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Bill Number: SB 1186 S2 **Patron:** Carroll Foy **Bill Title:** Health insurance; coverage for donor human milk, penalty

Bill Summary: The substitute bill prohibits any person from establishing or operating a donor human milk (DHM) 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 also establishes requirements, policies, and procedures, for the operation and administration of licensed DHM banks, including procedures relating to disciplinary actions, application fees, and inspections and interviews related to such DHM banks. The bill directs (i) the State Board of Health to establish a regulatory and statutory scheme for the licensure and regulation of DHM banks operating or doing business in the Commonwealth and (ii) the Commissioner to implement and enforce numerous regulations relating to the issuance, renewal, denial, suspension, and revocation of such licenses.

The bill requires health insurers, corporations providing health care coverage subscription contracts, and health maintenance organizations to provide coverage for expenses and the state plan for medical assistance services to include a provision for payment of medical assistance services incurred in the provision of pasteurized DHM for any infant that is younger than the age of six months and who satisfies certain criteria enumerated in the bill.

The substitute bill has a delayed effective date of July 1, 2026.

Budget Amendment Necessary: Yes **Items Impacted:** 292

Explanation: While the bill's delayed enactment would push some costs outside the current biennium, it

is assumed that certain administrative spending in FY 2026 is still necessary to ensure services can be begin as close to July 1, 2026 as possible. As such, funding is required for programs under the Virginia Department of Health (VDH) and Department of Medical Assistance Services (DMAS) in the current biennium. The impact on the State Corporation

Commission (SCC) has been updated to indeterminate.

Fiscal Summary: The proposed legislation will require expenditures for which agencies are not currently appropriated. See table and fiscal analysis below.

General Fund Expenditure Impact:

<u>Agency</u>	FY2025	FY2026	FY2027	FY2028	FY2029	FY2030
DHRM (129)	-	-	\$250,000	\$300,000	\$300,000	\$300,000
VDH (601)	-	\$425,000	\$45,000	\$45,000	\$45,000	\$45,000
DMAS (602)	-	\$250,000	\$3,194,621	\$3,354,352	\$3,522,069	\$3,698,173
SCC (171)	-	-	Indeterminate	Indeterminate	Indeterminate	Indeterminate
TOTAL	-	\$675,000	\$3,489,621	\$3,699,352	\$3,867,069	\$4,043,173

Nongeneral Fund Expenditure Impact:

<u>Agency</u>	<u>FY2025</u>	<u>FY2026</u>	<u>FY2027</u>	<u>FY2028</u>	<u>FY2029</u>	<u>FY2030</u>
DHRM (129)	-	-	\$250,000	\$300,000	\$300,000	\$300,000
VDH (601)	-	-	-	-	-	-
DMAS (602)	-	\$750,000	\$3,420,379	\$3,591,398	\$3,770,968	\$3,959,516
SCC (171)	-	-	Indeterminate	Indeterminate	Indeterminate	Indeterminate
TOTAL	-	\$750,000	\$3,670,379	\$3,891,398	\$4,070,968	\$4,259,516

Fiscal Analysis:

Department of Human Resource Management

The Department of Human Resource Management (DHRM) reports that the fiscal impact of this bill on state employee health insurance costs to be \$500,000 (\$250,000 general fund). The agency provided the following assumptions: cost of about \$15,000 per year per infant, inflation, five percent of COVA infants would utilize the benefit, and the expected duration would be three months. Although there is a cost to the state health plan, DHRM does not expect changes to the rates funded in the introduced bill.

Virginia Department of Health

VDH estimates that there will be a fiscal impact to implement the provisions of this bill. The agency'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 DHM 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 FY 2026 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 existing staff; therefore, no new positions would be required at this time. VDH estimates that it would be able to absorb regulatory costs to license and monitor the one existing facility in Virginia. Hospitals are generally providing DHM 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 DHM 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 DHM and human milk-derived products to meet the licensing standards and requirements for DHM banks. Should

the number of facilities increase, there may be increased demand on VDH resources which would necessitate additional 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.

Department of Medical Assistance Services

The bill requires DMAS to provide coverage for expenses incurred in the provision of DHM. The requirement applies if the covered person is an infant under the age of six months, the milk is obtained from a DHM bank that meets quality guidelines established by VDH, and a licensed medical practitioner has issued an order for an infant who satisfies certain criteria. 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 DHM is covered within the hospital inpatient payment for babies receiving care in neonatal intensive care units (NICU); however, Virginia, does not cover DHM 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 DHM is assumed to be \$5.00 per ounce. Assuming, on average, approximately 35 ounces of breast milk per baby is used each day, the average daily cost of providing outpatient DHM is approximately \$175. As this is a new service, there is no way to readily project the number of children that would receive DHM or length of time DHM 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 DHM. For the purposes of this statement, DMAS estimates that, on average, 200 eligible infants each day could utilize DHM between leaving the hospital and less than six months of age. 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 and FY 2024 data, the estimated baseline cost of providing DHM for eligible infants would be approximately \$1.1 million each month or \$6.3 million for six months. It is estimated that this amount would grow by approximately five percent in subsequent years. In addition, it is estimated that 7.9 percent of infants would be covered under FAMIS with the rest covered by Medicaid (ratio of FAMIS to Medicaid newborns in FY 2024).

It is assumed that Medicaid and CHIP coverage of DHM would coincide with the bill's effective date of July 1, 2026. Given the delayed enactment, it is assumed that DMAS will have sufficient time to establish the service and a full year of medical assistance costs are assumed in FY 2027. As such, based on these assumptions, a general estimate of this bill's impact on Medicaid and FAMIS medical costs is \$6.6 million (\$3.2 million general fund) in FY 2027 (\$6.3 million + five percent growth).

DMAS also estimates a cost of \$1.0 million (\$0.3 million general fund) in FY 2026 for administrative costs, including one-time changes to DMAS' Medicaid Enterprise Systems to allow coverage of DHM. System costs are eligible for an enhanced federal match rate.

State Corporation Commission

SCC reports that the total impact the provisions of this legislation would have on SCC Bureau of Insurance (BOI) cannot be determined. SCC maintains that the provisions of the substitute bill do not apply to qualified health plans (QHP) sold through the Health Benefit Exchange. Subdivision A 1 of § 38.2-6506 of the Code of Virginia provides that QHPs are not required to cover health benefits that are identified as in addition to the ones contained in the benchmark plan. However, in 81 FR 12243 ("Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017"), the Centers for Medicare and Medicaid Services (CMS) has cautioned that:

...imposing different benefit mandates depending on a plan's status as a QHP or because it is sold through the Exchange may violate section 1252 of the Affordable Care Act [42 U.S.C. § 18012]. Under this section, state standards or requirements implementing, or related to, standards or requirements in title I of the Act must be applied uniformly within a given insurance market. Thus, if a state requires that non-QHPs in the individual or small group market provide any benefits, under section 1252, the state must require QHPs sold through the exchange in that same market to provide those same benefits, and consistent with our earlier stated policy at § 155.170(a)(2), states would generally be required to defray the cost of QHPs providing the required benefits if they were required through State action taking place after December 31, 2011.

If CMS enforces this interpretation, then the bill could cause the state to defray costs of this benefit for QHPs, with the SCC BOI administering that defrayal. The annual defrayal payment amount would be upwards of \$375,000, based on the previous analysis SCC BOI presented to the Health Insurance Reform Commission in 2021 and adjusted based on enrollment changes in the individual market and for inflation using the Consumer Price Index medical care index. Defrayal payments are made from the general fund and SCC BOI acts as a pass-through entity to make defrayal payments to health carriers; SCC BOI also incurs some administrative costs as part of the defrayal payment process, which is paid for with nongeneral fund appropriations.

Other: The introduced budget includes language in Item 288 that requires a reserve amount be appropriated for new Medicaid initiatives. In addition to the cost of the initiative, the reserve equals the difference between the general fund appropriated for the initiative in FY 2026 and the highest annual general fund cost of the initiative over the next six fiscal years. While not reflected in the table above, the reserve amount is estimated at \$3.9 million general fund for the initiative required by this bill. Act language also delays initiative implementation until the reserve requirement is met.