

Department of Legislative Services
Maryland General Assembly
2023 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 482 (Delegate Shetty)
Health and Government Operations and
Judiciary

Health - Donor-Conceived Individuals and Gamete Agencies, Gamete Banks, and
Fertility Clinics

This bill provides for the licensing and regulation of "gamete agencies," "gamete banks," and "fertility clinics." Beginning January 1, 2026, these entities must be licensed by the Maryland Department of Health (MDH). The bill establishes data collection, maintenance, and disclosure requirements and requires a "donor" to consent to disclosure of their identity, as specified. MDH must develop, and licensed entities must distribute, certain written materials. The bill establishes limitations on the number of families that can be established using a single donor and requires MDH to adopt regulations establishing a limit on the total number of donor retrieval cycles per ovum donor. Beginning January 1, 2026, a donor must be at least age 21; a licensed entity must verify the age of the donor at the time of gamete collection. MDH must adopt regulations to implement the bill.

Fiscal Summary

State Effect: No effect in FY 2024. MDH general expenditures increase by \$90,400 in FY 2025 for personnel to establish the licensure program. Future years reflect annualization and elimination of one-time costs. General fund revenues increase by as much as \$53,000 annually from licensure fees beginning in FY 2026.

Table with 6 columns: (in dollars), FY 2024, FY 2025, FY 2026, FY 2027, FY 2028. Rows include GF Revenue, GF Expenditure, and Net Effect.

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

Local Effect: None.

Small Business Effect: Meaningful.

Analysis

Bill Summary:

Definitions

“Donor” means an individual who produces eggs or sperm collected by (or whose eggs or sperm created an embryo for use by) a gamete agency, gamete bank, or fertility clinic in assisted reproduction by a recipient unknown to the donor at the time of donation. “Donor-conceived individual” (DCI) means an individual (of any age) who was born as the result of assisted reproduction using gametes from a donor unknown to the recipient parent at the time of donation. “Fertility clinic” means an entity or organization that performs assisted reproduction medical procedures and receives donor gametes (1) for a recipient who is a resident of or is located in the State and (2) when the recipient and gamete donor are unknown to each other at the time of donation. “Gamete agency” means an oocyte or sperm donor matching agency that matches gamete donors with a recipient (1) who is a resident of or is located in the State and (2) when the recipient and gamete donor are unknown to each other at the time of donation. “Gamete bank” means an entity that (1) collects gametes from a donor or receives embryos and (2) provides gametes or embryos to a recipient or the recipient’s medical provider when the recipient is a resident of or is located in the State, and the recipient and donor are unknown to each other at the time of donation.

Licensure Requirement and Licensure Fees

Beginning January 1, 2026, a gamete agency, gamete bank, or fertility clinic must be licensed to operate in the State or to match or provide gametes or embryos to recipients in the State. A gamete agency, gamete bank, or fertility clinic must submit an annual application and license fee. A licensing application must include a proposed plan to permanently maintain records, as specified. MDH may not issue a license to an entity until it approves this plan. MDH must issue a license to an applicant that meets specified requirements. A license is valid for one year.

By January 1, 2026, MDH must adopt regulations establishing a schedule of licensure and other fees not to exceed a total of \$500 per year to meet the direct and indirect costs of administration and enforcement of the bill. MDH must assess and collect a fee from each licensed entity. A nonprofit organization is exempt from licensure fees.

License Renewal and Complaints: MDH must (1) review each renewal application to determine compliance and (2) receive and investigate complaints. If MDH finds a violation, the licensed entity must submit a corrective action plan, and MDH must conduct a follow-up review or investigation. MDH must investigate and review only records

relating to donors whose gametes or embryos were matched or provided to recipients in the State. MDH may not retain any identifying information and must keep confidential all health care information or documents obtained or viewed. MDH may revoke or refuse to renew a license of a licensed entity that fails to comply with the requirements of the bill or related regulations.

Provisional License: MDH may issue a provisional license to operate for a period of 90 days if the applicant is temporarily unable to comply with statutory or regulatory requirements. To obtain a provisional license, an applicant must show proof that good faith attempts are being made to comply. MDH may not issue more than two provisional licenses to an applicant in the same year.

Collection of Information by Gamete Agencies, Gamete Banks, and Fertility Clinics and Related Disclosures

On or after January 1, 2026, for gametes collected and embryos formed with gametes collected, each licensed entity that collects gametes from a donor or matches a donor with a recipient (with specified exceptions) must collect the donor's identifying information and medical history and request updated information from the donor at least once every three years. Each licensed entity that receives gametes or embryos collected by a different entity or collects gametes from a donor who was matched with a recipient by a gamete agency that is a separate entity must collect the name, address, telephone number, and e-mail address of the entity. Each fertility clinic that collects gametes from a donor who was matched by a gamete agency that is a separate entity must provide copies of all medical and screening records of the donor, including the results of genetic testing, to the gamete agency that matched the donor.

Agreement to Disclosure of Information by Donors: For gametes collected and embryos formed on or after January 1, 2026, each licensed entity (with specified exceptions) that matches or collects gametes from a donor must (1) provide the donor with information about the disclosure of donor identifying information and medical history, as specified; (2) obtain a declaration from the donor agreeing to the identity disclosure; and (3) maintain identifying information and medical history about each donor. The licensed entity that matched or collected the gametes or embryos must maintain records of donor and gamete screening and testing and comply with any related reporting requirements, as specified. A licensed entity must have each donor sign a declaration, attested to by a notary or two witnesses, that the donor agrees to the disclosure of the donor's identity to an individual conceived with the donor's gametes or an embryo formed with the donor's gametes on request of the DCI when the DCI is at least age 18.

Disclosure of Donor Information to a Donor-conceived Individual: For gametes collected and embryos formed with gametes collected after January 1, 2026, a licensed entity (with

specified exceptions) that matched or collected the gametes or embryos used in the assisted reproduction of a DCI must, on request of a DCI who is at least age 18, provide the DCI with the identifying information of the donor. A licensed entity may not impede or prohibit compliance with the bill or other specified communication.

On request of a DCI (or the parent or guardian of a minor DCI), a licensed entity that matched or collected the gametes used in the assisted reproduction must provide the DCI (or parent or guardian) access to any nonidentifying medical history of the donor that it maintains.

In addition, for gametes or embryos received on or after July 1, 2024, a gamete agency, gamete bank, or fertility clinic that received the gametes or embryos used in assisted reproduction from another entity must (1) permanently maintain the name, address, telephone number, and e-mail address of the entity from which it received the gametes or embryos and (2) on the request of a DCI (or a parent or guardian of a minor DCI), disclose that contact information.

Related Maintenance of Records

On or after July 1, 2024, each gamete agency, gamete bank, or fertility clinic that receives gametes or embryos from another such entity must permanently maintain specified contact information for the entity from which it received the gametes or embryos. Likewise, each gamete bank or fertility clinic that collected gametes from a donor who was matched with a recipient by a gamete agency that is a separate entity must permanently maintain specified contact information for the gamete agency that matched the donor and recipient.

For gametes collected and embryos formed with gametes collected on or after January 1, 2026, each licensed entity (with specified exceptions) must permanently maintain (1) identifying information and medical history for each donor, as specified; (2) information about the number of families established with each donor's gametes and the efforts of the entity to obtain other specified information; and (3) records of gamete screening and testing.

On dissolution, insolvency, or bankruptcy, a licensed entity (with specified exceptions) must (1) implement the permanent record maintenance plan approved by MDH as part of licensure and (2) file with MDH and provide, as specified, the name and contact information of any successor entity that will receive and maintain the records.

Written Materials for Intended Recipient of Gametes or Embryos or Gamete Donors

By January 1, 2026, MDH must, in collaboration with specified mental health professionals, develop specified written materials for (1) intended recipients of gametes or

embryos from a donor and (2) gamete donors. A licensed entity must provide the respective written materials to each potential gamete donor or intended recipient, as specified.

Limitations on and Data Collection Regarding Families Established with Gametes

For gametes matched or collected on or after January 1, 2026, each licensed entity must make a good faith effort to determine how many families are established with gametes matched or provided by the entity from each donor, as specified. A licensed entity (with specified exceptions) may not match or provide gametes from a donor to additional families once the entity has record of or should reasonably know that 25 families have been established using a single donor's gametes in or outside the State, as specified.

Limitations on Donor Retrieval Cycles Per Ovum Donor

By January 1, 2026, MDH must adopt regulations establishing a limit on the total number of donor retrieval cycles per ovum donor that may not exceed a lifetime limit of six. However, MDH may consider an exception for donors who provide informed consent to undergo additional retrieval cycles for families intending to conceive a child using the same donor used to conceive their other child.

Penalties

A person who violates a provision of the bill is subject to a civil penalty imposed by MDH of up to \$20,000 for each day a violation is committed.

Current Law: A tissue bank is an establishment that obtains, stores, processes, distributes, or sells human blood or other human tissue (including reproductive cells and tissue) for use in the human body. A tissue bank must have a permit to operate in Maryland and receive an inspection when an initial permit is sought and annually thereafter. MDH may issue a provisional permit before or after an initial inspection, which may be valid for up to 180 days. The current permit fee for tissue banks is \$200 for both initial and annual renewal permits.

The Office of Health Care Quality (OHCQ) permits and regulates tissue banks, which include both fertility clinics and gamete banks within and outside of Maryland that provide services to Maryland residents. Currently, OHCQ regulates 14 fertility clinics and gamete banks within Maryland and 32 outside of the State.

State Fiscal Effect: Gamete agencies, gamete banks, and fertility clinics must be licensed beginning January 1, 2026, to operate in Maryland or to match or provide gametes or embryos to recipients in the State. To establish this new licensure program, OHCQ general fund expenditures increase by \$90,355 in fiscal 2025 for additional personnel. General fund

revenues increase by as much as \$54,000 annually beginning in fiscal 2026 from the receipt of licensure fees.

General Fund Expenditures

OHCQ's clinical laboratory staff are assigned to complete existing federal and State mandates and cannot absorb additional duties. To implement the bill, OHCQ requires additional resources. Thus, OHCQ general fund expenditures increase by \$90,355 in fiscal 2025. This estimate reflects the cost of hiring two personnel effective January 1, 2025, (one year prior to when gamete agencies, gamete banks, and fertility clinics must be licensed); specifically, one administrative officer to adopt regulations and coordinate initial licensure and annual renewals and one laboratory scientist surveyor to conduct initial surveys, follow-up surveys, and complaint investigations. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Positions	2.0
Salaries and Fringe Benefits	\$76,056
Operating Expenses	<u>14,299</u>
Total FY 2025 State Expenditures	\$90,355

If on-site surveys are required (as are currently required of tissue banks), the surveyor must travel out-of-state (approximately 70% of licensees are anticipated to be located outside of Maryland) and expenditures for travel increase beginning in fiscal 2025.

Future year expenditures reflect full salaries with annual increases and employee turnover as well as annual increases in ongoing operating expenses.

General Fund Revenues

The bill authorizes an annual license fee of up to \$500 (nonprofit entities are exempt) for gamete agencies, gamete banks, and fertility clinics. OHCQ estimates that 60 gamete agencies and 46 gamete clinics or fertility clinics will seek licensure under the bill. Thus, general fund revenues increase by as much as \$53,000 annually. The number of entities that may be licensed that are nonprofit entities is unknown. This analysis assumes that all entities currently permitted as a tissue bank will also seek licensure under the bill. To the extent fewer licenses are issued or a lesser licensing fee is charged, revenues decrease.

Small Business Effect: Small business gamete agencies, gamete banks, and fertility clinics must be licensed under the bill on January 1, 2026, to operate in the State or provide services to individuals who are located in the State. Entities will be subject to licensure fees (in addition to any permit fees they pay currently), must comply with the bill's

requirements, and may be subject to corrective action plans and penalties for noncompliance.

Additional Comments: While licensure of gamete agencies, gamete banks, and fertility clinics is not required until January 1, 2026, and most provisions in the bill apply to actions on or after that date, two provisions apply earlier. Specifically, an entity that receives gametes or embryos from another entity on or after July 1, 2024, must (1) permanently maintain specified contact information about the entity that provided the gametes or embryos or matched a donor or recipient and (2) on request of a DCI (or a parent or guardian of a minor DCI), disclose that contact information.

Additional Information

Prior Introductions: Similar legislation has not been introduced within the last three years.

Designated Cross File: None.

Information Source(s): Maryland Department of Health; Department of Legislative Services

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km/ljm

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