

REPORT TO THE THIRTY-FIRST LEGISLATURE

**STATE OF HAWAI'I
2021**

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

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



PREPARED BY:

**STATE OF HAWAI'I
DEPARTMENT OF HEALTH
FAMILY HEALTH SERVICES DIVISION**

DECEMBER 2020

ANNUAL FINANCIAL REPORT FOR THE NEWBORN METABOLIC SCREENING SPECIAL FUND FISCAL YEAR 2020

The Hawai'i Newborn Metabolic Screening Program (NBMSPP) is administered by the Children with Special Health Needs Branch, Family Health Services Division, Hawai'i State Department of Health. NBMSPP has statewide responsibilities for assuring that all infants born in the State of Hawai'i are tested for phenylketonuria (PKU), congenital hypothyroidism, and other diseases which, if left untreated, could cause intellectual disabilities, developmental disorders, severe health problems, and even death. The program tracks and follows up on infants to assure satisfactory testing and that infants with the specified diseases are detected and provided with appropriate and timely treatment. Newborn screening (NBS) has existed since 1963 and is a mandated public health activity in all 50 states.

In Fiscal Year 2020, 16,206 infants were screened. Of these, 1,274 screens were presumptive positive, with one or more results out of the reference range and requiring further follow-up or a repeat test. Fifty-four infants were confirmed as having a disorder requiring medical treatment and management.

The 1996 legislature established a Newborn Metabolic Screening Special Fund (NBMSPPF), which is used for operating expenses. The Hawai'i Administrative Rules (HAR), Chapter 11-143, revised and adopted on May 27, 2017, pertains to NBMSPP. Effective May 27, 2017, the newborn screening fee increased from \$55.00 to \$99.00 per specimen kit. This was the first fee increase in five years. The additional fees cover the cost of adding new disorders requiring the use of DNA-based technology for testing, additional courier services to improve timeliness of specimen delivery, and program expenses. Fees also cover expenses for implementation of new disorders to the NBS panel.

The monies are deposited in the NBMSPPF, which pays for the following expenses:

- Centralized laboratory testing for more than 30 primary and secondary disorders. None of the laboratories in Hawai'i have the equipment, resources, expertise, or interest to complete newborn screening testing. From July 1 to October 6, 2020, the Oregon State Public Health Laboratory was the contracted laboratory. The Washington State Department of Health Laboratory was the contracted newborn screening testing laboratory for the remainder of fiscal year 2020 (selected through the State's procurement process).
- 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 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.
- Newborn Metabolic Screening Program staff salaries and fringe benefits
- Hawai'i Community Genetics for contracted Metabolic Clinic and Hemoglobinopathy Clinic follow-up services
- Contracted 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
- Equipment
- Indirect costs
- Administrative overhead and other operating expenses

On October 7, 2019, NBMSPP changed laboratories from the Oregon State Public Health Laboratory (OSPHL) to the Washington State Department of Health Laboratory (WSDHL). The transition was seamless for newborns in Hawai'i with minimal disruption in services. NBMSPP and WSDHL continue to make improvements to the NBS system to benefit the state's newborns.

During this transition year, WSDHL was proactive in their approach to obtain more accurate outcomes by reviewing Hawai'i NBS data. Through this effort, they were successful in identifying trends and patterns to determine more precise cutoffs for out-of-range results. Initially (October 2019 through January 2020), the state's NBS efforts found an increased occurrence of false positive results. This caused an increase in follow-up activities. For example, each day, NBMSPP followed up on at least one and up

to four or five presumptive positive cases for C3 (organic acid disorder) with symptoms that include lethargy, poor feeding, and vomiting. Organic acid disorders require immediate medical intervention to prevent a newborn from experiencing a metabolic crisis that could have severe developmental outcomes or even death. In January 2020, WSDHL made changes to the organic acid disorders cutoffs. This change was a positive step in improved management of newborn screening outcomes for the State of Hawai'i. NBMSF is staffed with two Registered Nurses (RNs), who rotate being on call over weekends and holidays. This is different from working with OSPHL since they were closed during weekends. The transition is a positive one with new experiences and changes to NBMSF policies and procedures.

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

- NBMSF will transfer 23 years of NBS data from the OSPHL to WSDHL so 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 review the historical NBS results. NBMSF is investigating options to house the data in Hawai'i.
- NBMSF may add two lysosomal disorders (Pompe disease and Mucopolysaccharidosis Type 1) and X-linked Adrenoleukodystrophy in 2021. The disorders were added to the federal Recommended Uniform Screening Panel. The Hawai'i stakeholders will review and decide whether to add 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.

The attached financial report for FY 2020 (July 1, 2019 to June 30, 2020), required by HRS §321-291, identifies all fund balances, transfers, and expenditures made from the NBMSF and the purposes for each expenditure.

Report on Non-General Fund Information for Submittal to the 2021 Legislature

Department: HEALTH

Date: October 19, 2020

Prepared by: Michelle C. Matsuoka

Phone: 733-9062

Name of Fund: Newborn Metabolic Screening Special Fund

Legal Authority: Section 321-291, H.R.S.

Fund Type (MOF): B

Approp. Acct. No.: S 302 H

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.

Current Program Activities:

The Newborn Metabolic Screening Program (NBMSp) has statewide responsibilities for assuring 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. NBMSp tracks and follows up on infants to assure that the infants with the specified diseases are detected and provided with appropriate and timely treatment. Other activities are assessment, quality assurance, continuing education, and standard setting.

	<u>FY 2020</u>
Beginning Cash Balance	\$ 2,115,924.10
Beginning Encumbrances	\$ 98,118
Revenues	\$ 1,567,105.46
Internal Transfers	N/A
Expenditures	\$ (2,035,188)
Transfers (List each transfer by JV# and date)	N/A
Net Total Transfers	\$ 0.00
Amount Derived from Bond Proceeds	\$ 0.00
Ending Cash Balance ¹	<u>\$ 1,549,723.35</u>

¹ Ending cash balance before encumbrances

Purposes for Expenditures in FY 2020

**I. Newborn Metabolic Screening Program
Personnel Costs**

A.	Payroll (5 FTE authorized) – includes salaries, overtime, differential, and fringe benefits	\$641,720.21	
B.	Subsistence allowance, intra-state and out-of-state employee travel	\$3,969.98	<u>\$645,690.20</u>

II. Implementation of Newborn Screening System Utilizing a Centralized Laboratory

A.	Oregon State Public Health Laboratory	\$432,311.00	
B.	Kapiolani Medical Specialists (2019)	\$60,000.00	
C.	Kapiolani Medical Specialists (2020)	\$40,000.00	
D.	Washington State Department of Health	\$701,182.55	
E.	Air freight charges to deliver specimens to the testing laboratory	\$38,191.58	
F.	Stationery and office supplies	\$5,324.54	
G.	Advertising and court reporter	\$0.00	
H.	Repair and maintenance of office equipment	\$250.84	
I.	Laboratory services for the uninsured	\$14,809.52	
J.	Other miscellaneous current expenditures ²	\$97,427.77	<u>\$1,389,497.80</u>
			<u>\$ 2,035,188</u>

² Includes Special Fund Assessment Fees