

2026 SESSION

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HOUSE BILL NO. 146

Offered January 14, 2026

Prefiled January 5, 2026

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 Health Care Learning Lab and Regulatory Improvement Program established.

Patron—Williams

Committee Referral Pending

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 LEARNING LAB AND REGULATORY IMPROVEMENT 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 that 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 Commonwealth.

"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 approach or delivery method" means the manner in which an established health care product or service is deployed or provided, including the use of blockchain technology, artificial intelligence, and telehealth or telemedicine, to address a problem or otherwise offer a product, service, business, or delivery mechanism within the Commonwealth or a region of the Commonwealth.

"Program" means the Health Care Learning Lab and Regulatory Improvement Program.

"Test" means to provide an innovative health care approach or delivery method in accordance with the provisions of this chapter.

§ 32.1-377. Health Care Learning Lab and Regulatory Improvement Program established.

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

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

60 2. Demonstrate that the applicant has established a physical or virtual location that is adequately

61 accessible to the Department, from which testing will be delivered and performed and where all required

62 records, documents, and data will be maintained;

63 3. Include personal and contact information for the applicant, including legal names, addresses,

64 telephone numbers, email addresses, website addresses, and other information required by the Board;

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

66 5. Demonstrate that the applicant has developed a plan and possesses the necessary resources, including

67 personnel and financial resources, and expertise to test, monitor, and assess the innovative health care

68 approach or delivery method;

69 6. Contain a description of the innovative health care approach or delivery method to be tested, including

70 statements regarding all of the following:

71 a. How the innovative health care approach or delivery method is subject to licensing or other

72 authorization requirements outside of the Program, including a specific list of all state laws, regulations, and

73 other requirements that the applicant is seeking to have waived during the testing period;

74 b. How the innovative health care approach or delivery method is different from health care products or

75 services currently available to consumers in the Commonwealth;

76 c. How the innovative health care approach or delivery method will benefit consumers in the

77 Commonwealth;

78 d. Any risks to consumers in the Commonwealth posed by the innovative health care approach or delivery

79 method;

80 e. How participating in the Program would enable a successful test of the innovative health care

81 approach or delivery method;

82 f. A description of the proposed testing plan, including estimated time periods for beginning the test,

83 ending the test, and obtaining necessary licensure or authorizations after the testing is complete;

84 g. How the applicant will perform ongoing duties, if applicable, after the test; and

85 h. How the applicant will end the test and protect consumers if the test fails, including providing evidence

86 of satisfactory liability coverage and financial reserves to protect consumers and to protect against

87 insolvency by the applicant;

88 7. Demonstrate that the applicant intends to offer such testing to communities or regions with diverse

89 demographics or a median household income that does not exceed 300 percent of the poverty guideline for

90 the 48 contiguous states and the District of Columbia as reported annually by the U.S. Department of Health

91 and Human Services under the authority of § 673(2) of the Omnibus Budget Reconciliation Act of 1981; and

92 8. Provide any other information required by the Board.

93 B. An applicant shall file a separate application for each innovative health care approach or delivery

94 method the applicant seeks to test in the Commonwealth.

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

96 to provide:

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

98 2. Proof of sufficient assets, accounts, liability coverage, surety bond coverage, or other preparation by

99 the applicant to ensure that consumers are protected and that the applicant will be able to meet ongoing

100 obligations upon termination or completion of testing.

101 D. If an applicant has requested a waiver of any law, regulation, or other requirement enforced by an

102 agency other than the Department, the Commissioner shall consult with the agency responsible for enforcing

103 such law, regulation, or other requirement and shall obtain the consent of such agency for a waiver of such

104 law, regulation, or requirement prior to approving an application submitted pursuant to this section.

105 E. In determining whether to approve applications received pursuant to this section, the Commissioner

106 shall consider whether (i) the Commissioner has previously issued a license or other authorization to the

107 applicant; (ii) the Commissioner has previously investigated, sanctioned, or pursued legal action against the

108 applicant; (iii) the applicant could obtain a license or other authorization from the Commissioner after

109 exiting the Program; (iv) certain licensure or other approval or regulatory requirements should not be

110 waived even if the applicant is accepted into the Program; (v) a competitor of the applicant is or has been a

111 Program participant and, if so, weigh that as a factor in favor of allowing the applicant to also become a

112 participant; (vi) waiver of a specific state law, regulation, or other requirement would jeopardize the public

113 health, safety, or welfare; (vii) the applicant has been convicted, entered a plea of nolo contendere, or

114 entered into a plea of guilty or nolo contendere held in abeyance for a crime involving theft, fraud, or

115 dishonesty or that bears a substantial relationship to the applicant's ability to safely or competently

116 participate in the Program; and (viii) an agency of the Commonwealth has refused to consent to a waiver of

117 law, regulation, or other requirement as specified in subsection D.

118 F. The Commissioner shall review each application submitted pursuant to this section and shall notify the

119 applicant as to his decision by a date that is no later than 90 calendar days after the date on which the

120 application was received by the Department. The Commissioner may (i) deny the application in full; (ii)

121 approve the application in full and waive all state laws, regulations, and other requirements requested to be
 122 waived as part of the application; or (iii) approve the application in part and waive some of the laws,
 123 regulations, and other approvals requested to be waived as part of the application but not all. If the
 124 Commissioner approves an application in full or in part, the Commissioner may also waive additional state
 125 laws, regulations, and approvals that were not requested to be waived as part of the application if the
 126 Commissioner finds that such waivers are necessary to allow testing of the innovative health care approach
 127 or delivery method. If the Commissioner denies an application, the Commissioner shall provide the applicant
 128 a written statement of the reason for the denial within the same 90-day period. The 90-day period for review
 129 of a completed application may be extended for up to an additional 90 calendar days upon agreement of the
 130 applicant and the Commissioner.

131 **§ 32.1-379. Scope of the Program.**

132 A. If the Commissioner approves an application under § 32.1-378, the participant may test an innovative
 133 health care approach or delivery method described in the participant's application for a period ending on a
 134 date that is 24 months after the day on which the application was approved or July 1, 2030, whichever occurs
 135 sooner. The testing period may be extended upon mutual agreement of the Commissioner and the applicant if
 136 such extension is deemed appropriate by the Commissioner for the successful testing of an innovative health
 137 care approach or delivery method. However, no testing period shall be extended beyond a date that is 30
 138 months from the participant's date of entry into the Program or July 1, 2030, whichever occurs sooner.

139 B. A participant testing an innovative health care approach or delivery method within the Program is
 140 subject to the following:

141 1. Consumers shall be residents of the Commonwealth;

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

144 3. The Commissioner may, on a case-by-case basis, limit the number of items and the maximum coverage
 145 amount for each item that is offered by a participant during the testing of an innovative health care approach
 146 or delivery method; and

147 4. The Commissioner may, on a case-by-case basis, specify minimum liability coverage and financial
 148 reserves that the participant shall meet during the testing of the innovative health care approach or delivery
 149 method.

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

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

156 E. Notwithstanding any other provision of law, a participant that is testing an innovative health care
 157 approach or delivery method shall not be subject to state laws, regulations, licensing requirements, or
 158 authorization requirements that were identified by the participant in the participant's application and
 159 approved by the Commissioner and waived in writing by the Commissioner.

160 F. Participants shall be liable for all expenses related to their involvement in the Program. The Board,
 161 Commissioner, and Department shall not be liable for any business losses or the recouping of application
 162 expenses related to the Program, including in the case of (i) denying an applicant's application to participate
 163 in the Program for any reason or (ii) ending a participant's participation in the Program at any time.

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

166 H. Nothing in this chapter shall be construed to waive any:

167 1. Licensure, certification, or registration requirement of any health regulatory board located within the
 168 Department of Health Professions related to the practice of any health care provider with prescriptive
 169 authority; or

170 2. Certificate of public need requirements of Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4.

171 **§ 32.1-380. Consumer protections.**

172 A. Prior to providing an innovative health care approach or delivery method to a consumer, a participant
 173 shall disclose the following to the consumer:

174 1. The name and contact information of the participant;

175 2. That the innovative health care approach or delivery method is authorized pursuant to the Program;

176 3. That the innovative health care approach or delivery method is undergoing testing and may not
 177 function as intended, potentially exposing the consumer to risk;

178 4. That the provider of the innovative health care approach or delivery method is not immune from civil
 179 liability for any losses or damages caused by the innovative health care approach or delivery method;

180 5. That the Commonwealth does not endorse or recommend the innovative health care approach or
 181 delivery method;

182 6. That the offering of the innovative health care approach or delivery method is a temporary test that

183 may be discontinued at the end of the testing period;

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

185 8. That a consumer may contact the Department to file a complaint regarding the innovative health care
186 approach or delivery method being tested and provide the Department's telephone number and website
187 address where a complaint may be filed.

188 B. The disclosures required by subsection A shall be provided to a consumer in a clear and conspicuous
189 manner and, for an internet-based or application-based innovative health care approach or delivery method,
190 a consumer shall acknowledge receipt of the disclosure before a transaction is completed.

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

193 D. The Department may conduct inspections and investigations in response to complaints regarding the
194 innovative health care approach or delivery method. The identity of the complainant shall be confidential and
195 shall not be open to inspection by members of the public. Nothing contained herein shall prevent the
196 Department, in its discretion, from disclosing to the participant the nature of the complaint or the identity of
197 the consumer who is the subject of the complaint. If the Department intends to rely, in whole or in part, on
198 any statements made by the complainant, at any administrative proceeding brought against the participant,
199 the Department shall disclose the identity of the complainant to the participant in a reasonable time in
200 advance of such proceeding. No participant shall retaliate or discriminate in any manner against a person
201 who (i) in good faith complains or provides information to or otherwise cooperates with the Department or
202 any other agency or person or entity operating under any contract with an agency of government having
203 responsibility for protecting the rights of consumers or (ii) attempts to assert any right protected by state or
204 federal law.

205 **§ 32.1-381. Program exit.**

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

207 1. Notify the Department that the participant will exit the Program, will discontinue the test, and will
208 cease offering those particular innovative health care products or services for which the participant applied
209 to the Program within 30 days after the day on which the testing period ends; or

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

211 B. Subject to subsection C, if the Department does not receive notification as required in subsection A, the
212 Program testing period ends at the end of the 24-month testing period and the participant shall immediately
213 stop offering each innovative health care approach or delivery method being tested.

214 C. If a test includes offering an innovative health care approach or delivery method that requires ongoing
215 duties, the participant shall continue to fulfill those duties or arrange for another individual or business to
216 fulfill those duties after the date on which the participant exits the Program.

217 D. By written notice, the Commissioner may:

218 1. Suspend a participant's participation in the Program at any time if the Commissioner determines that
219 continued testing of the innovative health care approach or delivery method constitutes a substantial danger
220 to the public health, safety, or welfare, provided that (i) the testing period shall be tolled during such
221 suspension and (ii) the Commissioner shall schedule an information conference pursuant to § 2.2-4019 to be
222 held within a reasonable time of the date of suspension to address the substantial danger to the public health,
223 safety, or welfare; or

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

231 **§ 32.1-382. Extensions.**

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

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

241 **§ 32.1-383. Recordkeeping and reporting requirements.**

242 A. A participant shall retain records, documents, and data produced in the ordinary course of business
243 regarding the innovative health care approach or delivery method tested in the Program, including data
244 related to the impact that an innovative health care approach or delivery method has had on communities or

245 regions with diverse demographics or a median household income that does not exceed 300 percent of the
246 poverty guideline as described in A 7 of § 32.1-378.

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

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

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

255 E. By October 1 of each year, the Commissioner shall provide a report to the Chairs of the House
256 Committee on Health and Human Services and the Senate Committee on Education and Health that provides
257 information regarding each Program participant and that provides recommendations regarding the
258 effectiveness of the Program.

259 2. That the Board of Health shall promulgate regulations to implement the provisions of this act to be
260 effective within 280 days of its enactment.

261 3. That the provisions of this act shall expire on July 1, 2030.

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