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HOUSE BILL NO. 80

Offered January 12, 2022
Prefiled January 4, 2022

A BILL to amend the Code of Virginia by adding in Title 32.1 a chapter numbered 21, consisting of sections numbered 32.1-376 through 32.1-383, relating to the Healthcare Regulatory Sandbox Program.

Patron—Davis

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Title 32.1 a chapter numbered 21, consisting of sections numbered 32.1-376 through 32.1-383, as follows:

CHAPTER 21.

HEALTHCARE REGULATORY SANDBOX PROGRAM.

§ 32.1-376. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Blockchain technology" means the use of a digital database containing records of financial transactions, which can be simultaneously used and shared within a decentralized, publicly accessible network and can record transactions between two parties in a verifiable and permanent way.

"Innovative healthcare product or service" means a product or service that includes the use or incorporation of a new or emerging technology or a use of existing technology, including blockchain technology, to address a problem, provide a benefit, or otherwise offer a product, service, business, or delivery mechanism that is not known by the Department to have a comparable widespread offering in the state or a region of the state.

"Hackathon" means a conference or meeting in collaboration with specialists in healthcare, innovation and technology, finance, and education and other relevant parties with the express intention of solving specific concerns of healthcare or the healthcare market within the state.

"Healthcare product or service" means a healthcare product or service that requires state licensure or other authorization pursuant to this title, including those products or services that incorporate a business model, delivery mechanism, or element that requires licensure or other authorization to do business or act as a producer or consultant.

"Program" means the Healthcare Regulatory Sandbox Program.

"Test" means to provide an innovative healthcare product or service in accordance with the provisions of this chapter.

§ 32.1-377. Healthcare Regulatory Sandbox Program established.

A. The Healthcare Regulatory Sandbox Program is established to foster the development of innovative healthcare products and services by allowing program participants to obtain limited access to the market in the Commonwealth to test an innovative healthcare product or service without obtaining a license or other authorization that would otherwise be required for the provision of such innovative healthcare product or service in the Commonwealth. As part of the Program, the Department may host or participate in healthcare hackathons or conferences to support the development of innovative healthcare products or services.

B. In establishing the Program, the Department may enter into agreements with the U.S. Consumer Financial Protection Bureau and follow best practices of other states that are administering similar programs.

§ 32.1-378. Application; review of applications; approval or denial.

A. A person who wishes to participate in the Program shall apply to the Department on a form approved by the Board that:

1. Demonstrates that the applicant is subject to the jurisdiction of the Commonwealth;

2. Demonstrates that the applicant has established a physical or virtual location that is adequately accessible to the Department, from which testing will be delivered and performed and where all required records, documents, and data will be maintained;

3. Includes person and contact information for the applicant, including legal names, addresses, telephone numbers, email addresses, website addresses, and other information required by the Department;

4. Discloses any criminal convictions of the applicant or other participating personnel, if any;

5. Demonstrates that the applicant has developed a plan and possesses the necessary resources,

including personnel and financial resources, and expertise to test, monitor, and assess the innovative healthcare product or service;

6. Contains a description of the innovative healthcare product or service to be tested, including statements regarding all of the following:

a. How the innovative healthcare product or service is subject to licensing or other authorization requirements outside of the Program, including a specific list of all state laws, regulations, and other requirements that the applicant is seeking to have waived during the testing period;

b. How the innovative healthcare product or service is different from healthcare products or services currently available to consumers in the Commonwealth;

c. How the innovative healthcare product or service will benefit consumers in the Commonwealth;

d. Any risks to consumers in the Commonwealth posed by the innovative healthcare product or service;

e. How participating in the Program would enable a successful test of the innovative healthcare product or service;

f. A description of the proposed testing plan, including estimated time periods for beginning the test, ending the test, and obtaining necessary licensure or authorizations after the testing is complete;

g. A description of how the applicant will perform ongoing duties, if applicable, after the test; and

h. A description of how the applicant will end the test and protect consumers if the test fails, including providing evidence of satisfactory liability coverage and financial reserves to protect consumers and to protect against insolvency by the applicant; and

7. Any other information required by the Board.

B. An applicant shall file a separate application for each innovative healthcare product or service the applicant seeks to test in the Commonwealth.

C. In addition to the information described in subsection A, the Department may also require an applicant to provide:

1. Evidence of industry ratings and other past performance of the applicant; and

2. Proof of sufficient assets, accounts, liability coverage, surety bond coverage, or other preparation by the applicant to ensure that consumers are protected and that the applicant will be able to meet ongoing obligations upon termination or completion of testing.

D. In reviewing applications received pursuant to this section, the Department shall consider whether (i) the Department has previously issued a license or other authorization to the applicant; (ii) the Department has previously investigated, sanctioned, or pursued legal action against the applicant; (iii) the applicant could obtain a license or other authorization from the Department after exiting the Program; (iv) certain licensure or other approval or regulatory requirements should not be waived even if the applicant is accepted into the Program; and (v) a competitor of the applicant is or has been a Program participant and, if so, weigh that as a factor in favor of allowing the applicant to also become a participant.

E. The Department shall review each application submitted pursuant to this section and shall notify the applicant as to whether the application is approved or denied by a date that is no later than 90 calendar days after the date on which the application was received by the Department. If the Department denies an application, the Department shall provide the applicant a written statement of the reason for the denial within the same 90-day period. The 90-day period for review of a completed application may be extended for up to an additional 90 calendar days upon agreement of the applicant and the Department.

F. The Department may deny an application if the applicant has been convicted, entered a plea of nolo contendere, or entered a plea of guilty or nolo contendere held in abeyance for a crime (i) involving theft, fraud, or dishonesty or (ii) that bears a substantial relationship to the applicant's ability to safely or competently participate in the Program.

§ 32.1-379. Scope of the Program.

A. If the Department approves an application under § 32.1-378, the participant has 24 months after the day on which the application was approved to test the innovative healthcare product or service described in the participant's application. The 24-month period may be extended upon mutual agreement of the Department and the applicant if such extension is deemed appropriate by the Department for the successful testing of an innovative healthcare product or service. However, no testing period shall be extended beyond a date that is 30 months from the participant's date of entry into the Program.

B. A participant testing an innovative healthcare product or service within the Program is subject to the following:

1. Consumers shall be residents of the Commonwealth;

2. The Department may, on a case-by-case basis, limit the number of consumers that enter into an agreement with the participant to use the innovative healthcare product or service;

3. The Department may, on a case-by-case basis, limit the number of items and the maximum coverage amount for each item that is offered by a participant during the testing of an innovative

healthcare product or service; and

4. The Board may, on a case-by-case basis, specify minimum liability coverage and financial reserves that the participant shall meet during the testing of the innovative healthcare product or service.

C. Nothing in this section shall restrict a participant who holds a license or other authorization in another jurisdiction from acting in accordance with that license or other authorization.

D. Notwithstanding any other provision of law, a participant, solely by way of being a participant in the Program, shall be deemed to possess an appropriate license or authorization under the laws of the Commonwealth for the purposes of any provision of federal law requiring state licensure or authorization for the duration of the testing period.

E. Notwithstanding any other provision of law, a participant that is testing an innovative healthcare product or service shall not be subject to state laws, regulations, licensing requirements, or authorization requirements that were identified by the participant in the participant's application and approved by the Department and shall be waived in writing by the Department.

F. By written notice, the Department may end a participant's participation in the Program at any time if the Department determines a participant is not operating in good faith to bring an innovative healthcare product or service to market in the Commonwealth.

G. The Department shall not be liable for any business losses or the recouping of application expenses related to the Program, including in the cases of (i) denying an applicant's application to participate in the Program for any reason or (ii) ending a participant's participation in the Program at any time.

H. No guaranty association in the Commonwealth shall be held liable for business losses or liabilities incurred as a result of Program-related activities undertaken by a participant.

§ 32.1-380. Consumer protections.

A. Prior to providing an innovative healthcare product or service to a consumer, a participant must disclose the following to the consumer:

1. The name and contact information of the participant;

2. That the innovative healthcare product or service is authorized pursuant to the Program;

3. That the innovative healthcare product or service is undergoing testing and may not function as intended, potentially exposing the consumer to risk;

4. That the provider of the innovative healthcare product or service is not immune from civil liability for any losses or damages caused by the innovative healthcare product or service;

5. That the Commonwealth does not endorse or recommend the innovative healthcare product or service;

6. That the offering of the innovative healthcare product or service is a temporary test that may be discontinued at the end of the testing period;

7. The expected end date of the testing period; and

8. That a consumer may contact the Department to file a complaint regarding the innovative healthcare product or service being tested and provide the Department's telephone number and website address where a complaint may be filed.

B. The disclosures required by subsection A shall be provided to a consumer in a clear and conspicuous manner and, for an Internet-based or application-based innovative healthcare product or service, a consumer shall acknowledge receipt of the disclosure before a transaction is completed.

C. The Department may require that a participant make additional disclosures to a consumer.

§ 32.1-381. Exit requirements.

A. At least 30 days before the end of the Program testing period, a participant shall:

1. Notify the Department that the participant will exit the Program, will discontinue the test, and will cease offering those particular innovative healthcare products or services for which the participant applied to the Program within 60 days after the day on which the testing period ends; or

2. Seek an extension in accordance with § 32.1-382.

B. Subject to subsection C, if the Department does not receive notification as required in subsection A, the Program testing period ends at the end of the 24-month testing period and the participant shall immediately stop offering each innovative healthcare product or service being tested.

C. If a test includes offering an innovative healthcare product or service that requires ongoing duties, the participant shall continue to fulfill those duties or arrange for another individual or business to fulfill those duties after the date on which the participant exits the Program.

§ 32.1-382. Extensions.

A. Not later than 30 days before the end of the Program testing period, a participant may request an extension of the testing period for the purpose of obtaining a license or other authorization required by law. The Department shall grant or deny a request for an extension by the end of the Program testing period. The Department may grant an extension for not more than six months after the end of the

Program testing period.

B. A participant that obtains an extension shall provide the Department with a written report every three months that provides an update on efforts to obtain a license or other authorization required by law, including any submitted applications for licensure or other authorization, rejected applications, or issued licenses or other authorizations.

§ 32.1-383. Recordkeeping and reporting requirements.

A. A participant shall retain records, documents, and data produced in the ordinary course of business regarding the innovative healthcare product or service tested in the Program.

B. If an innovative healthcare product or service fails before the end of the testing period, the participant shall notify the Department and report on actions taken by the participant to ensure consumers have not been harmed as a result of the failure.

C. The Department shall establish quarterly reporting requirements for a participant, including information about any customer complaints.

D. The Department may request records, documents, and data from a participant, and upon the Department's request, a participant shall make such records, documents, and data available for inspection by the Department.

E. If the Department determines that a participant has engaged in, is engaging in, or is about to engage in any practice or transaction that is in violation of this chapter of that constitutes a violation of a state or federal criminal law, the Department may remove the participant from the Program.

F. By October 1 of each year, the Department shall provide a 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.

2. That the provisions of this act shall expire on July 1, 2027.