## Department of Planning and Budget 2025 General Assembly Session State Fiscal Impact Statement

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**Bill Number:** HB1555 **Patron:** Williams Health Care Regulatory Sandbox Program established.

Bill Summary: Requires the Department of Health to establish the Health Care Regulatory Sandbox Program to enable a person to obtain limited access to the market in the Commonwealth to temporarily test an innovative health care product or service on a limited basis without otherwise being licensed or authorized to act under the laws of the Commonwealth. Under the Program, an applicant requests the waiver of certain laws, regulations, or other requirements for a 24-month testing period, with an option to request an additional six-month testing period. The bill provides application requirements, consumer protections, procedures for exiting the Program or requesting an extension, and recordkeeping and reporting requirements. The bill requires the Department to provide an annual report to the Chairs of the House Committee on Health and Human Services and the Senate Committee on Education and Health that provides information regarding each Program participant and recommendations regarding the effectiveness of the Program. The bill directs the Board of Health to adopt emergency regulations to implement the provisions of the bill and has an expiration date of July 1, 2030.

**Budget Amendment Necessary:** Yes **Items Impacted:** 276

**Fiscal Summary:** The provisions of this bill would have a fiscal impact on the Virginia Department of Health (VDH) to establish the Healthcare Regulatory Sandbox Program. The provisions of the bill create a new application and review process for participation in the program. Without additional funding support VDH cannot absorb the additional workload associated with this program. The bill provides that VDH review applications, draft recommendations for approval or denial, conduct inspections of the data, investigate complaints, manage retained documents and records, and develop an application portal.

## **General Fund Expenditure Impact:**

<u>Agency</u>	FY2025	FY2026	FY2027	FY2028	FY2029	FY2030
∨DH		\$3 <b>29,480</b>	\$108,280	\$108,280	\$108,280	\$108,280
TOTAL		\$329,480	\$108,280	\$108,280	\$108,280	\$108,280

**Fiscal Analysis:** The provisions of the bill state that if an applicant has requested a waiver of any law, regulation, or other requirement enforced by an agency other the Virginia Department of Health, the Commissioner shall consult with the agency responsible for enforcing such law, regulation, or other requirement and shall obtain the consent of such agency for a waiver of such law, regulation, or requirement prior to approving an application. VDH estimates it would need one position to for the increase in workload associated with the provisions of the bill estimated at \$52,980 per year. Depending on the volume of

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consultations requested, additional staff or other resources may be necessary. However, it is difficult to estimate this volume as the Healthcare Regulatory Sandbox Program is a new unknown program. Other states have created industry specific regulatory sandboxes and all-inclusive sandboxes, but not are specific to healthcare for comparison. VDH's Office of Licensure and Certification believes that given an unknown volume of consultations requested at least one wage position (1500 hours a year) would be necessary to fulfill the needs of the Healthcare Regulatory Sandbox Program. While application fees are able to be charged, it is unknown how much revenue this will produce. The bill provides that the Board of Health shall adopt regulations that are consistent with this chapter and shall establish a schedule of fees for applications for participation in the Program, to be applied to expenses for the administration and operation of the Program.

The creation of an application portal for the program may be necessary depending on the number of entities that request an exemption. Based on prior year calculations, VDHs Office of Information Management estimates the scope of the IT project to include an internet portal with restricted access so only registered users can login and submit proposals; an administration portal used by application review staff to review, approve, deny and/or correspond with an applicant; and a public facing view on the internet with list of submitted proposals and the current status that can be searchable with predefined criteria. VDH estimates there will be one-time IT development costs of \$276,500, with annual maintenance costs of \$55,300 starting in FY27.

Any costs to establish regulations or produce a report can be handled within existing resources.

Other: None.