

## Department of Planning and Budget 2024 Session Fiscal Impact Statement

1. **Bill Number:** SB 499

**House of Origin**     Introduced         Substitute         Engrossed  
**Second House**     In Committee     Substitute         Enrolled

2. **Patron:**        Carroll Foy

3. **Committee:** Labor and Commerce

4. **Title:**            Donor human milk banks, health insurance; coverage for donor human milk.

5. **Summary:** The substitute bill prohibits any person from establishing or operating a donor human milk bank, as defined in the bill, without first obtaining a license from the State Health Commissioner and makes it a Class 6 felony for any person to establish or operate a donor human milk bank in the Commonwealth without obtaining such license. The bill directs the State Board of Health to establish a regulatory and statutory scheme for the licensure and regulation of donor human milk banks operating or doing business in the Commonwealth. The bill also directs the Commissioner to implement and enforce numerous regulations relating to the issuance, renewal, denial, suspension, and revocation of such licenses. The bill specifies procedures relating to disciplinary actions, application fees, and inspections and interviews related to such donor human milk banks.

The bill requires health insurers, corporations providing health care coverage subscription contracts, and health maintenance organizations to provide coverage for expenses incurred in the provision of pasteurized donor human milk. The bill specifies that the requirement applies if the covered person is an infant younger than the age of six months and a licensed medical practitioner has issued an order for such infant who satisfies certain criteria enumerated in the bill. The bill applies to policies, contracts, and plans delivered, issued for delivery, or renewed on or after January 1, 2026. The bill also requires the state plan for medical assistance services to include a provision for payment of medical assistance services incurred in the provision of pasteurized donor human milk. The bill specifies that certain provisions will not become effective until the State Board promulgates regulations for the licensure of donor human milk banks and directs the State Board to adopt emergency regulations to implement certain provisions of the bill.

6. **Budget Amendment Necessary:** Yes, Items 276 and 288. See Item 8.

7. **Fiscal Impact Estimates:** Preliminary, See Item 8.

**Expenditure Impact:** Virginia Department of Health

<i>Fiscal Year</i>	<i>Dollars</i>	<i>Fund</i>
2025	\$425,000	General
2026	\$45,000	General
2027	\$45,000	General

2028	\$45,000	General
2029	\$45,000	General
2030	\$45,000	General

**Expenditure Impact:** Department of Medical Assistance Services

<i>Fiscal Year</i>	<i>Dollars</i>	<i>Fund</i>
2025	\$254,275	General
2025	\$745,725	Nongeneral
2026	\$4,129,996	General
2026	\$4,498,733	Nongeneral
2027	\$4,399,582	General
2027	\$4,792,388	Nongeneral
2028	\$4,686,766	General
2028	\$5,105,212	Nongeneral
2029	\$4,992,695	General
2029	\$5,438,456	Nongeneral
2030	\$5,318,594	General
2030	\$5,793,452	Nongeneral

- 8. Fiscal Implications:** The proposed legislation is expected to have a fiscal impact for the Virginia Department of Health, Department of Medical Assistance Services, and state health insurance plan.

Virginia Department of Health

The Virginia Department of Health (VDH) estimates that there will be a fiscal impact to implement the provisions of this bill. VDH's Office of Licensure and Certification (OLC) has an online application system for its existing licensure programs for medical care facility providers (e.g., hospitals, home care organizations, etc.). This system automates much of the previous manual licensing processes, includes electronic payment options, and brings transparency to licensing operations for applicants and the public. The proposed legislation would require VDH to modify its OLC application portal to create a new provider type for donor human milk banks with applications for an initial license, renewed license, or key changes in licensing record (e.g., change of location, change of capacity). VDH's information technology vendor has estimated a one-time cost of \$425,000 in fiscal year 2025 to support changes to its OLC application portal and an annual cost of \$45,000 for added operation, maintenance, and post-deployment enhancement support associated with a new provider type.

Since VDH is aware of only one accredited milk bank in Virginia, the inspection burden is anticipated to be limited to one facility at the present time. VDH has indicated that the inspections of the milk banks could be absorbed by an existing Health Care Compliance Specialist II; therefore, no new positions would be required at this time. VDH estimates that it would be able to absorb regulatory costs associated to license and monitor the one existing facility in Virginia. Hospitals are generally providing PDHM at their own expense for babies in the pediatric intensive care units (PICUs) and neonatal intensive care units (NICUs). It is expected that the introduction of this bill may change this situation, potentially adding approximately 45 facilities with a NICU, PICU, or both as donor human milk banks. At this time, however, it cannot be determined how many facilities may seek licensure in the future.

VDH also anticipates that the number of facilities required to be licensed may increase due to the provision in the bill that requires entities who operate or do business within the Commonwealth that collect, store, sell, distribute, or pasteurize donor human milk and human milk-derived products to meet the licensing standards and requirements for donor human milk banks. Should the number of facilities increase, there may be increased demand on VDH resources which would necessitate additional FTE positions.

While the proposal gives the State Board of Health the authority to collect fees in connection with its licensure program, because the known population of regulants is one, the agency would be unable to set reasonable fees commensurate with the cost of the program. Therefore, the expenditures associated with this bill would need to be supported by the general fund at least until a stable population of regulants is established. It is unclear if VDH will be able to implement the regulations by the timeframes prescribed in the bill without additional authority, i.e. emergency regulations.

#### Department of Medical Assistance Services

The bill requires the Department of Medical Assistance Services (DMAS) and the department's contracted managed care organizations (MCO) to provide coverage for expenses incurred in the provision of pasteurized human donated milk (HDM). The requirement applies if the covered person is an infant under the age of six months, the milk is obtained from a human milk bank that meets quality guidelines established by VDH, and a licensed medical practitioner has issued an order for an infant who satisfies certain criteria. Also, based on recent information provided by DMAS, the bill's provisions are expected to apply to both Medicaid and Family Access to Medical Insurance Security (FAMIS) Plan for infants.

DMAS reports that the cost of HDM is covered within the hospital inpatient payment for babies receiving care in neonatal intensive care units (NICU); however, Virginia, does not cover HDM costs once an infant is discharged from the hospital (i.e. outpatient costs). Based on information from the American Academy of Pediatrics, the average cost of pasteurized donated human breast milk ranges from \$4.00 to \$5.00 per ounce, as such this statement assumes a cost of \$4.50 per ounce. Assuming, on average, approximately 25 ounces of breast milk per baby is used each day, the average daily cost of providing outpatient HDM is approximately \$112.50. As this is a new service, there is no way to readily project the number of children that would receive HDM or length of time HDM may be utilized on an outpatient basis. National data and scholarly articles report a wide range of potential utilization expectations related to the use of HDM.

For the purposes of this statement, DMAS estimates that, on average, 200 eligible infants each day could utilize HDM between leaving the hospital and six months of age. This number represents approximately 0.6 percent of the 31,983 births paid for by Medicaid and FAMIS in 2023. However, this assumption is a general estimate, and the actual number will largely depend on how many children meet the bill's eligibility criteria. Based on these assumptions, the estimated cost of providing HDM for eligible infants would be approximately \$675,000 per month or \$8.1 million annually.

The bill appears to restrict the distribution of donor milk until VDH regulations are in place on July 1, 2025. Therefore, DMAS assumes an effective date of July 1, 2025, and an annual increase equal to the rate of increase in covered newborn members over the past six years (approximately 6.5 percent). In addition, it is estimated that 7.8 percent of infants would be covered under FAMIS with the rest covered by Medicaid (ratio of FAMIS to Medicaid newborns in fiscal year 2021). Use of this program is expected to ramp up over a period of seven months. As such, based on the before mentioned assumptions, a general estimate of this bill's impact on Medicaid and FAMIS medical costs is \$8.6 million (\$4.2 million general fund) in FY 2026.

DMAS also estimates a cost of \$1.0 million (\$0.3 million general fund) in FY 2025 for one-time changes to DMAS' Medicaid Enterprise Systems to allow coverage of HDM. System costs are eligible for an enhanced federal match rate of 75 percent for Medicaid.

#### Department of Human Resource Management

According to the Department of Human Resource Management, the proposed legislation is expected to have an annual fiscal impact of \$460,000 on the state health insurance plan. Approximately half of this amount would be supported with general fund. The fiscal impact is not expected to change the health insurance premiums funded in HB/SB 30.

#### State Corporation Commission

According to the State Corporation Commission (SCC), qualified health plans (QHPs) sold through the Health Benefit Exchange are not impacted by the provisions of this bill. Section 38.2-6506 A 1, Code of Virginia, states that if services are identified in addition to the ones contained in the state's Benchmark Plan, QHPs sold through the Exchange would not be required to cover these services. However, the Centers for Medicare and Medicaid Services (CMS) has cautioned that state standards must be applied uniformly within a market for all individual and small group plans according to the Affordable Care Act. This requirement could cause the state to defray costs of this benefit for QHPs, with the SCC's Bureau of Insurance administering that defrayal.

### **9. Specific Agency or Political Subdivisions Affected:**

Department of Human Resource Management  
Virginia Department of Health  
Department of Medical Assistance Services  
State Corporation Commission

### **10. Technical Amendment Necessary:** Yes. On page 16, line 953, after "Department" insert "of Health." There are two Departments within Title 32.1—VDH and DMAS—and § 32.1-325 of the Code of Virginia is in the portion of Title 32.1 that pertains to DMAS; line 953, as currently drafted, is ambiguous as to which Department it is referencing.

### **11. Other Comments:** None