

SENATE FILE NO. SF0156

Medical digital innovation sandbox.

Sponsored by: Senator(s) Dockstader and Driskill

A BILL

for

1 AN ACT relating to trade and commerce; creating the medical
2 digital innovation sandbox; authorizing innovative medical
3 digital assessment products and services as specified;
4 authorizing limited waivers from specified statutes and rules
5 under certain conditions; establishing standards and
6 procedures for sandbox applications and operations; requiring
7 criminal history background checks; creating an account;
8 requiring a consumer protection bond; requiring the adoption
9 of rules; and providing for an effective date.

10

11 *Be It Enacted by the Legislature of the State of Wyoming:*

12

13 **Section 1.** W.S. 33-1-119 and 40-28-101 through
14 40-28-108 are created to read:

15

1 **33-1-119. Applicability of Medical Digital Innovation**
2 **Sandbox Act.**

3
4 The Medical Digital Innovation Sandbox Act shall apply to the
5 chapters within this title listed in W.S. 40-28-102(a).

6

7

CHAPTER 28

8

MEDICAL DIGITAL INNOVATION SANDBOX ACT

9

10 **40-28-101. Short title; definitions.**

11

12 (a) This act may be cited as the "Medical Digital
13 Innovation Sandbox Act".

14

15 (b) As used in this act:

16

17 (i) "Department" means the department of health;

18

19 (ii) "Sandbox" means a time limited test
20 environment or program in which innovative technologies,
21 products or services may be developed or explored and made
22 available to consumers prior to general authorized use or
23 deployment;

1

2 (iii) "This act" means W.S. 40-28-101 through
3 40-28-108.

4

5 **40-28-102. Medical digital innovation sandbox waiver;**
6 **applicability of criminal statutes; referrals; civil**
7 **liability.**

8

9 (a) Notwithstanding any other provision of law, a
10 person who makes an innovative medical digital assessment
11 product or service available to consumers in the medical
12 digital innovation sandbox may be granted a waiver from
13 specified requirements imposed by statute or rule, or
14 portions thereof, if these statutes or rules do not currently
15 permit the product or service to be made available to
16 consumers. A waiver under this subsection shall be no broader
17 than necessary to accomplish the purposes and standards set
18 forth in this act, as determined by the department or the
19 appropriate licensing board or authority under the chapters
20 listed in this subsection. The statutes within the following
21 chapters of title 33 of the Wyoming statutes, and the rules
22 adopted under them, or portions thereof, may be waived by the
23 department and the appropriate licensing boards or

1 authorities, upon receipt and approval of an application made
2 to the department pursuant to W.S. 40-28-103:

3

4 (i) Chapter 1, licensing generally;

5

6 (ii) Chapter 9, podiatrists;

7

8 (iii) Chapter 10, chiropractors;

9

10 (iv) Chapter 15, dentists and dental hygienists;

11

12 (v) Chapter 21, nurses;

13

14 (vi) Chapter 23, optometrists;

15

16 (vii) Chapter 25, physical therapists;

17

18 (viii) Chapter 26, physicians and surgeons;

19

20 (ix) Chapter 27, psychologists;

21

22 (x) Chapter 32, eye Care practitioners;

23

- 1 (xi) Chapter 33, speech language pathologists and
2 audiologists;
3
- 4 (xii) Chapter 34, clinical laboratories and blood
5 banks;
6
- 7 (xiii) Chapter 35, hearing aid specialists;
8
- 9 (xiv) Chapter 36, emergency medical services;
10
- 11 (xv) Chapter 37, radiologic technologists;
12
- 13 (xvi) Chapter 40, occupational therapy;
14
- 15 (xvii) Chapter 43, respiratory care
16 practitioners;
17
- 18 (xviii) Chapter 46, midwives;
19
- 20 (xix) Chapter 47, dietetics.
21

1 (b) A person who makes an innovative medical digital
2 assessment product or service available to consumers in the
3 medical digital innovation sandbox is:

4

5 (i) Not immune from civil damages for acts and
6 omissions relating to this act; and

7

8 (ii) Subject to all criminal laws.

9

10 (c) The department may refer suspected violations of
11 law relating to this act to appropriate state or federal
12 agencies for investigation, prosecution, civil penalties and
13 other appropriate enforcement actions.

14

15 **40-28-103. Medical digital innovation sandbox**
16 **application; standards for approval; consumer protection**
17 **bond.**

18

19 (a) A person shall apply to the department to make an
20 innovative medical digital assessment product or service
21 available to consumers in the medical digital innovation
22 sandbox, based on the licensing board or authority that
23 administers the statute or rule, or portion thereof, for which

1 a waiver is sought. If an application is filed with a
2 licensing board or authority that does not administer the
3 statute or rule for which a waiver is sought, the receiving
4 board or authority shall forward the application to the
5 correct board or authority. The person shall specify in an
6 application the statutory or rule requirements for which a
7 waiver is sought and the reasons why these requirements
8 prohibit the innovative medical digital assessment product or
9 service from being made available to consumers. The
10 application shall also contain the elements required for
11 authorization which are set forth in subsection (f) of this
12 section. The department shall, by rule, prescribe a method of
13 application.

14

15 (b) A business entity making an application under this
16 section shall be a domestic corporation or other organized
17 domestic entity with a physical presence, other than that of
18 a registered office or agent, in Wyoming.

19

20 (c) Before an employee applies on behalf of an
21 institution, firm or other entity intending to make an
22 innovative medical digital assessment product or service
23 available through the medical digital innovation sandbox, the

1 employee shall obtain the consent of the institution, firm or
2 entity before filing an application under this section.

3

4 (d) The individual filing an application under this
5 section and the individuals who are substantially involved in
6 the development, operation or management of the innovative
7 medical digital assessment product or service shall, if
8 requested by the department as a condition of the application,
9 submit to a criminal history background check pursuant to
10 W.S. 7-19-201.

11

12 (e) An application made under this section shall be
13 accompanied by a fee of five hundred dollars (\$500.00).
14 The fee shall be deposited into the medical digital
15 innovation account as provided in W.S. 40-28-104.

16

17 (f) The department shall authorize or deny a medical
18 digital innovation sandbox application in writing within
19 ninety (90) days of receiving the application. The department
20 and the person who has made an application may jointly agree
21 to extend the time beyond ninety (90) days. The department
22 may impose conditions on any authorization, consistent with
23 this act. In deciding to authorize or deny an application

1 under this subsection, the department shall consider each of
2 the following:

3

4 (i) The nature of the innovative medical digital
5 assessment product or service proposed to be made available
6 to consumers in the sandbox, including all relevant technical
7 details;

8

9 (ii) The potential risk to consumers and methods
10 which will be used to protect consumers and resolve complaints
11 during the sandbox period;

12

13 (iii) A prototyping, use case or scaling plan
14 proposed by the person, including a statement of arranged
15 capital;

16

17 (iv) Whether the person has the necessary
18 personnel, adequate medical digital and technical expertise
19 and a sufficient plan to test, monitor and assess the
20 innovative medical digital assessment product or service;

21

1 (v) Whether any person substantially involved in
2 the development, operation or management of the innovative
3 medical digital assessment product or service has:

4

5 (A) Been convicted of, or is currently under
6 investigation for, fraud, state or federal securities
7 violations;

8

9 (B) Had any professional license revoked or
10 suspended; or

11

12 (C) Any other past criminal conduct the
13 department deems relevant.

14

15 (g) If an application is authorized under subsection
16 (f) of this section, the department shall specify the
17 statutory or rule requirements, or portions thereof, for
18 which a waiver is granted and the length of the initial
19 sandbox period. The department shall also post notice of the
20 approval of a sandbox application under this subsection, a
21 summary of the innovative medical digital assessment product
22 or service and the contact information of the person making

1 the product or service available through the sandbox on the
2 internet website of the department.

3

4 (h) A person authorized under subsection (f) of this
5 section to enter into the medical digital innovation sandbox
6 shall post a consumer protection bond with the department as
7 security for potential losses suffered by consumers who use
8 an innovative medical digital assessment product or service
9 offered by the person. The bond amount shall be determined by
10 the department in an amount not less than ten thousand dollars
11 (\$10,000.00) and shall be commensurate with the risk profile
12 of the innovative medical digital assessment product or
13 service. The department may require that a bond under this
14 subsection be increased or decreased at any time based on
15 risk profile. Unless a bond is enforced under W.S.
16 40-28-108(b)(ii), the department shall cancel or allow the
17 bond to expire two (2) years after the date of the conclusion
18 of the sandbox period.

19

20 (j) Authorization under subsection (f) of this section
21 shall not be construed to create a property right.

22

23 **40-28-104. Medical digital innovation account.**

1

2 (a) There is created the medical digital innovation
3 account. Funds within the account shall only be expended by
4 legislative appropriation. All funds within the account shall
5 be invested by the state treasurer and all investment earnings
6 from the account shall be credited to the general fund.

7

8 (b) Subject to legislative appropriation, application
9 fees remitted to the account pursuant to W.S. 40-28-103(e),
10 and any additional funds appropriated by the legislature,
11 shall be used by the department only for the purposes of
12 administering this act, including processing of sandbox
13 applications and monitoring, examination and enforcement
14 activities relating to this act.

15

16 **40-28-105. Operation of medical digital innovation**
17 **sandbox.**

18

19 (a) Except as otherwise provided by W.S. 40-28-107, a
20 person authorized under W.S. 40-28-103(f) to enter into the
21 medical digital innovation sandbox may make an innovative
22 medical digital assessment product or service available to
23 consumers during the sandbox period.

1

2 (b) Before a consumer purchases or enters into an
3 agreement to receive an innovative medical digital assessment
4 product or service through the medical digital innovation
5 sandbox, the person making the product or service available
6 shall provide a written statement of the following to the
7 consumer:

8

9 (i) The name and contact information of the person
10 making the product or service available to consumers;

11

12 (ii) That the product or service has been
13 authorized to be made available to consumers for a temporary
14 period by the department and the appropriate licensing board
15 or authority, as applicable, under the laws of Wyoming;

16

17 (iii) That the state of Wyoming does not endorse
18 the product or service and is not subject to liability for
19 losses or damages caused by the product or service;

20

21 (iv) That the product or service is undergoing
22 testing, may not function as intended and may entail medical
23 assessment risk;

1

2 (v) That the person making the product or service
3 available to consumers is not immune from civil liability for
4 any losses or damages caused by the product or service;

5

6 (vi) The expected end date of the sandbox period;

7

8 (vii) The name and contact information of the
9 department and board or authority, as applicable, and
10 notification that suspected legal violations, complaints or
11 other comments related to the product or service may be
12 submitted to the department;

13

14 (viii) Any other statements or disclosures
15 required by rule of the department which are necessary to
16 further the purposes of this act.

17

18 (c) A person authorized to make an innovative medical
19 digital assessment product or service available to consumers
20 in the medical digital innovation sandbox shall maintain
21 comprehensive records relating to the innovative medical
22 digital assessment product or service. The person shall keep
23 these records for not less than five (5) years after the

1 conclusion of the sandbox period. The department may specify
2 further records requirements under this subsection by rule.

3

4 (d) The department or licensing board or authority, as
5 applicable, may examine the records maintained under
6 subsection (c) of this section at any time, with or without
7 notice. All direct and indirect costs of an examination
8 conducted under this subsection shall be paid by the person
9 making the innovative medical digital assessment product or
10 service available in the medical digital innovation sandbox.
11 Records made available under this subsection shall be
12 confidential and shall not be subject to disclosure under the
13 Wyoming Public Records Act but may be released to appropriate
14 state and federal agencies for the purposes of investigation.

15

16 (e) Unless granted an extension pursuant to W.S.
17 40-28-107, not less than thirty (30) days before the
18 conclusion of the sandbox period, a person who makes an
19 innovative medical digital assessment product or service
20 available in the medical digital innovation sandbox shall
21 provide written notification to consumers regarding the
22 conclusion of the sandbox period and shall not make the
23 product or service available to any new consumers after the

1 conclusion of the sandbox period until legal authority
2 outside of the sandbox exists to make the product or service
3 available to consumers. The person shall wind down operations
4 with existing consumers within sixty (60) days after the
5 conclusion of the sandbox period, except that, after the
6 sixtieth day, the person may:

7

8 (i) Collect and receive money owed to the person
9 and service loans made by the person, based on agreements
10 with consumers made before the conclusion of the sandbox
11 period;

12

13 (ii) Take necessary legal action; and

14

15 (iii) Take other actions authorized by the
16 department by rule which are not inconsistent with this
17 subsection.

18

19 (f) The department may enter into agreements with
20 state, federal or foreign regulatory agencies to allow
21 persons who make an innovative medical digital assessment
22 product or service available in Wyoming through the medical
23 digital innovation sandbox to make their products or services

1 available in other jurisdictions and to allow persons
2 operating in similar medical digital innovation sandboxes in
3 other jurisdictions to make innovative medical digital
4 assessment products and services available in Wyoming under
5 the standards of this act.

6

7 **40-28-106. Revocation or suspension of medical digital**
8 **innovation sandbox authorization.**

9

10 (a) The department may, by order, revoke or suspend
11 authorization granted to a person under W.S. 40-28-103(f) if:

12

13 (i) The person has violated or refused to comply
14 with this act or any lawful rule, order or decision adopted
15 by the department;

16

17 (ii) A fact or condition exists that, if it had
18 existed or become known at the time of the medical digital
19 innovation sandbox application, would have warranted denial
20 of the application or the imposition of material conditions;

21

1 (iii) A material error, false statement,
2 misrepresentation or material omission was made in the
3 medical digital innovation sandbox application; or

4

5 (iv) After consultation with the person, continued
6 testing of the innovative medical digital assessment product
7 or service would:

8

9 (A) Be likely to harm consumers; or

10

11 (B) No longer serve the purposes of this act
12 because of the medical digital or operational failure of the
13 product or service.

14

15 (b) Written notification of a revocation or suspension
16 order made under subsection (a) of this section shall be
17 served using any means authorized by law, and if the notice
18 relates to a suspension, include any conditions or remedial
19 action which shall be completed before the suspension will be
20 lifted by the department.

21

22 **40-28-107. Extension of sandbox period.**

23

1 (a) A person granted authorization under W.S.
2 40-28-103(f) may apply for an extension of the initial sandbox
3 period for not more than twelve (12) additional months. An
4 application for an extension shall be made not later than
5 sixty (60) days before the conclusion of the initial sandbox
6 period specified by the department. The department shall
7 approve or deny the application for extension in writing not
8 later than thirty-five (35) days before the conclusion of the
9 initial sandbox period. An application for extension by a
10 person shall cite one (1) of the following reasons as the
11 basis for the application and provide all relevant supporting
12 information that:

13

14 (i) Statutory or rule amendments are necessary to
15 conduct business in Wyoming on a permanent basis;

16

17 (ii) An application for a license or other
18 authorization required to conduct business in Wyoming on a
19 permanent basis has been filed with the appropriate office
20 and approval is currently pending.

21

1 **40-28-108. Rules and orders; enforcement of bond;**
2 **restitution; applicability of Wyoming Administrative**
3 **Procedure Act.**

4

5 (a) The department shall adopt rules to implement this
6 act.

7

8 (b) The department may issue:

9

10 (i) All necessary orders to enforce this act,
11 including ordering the payment of restitution, and enforce
12 these orders in any court of competent jurisdiction;

13

14 (ii) An order under paragraph (i) of this
15 subsection to enforce the bond posted under W.S.
16 40-28-103(h), or a portion of this bond, and use proceeds
17 from the bond to offset losses suffered by consumers as a
18 result of an innovative medical digital assessment product or
19 service.

20

21 (c) All actions of the department under this act shall
22 be subject to the Wyoming Administrative Procedure Act.

23

1 **Section 2.** W.S. 7-19-106(a) by creating a new paragraph
2 (xxx) and 7-19-201(a) by creating a new paragraph (xxvi) are
3 amended to read:

4
5 **7-19-106. Access to, and dissemination of, information.**

6
7 (a) Criminal history record information shall be
8 disseminated by criminal justice agencies in this state,
9 whether directly or through any intermediary, only to:

10
11 (xxx) The department of health for purposes of
12 obtaining background information on persons specified in W.S.
13 40-28-103(d) as part of a medical digital innovation sandbox
14 application.

15
16 **7-19-201. State or national criminal history record**
17 **information.**

18
19 (a) The following persons shall be required to submit
20 to fingerprinting in order to obtain state and national
21 criminal history record information:

22

