Fiscal Note

State of Alaska
2016 Legislative Session

Bill Version: HB 227
Fiscal Note Number:
() Publish Date:

Identifier: HB227-DHSS-WCFH-1-29-16
Title: MEDICAL ASSISTANCE REFORM
Sponsor: SEATON
Requester: House HSS

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)

	FY2017 Appropriation Requested	Included in Governor's FY2017 Request	Out-Year Cost Estimates				
OPERATING EXPENDITURES	**FY 2017**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**
Personal Services	143.1		143.1	143.1			
Travel	8.0		8.0	8.0			
Services	500.0		500.0	500.0			
Commodities	10.0		10.0	10.0			
Capital Outlay							
Grants & Benefits							
Miscellaneous							
Total Operating	**661.1**	**0.0**	**661.1**	**661.1**	**0.0**	**0.0**	**0.0**
Fund Source (Operating Only)							
1004 Gen Fund	661.1		661.1	661.1			
Total	**661.1**	**0.0**	**661.1**	**661.1**	**0.0**	**0.0**	**0.0**
Positions							
Full-time							
Part-time							
Temporary							
Change in Revenues							

Estimated SUPPLEMENTAL (FY2016) cost: 0.0 *(separate supplemental appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY2017) 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If yes, by what date are the regulations to be adopted, amended or repealed? 01/01/17

Why this fiscal note differs from previous version:

Not applicable; initial version.

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Division: Public Health Date: 01/26/2016 03:00 PM
Approved By: Sana Efird, Asst. Commissioner, Finance and Management Services Date: 01/29/16
Agency: Health and Social Services

Analysis

Section 15
On or before January 1, 2017, the department is directed to design and implement a "demonstration project" for the purpose of reducing pre-term birth rates in the state from the current rate of 8.5%. The Department is directed to provide for a "voluntary enrollment of approximately 500 recipients who are eligible for medical assistance." In addition, the Department is directed to "offer pregnancy counseling, nutritional counseling, and, as necessary, vitamin D supplementation to maintain levels of 40ng/ml vitamin D levels during pregnancy" for those enrolled in the demonstration project.

The total cost for this project is estimated to be $1,983.3 ($661.1 per year for 3 years).

This project constitutes a human subjects research project and would require approval from an institutional review board. An institutional review board (IRB) is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans. The department does not have the capacity to engage in research involving human subjects and would need to establish a contract with a university or medical school affiliated organization experienced in clinical research.

A 1.0 FTE Nurse Consultant II (range 24, step C, GG, Anchorage) with clinical training is needed to coordinate and oversee the project and overall study fidelity, write the request for proposals, and manage the awarded contract. In addition, the position would be responsible for researching the best practices for content to fulfill the required "pregnancy counseling" and "nutritional counseling," develop or research the training for clinicians to use with enrolled pregnant women to meet the research protocol and IRB requirements, as well develop the materials for the patients that meet cultural norms and standards for Alaska. An existing position will be repurposed. Salary $92.8, benefits $50.3.

The contractor would write the study design and protocol, obtain IRB approval from not only the contracted university, but potentially numerous tribal IRBs. The study would enroll 500 Medicaid eligible pregnant women, follow them through their pregnancies, take blood samples at designated periods during the study, run the samples and collect the results, supervise the "pregnancy counseling and nutritional counseling" including distribution and supervision of the administration of vitamin D supplementation, analyze the data, and write the report for the legislature. In order to validate the data and determine significance, a control group would be needed as a comparison which could escalate the cost of the study from the current estimate. Reducing the treatment group to 250 pregnant women is an option, but this number as an experimental group may not provide adequate power to the study to ascertain significance.

The contractor would be required to contract with a certified laboratory that would be required to use standard testing methodology. The University of Alaska is not known to be conducting national clinical research on newborn and prenatal vitamin D levels so presumably the contracted laboratory would be from out of state. Standard laboratory procedure for vitamin D testing for certified labs require serum taken via venipuncture and use Liquid Chromatography Tandem Mass Spectrography instrumentation. This type of testing requires CLIA (Clinical Laboratory Improvement Amendments of 1988) approval, as it is a highly complex test to determine vitamin D levels. CLIA are federal laboratory regulations that apply to all clinical laboratories that test human specimens for diagnosing, preventing, or treating disease. The costs quoted by two nationally certified laboratories ranged from $125 to $230 per test; this fiscal note assumes $180 per test for upwards of three tests for 500 enrolled.

The fiscal note includes additional costs for supplies, rent, utilities, phone, IT, and other administrative services. 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.

Analysis Continued

Likely, enrolled participants in the study would be dispersed across Alaska, so travel for training and counseling is included in the direct 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 study would not start until FY2018 and is estimated to take a full 18 months. The IRB process alone would take a full 12 months. Staff will need to be hired prior to the January 1, 2017 start date of this project to promulgate regulations, procure contract agreements, develop educational materials and begin planning the research protocol.

The fund source is GF because Medicaid does not reimburse costs for studies of an experimental nature.