HOUSE BILL NO. 80

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Appropriations

on _____)

(Patron Prior to Substitute--Delegate Davis)

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 Health Care Regulatory Sandbox Program.

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.

HEALTH CARE 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 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.

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

"Health care product or service" means a health care 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.

"Innovative health care product or service" means a health care 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.

"Program" means the Health Care Regulatory Sandbox Program.

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

§ 32.1-377. Health Care Regulatory Sandbox Program established.

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

C. The Board 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.

D. If the Commissioner has a conflicting interest, as determined by the Board, in an application, applicant, or participant, the Commissioner shall designate an employee of the Department who does not have a conflicting interest in such application, applicant, or participant to exercise the powers and carry out the duties of the Commissioner set forth in this chapter with regard to the application, applicant, or participant. If a member of the Board has a conflicting a conflicting interest in an application, applicant,

or participant, such member shall not participate in any decision regarding the existence of a conflict on behalf of the Commissioner with regard such application, applicant, or participant.

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

A. A person who wishes to participate in the Program shall submit to the Department an application on a form approved by the Board together with a fee prescribed by the Board. Such form shall:

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

2. Demonstrate 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. Include personal and contact information for the applicant, including legal names, addresses, telephone numbers, email addresses, website addresses, and other information required by the Board;

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

5. Demonstrate 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 health care product or service;

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

a. How the innovative health care 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 health care product or service is different from health care products or services currently available to consumers in the Commonwealth;

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

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

e. How participating in the Program would enable a successful test of the innovative health care 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. How the applicant will perform ongoing duties, if applicable, after the test; and

h. 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. Provide any other information required by the Board.

B. An applicant shall file a separate application for each innovative health care 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. If an applicant has requested a waiver of any law, regulation, or other requirement enforced by an agency other the Department, 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 submitted pursuant to this section.

E. In determining whether to approve applications received pursuant to this section, the Commissioner shall consider whether (i) the Commissioner has previously issued a license or other authorization to the applicant; (ii) the Commissioner has previously investigated, sanctioned, or pursued legal action against the applicant; (iii) the applicant could obtain a license or other authorization from the Commissioner 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; (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; (vi) waiver of a specific state law, regulation, or other requirement

would jeopardize the public health, safety, or welfare; (vii) the applicant has been convicted, entered a plea of nolo contendere, or entered into a plea of guilty or nolo contender held in abeyance for a crime involving theft, fraud, or dishonesty or that bears a substantial relationship to the applicant's ability to safely or competently participate in the Program; and (viii) an agency of the Commonwealth has refused to consent to a waiver of law, regulation, or other requirement as specified in subsection D.

F. The Commissioner shall review each application submitted pursuant to this section and shall notify the applicant as to his decision by a date that is no later than 90 calendar days after the date on which the application was received by the Department. The Commissioner may (i) deny the application in full; (ii) approve the application in full and waive all state laws, regulations, and other requirements requested to be waived as part of the application; or (iii) approve the application in part and waive some of the laws, regulations, and other approvals requested to be waived as part of the application but not all. If the Commissioner approves an application in full or in part, the Commissioner may also waive additional state laws, regulations, and approvals that were not requested to be waived as part of the application if the Commissioner finds that such waivers are necessary to allow testing of the innovative health care product. If the Commissioner denies an application, the Commissioner 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 Commissioner.

§ 32.1-379. Scope of the Program.

A. If the Commissioner approves an application under § 32.1-378, the participant may test the innovative health care product or service described in the participant's application for a period ending on a date that is 24 months after the day on which the application was approved or July 1, 2027, whichever occurs sooner. The testing period may be extended upon mutual agreement of the Commissioner and the applicant if such extension is deemed appropriate by the Commissioner for the successful testing of an innovative health care 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 or July 1, 2027, whichever occurs sooner.

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

1. Consumers shall be residents of the Commonwealth;

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

3. The Commissioner 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 health care product or service; and

4. The Commissioner 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 health care 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 health care 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 Commissioner and waived in writing by the Commissioner.

F. The Board, Commissioner, and 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.

G. 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.

H. Nothing in this chapter shall be construed to waive any licensure, certification, or registration requirement of any health regulatory board located within the Department of Health Professions related to the practice of any health care provider with prescriptive authority.

§ 32.1-380. Consumer protections.

A. Prior to providing an innovative health care product or service to a consumer, a participant shall disclose the following to the consumer:

1. The name and contact information of the participant;

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

3. That the innovative health care 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 health care product or service is not immune from civil liability for any losses or damages caused by the innovative health care product or service;

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

6. That the offering of the innovative health care 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 health care 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 health care product or service, a consumer shall acknowledge receipt of the disclosure before a transaction is completed.

C. The Commissioner may, in accordance with regulations of the Board, require that a participant make additional disclosures to a consumer.

D. The Department may conduct inspections and investigations in response to complaints regarding the innovative health care service. The identity of the complainant shall be confidential and

shall not be open to inspection by members of the public Nothing contained herein shall prevent the Department, in its discretion, from disclosing to the participant the nature of the complaint or the identity of the patient who is the subject of the complaint. If the Department intends to rely, in whole or in part, on any statements made by the complainant, at any administrative proceeding brought against the participant, the Department shall disclose to the identity of the complainant to the participant in a reasonable time in advance of such proceeding. No participant shall retaliate or discriminate in any manner against a person who (i) in good faith complains or provides information to or otherwise cooperates with the Department or any other agency or person or entity operating under any contract with an agency of government having responsibility for protecting the rights of consumers or (ii) attempts to assert any right protected by state or federal law.

§ 32.1-381. Program exit.

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 health care products or services for which the participant applied to the Program within 30 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 health care product or service being tested.

C. If a test includes offering an innovative health care 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.

D. By written notice, the Commissioner may:

1. Suspend a participant's participation in the Program at any time if the Commissioner determines that continued testing of the innovative health care service or product constitutes a substantial danger to the public health, safety, or welfare, provided that (i) the testing period shall be tolled during such suspension and (ii) the Commissioner shall schedule an information conference pursuant to § 2.2-4019 to

be held within a reasonable time of the date of suspension to address the substantial danger to the participant; or

2. Revoke a participant's participation in the Program at any time if the Commissioner determines that (i) the participant is not operating in good faith to bring an innovative health care product or service to market in the Commonwealth; (ii) the participant fails or refuses to resolve a substantial danger to the public health, safety, or welfare; (iii) the innovative health care service or product constitutes a risk of or has resulted in actual harm to the public health, safety, or welfare; or (iv) a participant has engaged in, is in engaging in, or is about to engage in any practice or transaction that is in violation of this chapter or that constitutes a violation of a state or federal criminal law.

§ 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 Commissioner shall grant or deny a request for an extension by the end of the Program testing period. The Commissioner 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 health care product or service tested in the Program.

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

C. The Commissioner, in accordance with regulations adopted by the Board, shall establish quarterly reporting requirements for a participant, including information about any customer complaints.

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

E. By October 1 of each year, the Commissioner 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 Board of Health shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.

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

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