

## Department of Planning and Budget

### 2022 Fiscal Impact Statement

**1. Bill Number:** HB80

<b>House of Origin</b>	<input type="checkbox"/> Introduced	<input checked="" type="checkbox"/> Substitute	<input type="checkbox"/> Engrossed
<b>Second House</b>	<input type="checkbox"/> In Committee	<input type="checkbox"/> Substitute	<input type="checkbox"/> Enrolled

**2. Patron:** Davis

**3. Committee:** Health, Welfare and Institutions

**4. Title:** Healthcare Regulatory Sandbox Program; established.

**5. Summary:** Requires the Department of Health to establish the Healthcare Regulatory Sandbox Program to enable a person to obtain limited access to the market in the Commonwealth to temporarily test an innovative healthcare 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 Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health that provides information regarding each Program participant and that provides recommendations regarding the effectiveness of the Program. The bill has an expiration date of July 1, 2027.

**6. Budget Amendment Necessary:** Yes, item 292 (program 40607) and item 299 (program 49902).

**7. Fiscal Impact Estimates:** Preliminary, see item 8.

**7a. Expenditure Impact:**

<i>Fiscal Year</i>	<i>Dollars</i>	<i>Positions</i>	<i>Fund</i>
2022			
2023	\$729,392	4	01000
2024	\$508,192	4	Indeterminate
2025	\$508,192	4	Indeterminate
2026	\$508,192	4	Indeterminate
2027	\$508,192	4	Indeterminate

**8. Fiscal Implications:** 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 in FY23. 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.

To accomplish this VDH's anticipates it would need four FTEs; one Health Care Compliance Manager, two Health Care Compliance Specialist II, and Administrative Office Specialist II. Any travel-related expenditures for complaint investigations conducted under the Program cannot be determined.

The Health Care Compliance Manager will oversee the day-to-day functioning of the Program, supervising and providing guidance to the other FTEs previously identified in their work, and serving as the records coordinator and primary point-of-contact for members of the public with Freedom of Information Act requests. This position would also have primary responsibility for elevating concerns about a Program participant, with appropriate and comprehensive documentation, to the Commissioner in the event a Program participant should be terminated from the Program. They would also be the primary reviewer of extension requests and draft recommendations regarding approval or denial of extension requests. Based on current expenditures for existing staff, VDH estimates this position would have an annual cost of \$139,411, including salary, fringe, other office supplies and equipment.

The two Health Care Compliance Specialists will serve as the primary reviewers of applications and draft recommendations regarding the approval or denial of applications. They may also conduct inspections in response to complaints if necessary, as Program participants are required to give testers VDH's complaint contact information. These FTEs will also be responsible for ongoing monitoring of Program participants and be a point-of-contact for Program participants. Based on current expenditures for existing staff, VDH estimates these positions would have an annual cost of \$239,236 (\$119,618 each), including salary, fringe, other office supplies and equipment.

The Administrative and Office Specialist will have the primary responsibility for administrative tasks for the Program, such as establishing and maintaining filing systems and other records. Additionally, if necessary, this position will be a point-of-contact for both applicants and complainants. Based on current expenditures for existing staff, VDH estimates this position would have an annual cost of \$74,245, including salary, fringe, other office supplies and equipment.

Lastly, the creation of an application portal for the program is necessary for the Program. VDH's 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 FY24. VDH assumes all software and hardware for this portal development and hosting can be completed done using existing infrastructure.

Section 32.1-377 paragraph C provides that, “The Board shall adopt regulations that are consistent with this chapter and may 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.” However, these fees cannot be realized until the initial funding for the state share of implementation costs is provided. As such, it is assumed that the initial costs (FY 2023) would need to be supported with general fund dollars; after which new program costs may be covered with revenue from applicants. Should this revenue not be available or sufficient, then those costs would shift to the general fund.

**9. Specific Agency or Political Subdivisions Affected:** Virginia Department of Health.

**10. Technical Amendment Necessary:** No.

**11. Other Comments:** None.