testing for indigent families; overnight courier services; laboratory services; follow-up diagnostic tests as determined by the program; clinical genetic services; educational materials and activities; and quality assurance and improvement activities. Fees also cover expenses for implementing new disorders to the NBS panel. In July 2023, the program added two disorders to the newborn screening panel: Pompe disease and Mucopolysaccharidosis Type I. X-linked adrenoleukodystrophy and spinal muscular atrophy were approved for addition to the Hawai'i NBS panel in early 2024.

1. Statement of Objectives

The NBMSp provides screening and follow-up services for newborns in the State of Hawai'i with the following objectives:

- a. Screen 99% of the newborns in the State of Hawai'i (95% is the national goal).
- b. All newborns with out-of-range results will receive immediate follow-ups, including repeat newborn screening (NBS), additional diagnostic testing, and referrals to specialists as needed.
- c. Suitable specimen collection: complete saturation of blood spot, proper drying technique, non-layered blood spot.
- d. Timeliness of newborn screening activities: collection time, transport time, reporting time, follow-up time.
- e. Provide education to parents and families about the importance of

- newborn screening.
- f. Provide education/training to healthcare providers/facility staff on all aspects of newborn screening, including best techniques for obtaining newborn blood spots.
- g. Provide physicians with information on each disorder with the necessary next steps and recommended laboratory tests to rule out/diagnose newborns.

2. Measures Quantifying the Target Population to be Served for the Next Six Fiscal Years

Target Population	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
All newborns in the State of Hawai'i will get screened at a rate of 99%.	99%	99%	99%	99%	99%	99%

3. Measures Assessing the Effectiveness in Attaining the Objectives

- a. Each birthing facility is reviewed monthly for the measures outlined in number 1 above. Feedback will be provided to facilities with actions for performance improvement.
- b. All out-of-range results will receive timely follow-up care with linkage to specialists as needed.
- c. Meet all national quality indicators to include acceptable collection/transport; complete essential data fields; timeliness of newborn screening activities; tracking data for babies with out-of-range results; number of newborns with confirmed diagnosis by a medical professional; and number of missed cases.

4. Level of Effectiveness Planned for the Next Six Fiscal Years

Measure of Effectiveness	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
1. Errors of specimen collection cards to less than 5%.	9%	8%	7%	5%	4%	4%
2. Specimens arriving to laboratory within 24 hours after collection.	91%	92%	93%	94%	95%	95%
3. Out-of-range results for critical disorders reported within 5 days of specimen collection.	99%	99%	99%	99%	99%	99%

5. Brief Description of Activities

Activities paid by the NMSSF:

- Centralized laboratory testing for 39 primary and secondary disorders. None of the laboratories in Hawai'i have the equipment, resources, expertise, or interest to complete newborn screening testing. All the laboratories have expressed to the program that they will not make the investment to do newborn screening. The Washington State Department of Health Laboratory (WSDHL) is the contracted newborn screening testing laboratory for the Hawai'i program.
- Repeat testing for initial specimens collected at less than 24 hours of age because the laboratory testing is not as accurate before 24 hours of age per national standards.
- Confirmatory testing up to the point of diagnosis, and when necessary, if specimens are sent to the designated testing laboratory.
- Specimen collection and handling.
- Overnight mailing costs of the initial specimens to the testing laboratory. Courier services must include tracking and overnight delivery capabilities to ensure that newborn screening specimens are not delayed, misplaced, or lost. Services include additional costs for Saturday pick-up when available. Timely screening tests performed on the newborn screening blood specimens are essential for early detection of disorders that can cause intellectual disability, growth retardation, severe illness, and even death if not treated early in the newborn period.
- NBMSF staff salaries and fringe benefits.
- Hawai'i Community Genetics in Hawai'i Pacific Health for contracted Metabolic Clinic and Hemoglobinopathy Clinic follow-up services.
- Contracts with clinical specialists as needed for the disorders on the panel.
- Contract for alpha thalassemia DNA testing for alpha thalassemia follow-up.
- Screening and diagnostic costs for the uninsured indigent.
- Tracking, follow-up, and the administration of the statewide newborn screening system.
- Continuing education and educational materials for program/hospital staff and families.
- Quality assurance activities to monitor performance, identify issues, and activities to improve performance of the program activities.
- Supplies for the program.
- Indirect costs.
- Administrative overhead and other operating expenses.

The WSDHL maintains a proactive approach to achieving better accuracy in screening outcomes by reviewing Hawai'i's NBS data and revising laboratory result cutoffs to minimize false positive newborn screening results. Through this effort, they successfully identified trends and patterns to determine more precise cutoffs for out-of-range results.

During this next fiscal year, NBMSF has two additional activities that will require the use of NMSSF funds:

- NBMSF transferred 23 years of NBS data from the previously contracted Oregon State Public Health Laboratory to the WSDHL so that the Hawai'i NBMSF can maintain access to the data. WSDHL needs to house the data since NBMSF does not have the data infrastructure or the expensive software license to access the historical NBS results. NBMSF will continue to investigate options to house the data in Hawai'i.
- NBMSF to add X-linked Adrenoleukodystrophy (X-ALD) and Spinal Muscular Atrophy (SMA) in FY24. These disorders were added to the federal Recommended Uniform Screening Panel. Hawai'i stakeholders have reviewed and added the disorders to the Hawai'i NBS Panel to meet the federal recommendations. The last time disorders were added to the panel, implementation costs were about \$1 million for all related and integrated screening preparation and implementation.

6. Program Size Indicators

The percentage of eligible newborns receiving newborn metabolic screening:

In Fiscal Year 2023, 15,110 infants (99.5%) were screened. Of these, 1,478 screens were presumptive positive, with one or more results out of the reference range, requiring further follow-up or a repeat test. Thirty-seven (37) infants were confirmed as having a critical disorder requiring medical treatment and management. Key findings identified in demographic analyses of the critical cases showed 29 cases in O'ahu County, 5 in Hawai'i County, and 3 in Maui County.

7. Program Size Planned for Each of the Next Six Fiscal Years

Program Size	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
Registered Nurse V	1.0 FTE	1.0 FTE	1.0 FTE	1.0 FTE	1.0 FTE	1.0 FTE
Registered Nurse IV	1.0 FTE	1.0 FTE	1.0 FTE	1.0 FTE	1.0 FTE	1.0 FTE
Human Services Professional	1.0 FTE	1.0 FTE	1.0 FTE	1.0 FTE	1.0 FTE	1.0 FTE
Office Assistant III	1.0 FTE	1.0 FTE	1.0 FTE	1.0 FTE	1.0 FTE	1.0 FTE
Office Assistant III	1.0 FTE	1.0 FTE	1.0 FTE	1.0 FTE	1.0 FTE	1.0 FTE

COST ELEMENT REPORT

1. Budget Details by Cost Element

Description	Amount
Payroll	\$ 609,833.35
Out-of-State Travel	\$ 4,117.00
Stationery and Office Supplies	\$ 492.20
Other Supplies	\$ 4,105.77
Subscription	\$ 3,913.36
Air Freight	\$ 45,122.93
Printing	\$ 4,900.52
R & M Office Furniture and Equipment	\$ 665.64
Laboratory	\$ 3,996.40
Other Non-State Employee Services on a Fee Basis	\$ 868,039.25
Other Miscellaneous Current Expenses	\$ 82,826.54
M & E – Other Machinery and Equipment	\$ 357,923.04
TOTAL	\$ 1,985,936.00

2. Fund Name and Account Code for Each Item or Account Code

Name of Fund: Newborn Metabolic Screening Special Fund
Acct. No.: S 302 H

REPORTING OF NON-GENERAL FUND INFORMATION

1. **Name of Fund:** Newborn Metabolic Screening Special Fund
Legal Authority: Section 321-291, H.R.S.

2. Intended Purpose

This fund is to be used for payment of its lawful operating expenditures, including, but not limited to, laboratory testing, follow-up testing, educational materials, continuing education, quality assurance, equipment, and indirect costs.

3. Current Program Activities

The NBMSF has statewide responsibilities for ensuring that infants born in the State of Hawai'i are satisfactorily tested for disorders that can cause intellectual disability and even death if not detected and treated early in the newborn period. NBMSF tracks and follows up on infants to ensure that the infants with the specified diseases are detected and provided with appropriate and timely treatment. Other activities include assessment, quality assurance, continuing education, standards setting, and activities to add new disorders to the newborn screening panel.

4-11. Requested Fund Information

	FY 2023
Beginning Cash Balance	\$ 2,098,483.45
Beginning Encumbrances	\$ 0.00
Revenues	\$ 1,347,386.00
Internal Transfers	\$ 0.00
Expenditures	\$ (1,985,936.00)
Transfers (List each transfer by JV# and date)	N/A
Net Total Transfers	\$ (1,899,146.85)
Amount Derived from Bond Proceeds	\$ 0.00
Ending Cash Balance¹	\$ 2,138,483.00

¹ Ending cash balance before encumbrances

EXPENDITURES IN FY 2023

I. Newborn Metabolic Screening Program Personnel Costs

A. Payroll (5 FTE authorized) – includes salaries, overtime, differential, and fringe benefits	\$ 609,833.35	
B. Subsistence allowance, intrastate and out-of-state employee travel	\$ 4,117.00	
SUBTOTAL		\$ 613,950.35

II. Implementation of Newborn Screening System Utilizing a Centralized Laboratory, All Other Expenditures

A. Kapi'olani Medical Specialists (2023)	\$ 10,000.00	
B. Invitae \$950.00 (2023)	\$ 950.00	
C. Altres Staffing (2022) – Registered Nurse	\$ 18,939.25	
D. Amy M. Gaviglio (2023)	\$ 9,250.00	
E. Michael Maeda \$1,960 (2023)	\$ 1,960.00	
Washington State Dept of Health Lab		
F. \$651,364.00 (2023)	\$ 651,364.00	
G. Other supplies & subscriptions (2023)	\$ 8,511.33	
Air freight, postage & other printing		
H. (2023)	\$ 50,023.45	
I. Office & other equipment, R&M (2023)	\$ 7,298.90	
Laboratory services for the uninsured		
J. (2023)	\$ 3,996.40	
Other miscellaneous current		
K. Expenditures ² (2023)	\$ 609,692.32	
TOTAL		\$ 1,371,985.00
		<u>\$ 1,985,936.00</u>

² Includes Special Fund Assessment Fees