

Fiscal Note

State of Alaska
2014 Legislative Session

Bill Version: CSHB 90(HSS)
Fiscal Note Number: 1
(H) Publish Date: 4/9/14

Identifier: HB090CS(HSS)-DHSS-WCFH-04-08-14
Title: TESTING NEWBORNS FOR VITAMIN D
Sponsor: SEATON
Requester: House HSS Committee

Department: Department of Health and Social Services
Appropriation: Public Health
Allocation: Women, Children and Family Health
OMB Component Number: 2788

Expenditures/Revenues

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

	FY2015	Included in	Out-Year Cost Estimates				
	Appropriation Requested	Governor's FY2015 Request	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
OPERATING EXPENDITURES	FY 2015	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
Personal Services	76.8		76.8	38.4			
Travel	8.0		5.0	3.0			
Services	30.0		151.5	136.5			
Commodities	1.5		1.5	0.5			
Capital Outlay							
Grants & Benefits			50.0	50.0			
Miscellaneous							
Total Operating	116.3	0.0	284.8	228.4	0.0	0.0	0.0

Fund Source (Operating Only)

1004 Gen Fund	116.3		284.8	228.4			
Total	116.3	0.0	284.8	228.4	0.0	0.0	0.0

Positions

Full-time							
Part-time							
Temporary	1.0		1.0	1.0			

Change in Revenues							

Estimated SUPPLEMENTAL (FY2014) cost: 0.0 *(separate supplemental appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY2015) cost: 0.0 *(separate capital appropriation required)*
(discuss reasons and fund source(s) in analysis section)

ASSOCIATED REGULATIONS

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? Yes
If yes, by what date are the regulations to be adopted, amended or repealed? 01/01/15

Why this fiscal note differs from previous version:

HB090 version Yextends the project length from 12 months to 24 months; reduces the test group from all Alaska newborns to 500 pregnant women and their newborns; directs the department to provide a matching grant to a nonprofit entity of the lesser of \$100,000 or 20% of the project cost. The services described in this subsection include items relating to collecting blood tests, providing vitamin D supplementation as needed, and providing information to the participants and the public on the project and on vitamin D sufficiency. Previously the department was to perform these tasks at a cost for testing and analysis of \$60 each.

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Division:	Public Health	Date:	04/08/2014 01:00 PM
Approved By:	Sarah Woods, Deputy Director, Finance & Management Services	Date:	04/08/14
Agency:	Health & Social Services		

**STATE OF ALASKA
2014 LEGISLATIVE SESSION****Analysis****Summary:**

On or before January 1, 2015, the department is directed to coordinate a 24 month project for the purpose of acquiring data on Vitamin D levels of 500 pregnant women and their newborns. Total costs are estimated at \$629,500.

The bill directs the department to award a matching grant of not more than 20% of the entire project cost, not to exceed \$100,000, to a non-profit entity to provide at no cost to the parents the following: determine Vitamin D levels of 500 pregnant women and 500 newborns (1,000 samples); provide Vitamin D supplementation as needed; provide public information regarding the project and the effects of Vitamin D deficiency; take or supervise the taking of blood spot samples; conduct, to the extent feasible, the testing at the same time as other newborn or cord blood testing; ensure that the sampling complies with federal and state privacy laws; submit the samples to the group that is under contract with the department to analyze samples; and provide follow-up to project participants to provide nutritional education and supplementation as needed.

The cost of the entire project for the grantee would be expected to include one or more nurses to take or supervise the taking of samples; one or more nutritionists to provide nutritional education and Vitamin D supplementation; one or more other employees to provide public information; and submit samples; and an indeterminate amount to provide Vitamin D supplementation. Under these assumptions, total project costs could exceed \$500,000, which could result in the maximum grant of \$100,000. Costs would occur between January 1, 2016 and January 1, 2017, after the institutional review board approvals are finalized.

The bill also directs the department to contract with a research group that is university-affiliated and conducting national clinical research on newborn and prenatal Vitamin D levels. The contractor will provide technical support and analyze the samples and data by the grantee. There would be a total of 1,000 samples tested and analyzed. The project will require Institutional Review Board (IRB) approval from both the IRB of record for the department and multiple tribal IRBs before volunteer participants could enroll in the study, which could take six months to a year. Any research laboratory contracted for this study by the department would be required to use standard testing methodology. These labs require serum taken via a venipuncture and use Liquid Chromatography Tandem Mass Spectrography instrumentation which is standard laboratory procedure for Vitamin D testing. This type of testing is CLIA approved as a highly complex test for Vitamin D.

The University of Alaska is not known to be conducting national clinical research on newborn and prenatal Vitamin D levels so presumably the contractor would be from out of state. The costs quoted by two nationally certified laboratories ranged from \$125 to \$230 per test; this fiscal note assumes \$180 per test for a total of \$180,000 to begin no earlier than July 1, 2016 (after the IRB approval) and continue until January 1, 2017. It is assumed that the university will charge 35%, or \$63,000, for indirect costs. The bill does not address a final report to be published; therefore, this fiscal note does not include any costs for the contractor to write a scientific report or article.

The department will need to manage and provide oversight for both the grant and the contract. This would require \$76,800 for a minimum of 1.0 FTE long term, non permanent, range 20 Public Health Specialist II to provide technical assistance with study design, manage the contract and grant, notify providers of the research program, and review the data analysis and reports to be published (if any) regarding the research. There are additional costs for supplies, rent, utilities, phone, IT and other administrative services, and travel. If the department is expected to provide ongoing technical assistance to the participating health care providers on the project, testing procedures, or research protocols, additional staff may be required. Staff will need to be hired 6 months prior to the January 1, 2015 start date of this project to promulgate regulations, procure the grant and contract agreements, and begin planning the research protocol. The position will terminate January 1, 2017 when the 24 month project ends.