

Wyoming Administrative Rules

**Health, Department of**

Medical Digital Innovation

Chapter 1: Rules and Regulations for the Medical Digital Innovation Sandbox

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## CHAPTER 1

### Rules and Regulations for the Medical Digital Innovation Sandbox

#### Section 1. Authority.

The Wyoming Department of Health (“Department”) promulgates these rules pursuant to Wyoming Statute 40-28-108.

#### Section 2. Purpose and Applicability.

These rules implement the Medical Digital Innovation Sandbox Act, W.S. 40-28-101 to -108.

#### Section 3. Definitions.

(a) The following definitions apply to these rules:

(i) “Director” means the Director of the Wyoming Department of Health, including the Director’s designee.

(ii) “Sandbox” means a time limited test environment or program in which innovative technologies, products or services may be developed or explored and made available to consumers prior to general authorized use or deployment, as defined under W.S. 40-28-101.

(iii) “Sandbox period” means the period of time, initially not longer than twenty-four (24) months, in which the department or the appropriate licensing board or authority has authorized an innovative medical digital assessment product or service to be made available to consumers, as defined under W.S. 40-28-101.

#### Section 4. Eligibility for the Medical Digital Innovation Sandbox.

(a) A person is eligible to apply to the Department to make an innovative medical digital assessment product or service available to consumers in the medical digital innovation sandbox subject to the following conditions:

(i) The person shall own, operate, or belong to a business entity with necessary personnel and adequate medical digital and technical expertise to test, monitor, and assess the innovative medical digital assessment product or service;

(ii) The business entity shall be a domestic corporation or other organized domestic entity;

(iii) The business entity shall have a physical presence in Wyoming, other than that of a registered office or agent, as verified by the Wyoming Secretary of State’s Office; and

(iv) If the person applying is only an employee of the business entity, the person shall obtain the consent of the entity to apply on its behalf.

**Section 5. Method of Application.**

(a) If eligible under Section 4 of this Chapter, a person may apply to the Department to make an innovative medical digital assessment product or service available to consumers in the medical digital innovation sandbox in the form and manner publicly-posted online at the Department's website: <https://health.wyo.gov>.

(b) At a minimum, the application must include:

(i) A statement of:

(A) The specific statutory or rule requirements for which a waiver is sought; and

(B) The reasons why these requirements prohibit the innovative medical digital assessment product or service from being made available to consumers;

(ii) A description of the innovative medical digital assessment product or service proposed to be made available to consumers in the sandbox, including all relevant technical details;

(iii) A description of the potential risks to consumers and the methods that will be used to protect consumers and resolve complaints during the sandbox period;

(iv) A proposed prototyping, use case, or scaling plan, including a statement of arranged capital;

(v) A summary of the experiences and qualifications of the personnel who will test, monitor, and assess the innovative medical digital assessment product or service;

(vi) A description of the business entity's medical digital and technical expertise, including a summary of any products or services currently available to consumers from the business entity;

(vii) A description of the business entity's plan to test, monitor, and assess the innovative medical digital assessment product or service;

(viii) A statement whether any person substantially involved in the development, operation, or management of the innovative medical digital assessment product or services has:

(A) Been convicted of or is currently under investigation for federal or state crimes; or

(B) Had any professional license revoked or suspended;

(ix) Proof that the business entity is a domestic corporation or other organized domestic entity;

(x) Proof that the business entity has a physical presence, other than that of a registered office or agent, in Wyoming;

(xi) If the applicant is an employee of the business entity, a letter documenting the entity's consent signed by an authority authorized to act on the entity's behalf, including, as relevant, the owner, managing partner, board of directors, president, chief executive officer, or managing member; and

(xii) The five hundred dollar (\$500) application fee.

(c) The Department may require the applicant and any other individuals who are substantially involved in the development, operation, or management of the innovative medical digital assessment product or service to submit to a criminal history background check pursuant to W.S. 7-19-201.

#### **Section 6. Authorization or Denial of Application.**

(a) The Director shall authorize or deny a medical digital innovation sandbox application within ninety (90) days of receiving the application, subject to the following conditions:

(i) If the Department requires a criminal history background check under Section 5(c) of this Chapter, the application is not considered received until the Department receives the required state and national criminal history record information.

(ii) The Department and the applicant may jointly agree to extend the deadline beyond ninety (90) days.

(b) Upon receipt of a medical digital innovation sandbox application, the Department shall evaluate the application according to the following procedures and standards:

(i) The Department shall initially evaluate the application to determine if:

(A) The applicant is eligible pursuant to Section 4 of this Chapter; and

(B) The application is complete pursuant to Section 5 of this Chapter.

(ii) If the Department determines that a complete application has been submitted by an eligible applicant, the Department shall forward the application to the licensing board or authority that administers the statutory or rules requirements for which a waiver is

sought, or to each of the respective licensing boards or authorities if a waiver is sought for more than one statutory or rules requirement.

(A) The licensing board or authority shall grant or deny the waiver within forty-five (45) days of receiving the forwarded application from the Department. The licensing board or authority shall promptly notify the Department of its decision in writing.

(B) The licensing board or authority may not grant a waiver unless the waiver is no broader than necessary to accomplish the purposes and standards set forth under the Medical Digital Innovation Sandbox Act, W.S. 40-28-101 to -108.

(C) If the licensing board or authority grants the waiver, the licensing board or authority shall specify in its notice to the Department:

(I) The statutory or rules requirements, or portions thereof, for which a waiver is granted; and

(II) Any minimum record keeping requirements recommended by the licensing board or authority under W.S. 40-28-105(c).

(D) The waiver is not deemed effective unless:

(I) The Director authorizes the application pursuant to subsection (c) of this Section; and

(II) A consumer protection bond is posted with the Department pursuant to Section 7(a) of this Chapter.

(iii) If the licensing board or authority grants the waiver, the Department shall convene a review committee to evaluate the medical digital innovation sandbox application. In the event that a waiver is sought for more than one statutory or rules requirement, the Department shall convene a review committee only if each of the respective licensing boards and authorities approves their respective waiver.

(A) The review committee must be comprised of at least three Department officials or employees, who possess relevant subject matter expertise and no conflicts of interest.

(B) The review committee shall evaluate the application based on the criteria established under W.S. 40-28-103(f). The review committee may request additional information from the applicant or from outside experts as needed to evaluate the application.

(C) Following its evaluation, the review committee shall recommend the Director to either authorize or deny an application in writing, explaining the basis for the committee's recommendation.

(c) Following the Department's evaluation pursuant to subsection (b) of this Section, the Director shall authorize or deny the medical digital innovation sandbox application, according to the following conditions:

- (i) The Director shall deny the application if:
  - (A) The Department determines the applicant is ineligible;
  - (B) The Department determines the application is incomplete; or
  - (C) An appropriate licensing board or authority denies the waiver.

(ii) If the Department determines the applicant is eligible and the licensing board or authority grants the waiver, the Director shall base the decision to authorize or deny the application on the review committee's recommendation. The Director may reach a decision contrary to the review committee's recommendation, subject to his or her discretion and an independent evaluation of the application based on the criteria established under W.S. 40-28-103(f).

(iii) If the Director authorizes an application, the Director may impose conditions on the authorization consistent with the Medical Digital Innovation Sandbox Act, W.S. 40-28-101 to -108

(iv) If the Director denies an application, the applicant is not entitled to request a contested case proceeding pursuant to the Wyoming Administrative Procedure Act, W.S. 16-3-101 to -115.

(v) The Director shall issue his or her decision in writing.

(A) If the Director authorizes the application, the written decision must specify:

(I) The statutory or rule requirements, or portions thereof, for which the waiver is granted;

(II) The length of the initial sandbox period; and

(III) The conditions imposed on the authorization, if any.

(B) If the Director denies the application, the written decision must specify the reason for denial.

## **Section 7. Operation in the Sandbox.**

(a) Prior to the commencement of the sandbox period, a person authorized to operate in the sandbox shall:

(i) Post a consumer protection bond with the Department in an amount established by the Department pursuant to W.S. 40-28-103(h); and

(ii) Provide the Department a copy of the written statement to consumers required under W.S. 40-28-105(b).

(b) A person authorized to operate in the sandbox shall maintain comprehensive records relating to the innovative medical digital assessment product or service pursuant to W.S. 40-28-105(c).

(c) No less than thirty days prior to the expiration of the sandbox period, a person authorized to operate in the sandbox shall:

(i) Provide notice to all consumers pursuant to W.S. 40-28-105(e); and

(ii) Provide the Department a written description of the plan to wind-down operations with existing consumers pursuant to W.S. 40-28-105(e), as well as a copy of the notice provided to consumers.

(d) The Director may revoke or suspend an authorization to operate in the sandbox at any time pursuant to W.S. 40-28-106. If the Director revokes or suspends an authorization, the person formerly authorized to operate in the sandbox is not entitled to request a contested case proceeding pursuant to the Wyoming Administrative Procedure Act, W.S. 16-3-101 to -115.

(e) A person authorized to operate in the sandbox may apply for an extension of the initial sandbox period pursuant to W.S. 40-28-107, in the form and manner publicly-posted online at the Department's website: <https://health.wyo.gov>. If the Director denies an application for extension, the applicant is not entitled to request a contested case proceeding pursuant to the Wyoming Administrative Procedure Act, W.S. 16-3-101 to -115. An application for extension shall, at minimum, include the following:

(i) All relevant supporting information demonstrating that either:

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

(B) An application for a license or other authorization required to conduct business in Wyoming on a permanent basis has been filed with the appropriate office and approval is currently pending;

(ii) The length of time for which an extension is requested, not to exceed twelve months; and

(iii) Written approval of the extension from the licensing board or authority, or each of the licensing boards and authorities, if more than one, that approved the initial waiver.