

Medical Digital Innovation Sandbox

Application for Waiver

Administered by



Wyoming
Department
of Health

Introduction

During the 2019 General Session, the Wyoming Legislature passed, and Governor Gordon signed into law, Senate File 156 (Senate Enrolled Act 75), Medical Digital Innovation Sandbox Act. The Sandbox Act permits the Wyoming Department of Health to grant a waiver from requirements imposed by statute or rule for innovative medical digital assessment products or services.

Enclosed are the application materials and instructions. Technical questions regarding the application or the application process can be directed to:

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Policy Administrator
Wyoming Department of Health
Jeri.hendricks@wyo.gov
307-777-2438

APPLICATIONS FOR WAIVER

1. ELIGIBILITY

- 1.1. The applicant must own, operate, or belong to a business entity with necessary personnel and adequate medical digital and technical expertise to test, monitor, or assess the innovative medical digital assessment product or serve.
- 1.2. The applicant must be a domestic corporation or other organized domestic entity.
- 1.3. The applicant must have a physical presence in Wyoming.
- 1.4. If the applicant is an employee, the applicant must obtain consent of the business entity to apply on its behalf.

2. REVIEW OF APPLICATIONS

- 2.1. The Director shall authorize or deny a medical digital innovation sandbox application within ninety (90) days of receiving the application.
- 2.2. 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.
- 2.3. 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.
- 2.4. If the licensing board or authority grants the waiver, the Department shall convene a review committee to evaluate the medical digital innovation sandbox application. 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.
- 2.5. The Director shall issue his or her decision in writing. If the Director denies the application, the written decision must specify the reason for denial.

3. SUBMISSION OF APPLICATIONS

- 3.1. Applications can be submitted electronically via email to wdh-healthcareinnovation@wyo.gov, or delivered in hard copy to:

Digital Innovation Sandbox

c/o Director's Unit for Policy, Research, & Evaluation
Wyoming Department of Health
401 Hathaway Building
Cheyenne WY 82002

- 3.2. Applications must contain all information specified in Sections 4 through 8, below.
 - 3.2.1. Responses to each section must appear in the order specified.
 - 3.2.2. Responses to each section must be clearly numbered.
4. APPLICANT INFORMATION
 - 4.1. Name of the entity applying, including any subsidiary or proposed subcontractor information.
 - 4.2. Identify a single point of contact for all correspondence for the application materials, including: Name, role, phone, & email.
5. MEDICAL INNOVATION DESCRIPTION
 - 5.1. The specific statutory or rule requirements for which a waiver is sought and the reasons why these requirements prohibit the innovative medical digital assessment product or service from being made available to consumers;
 - 5.2. 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;
 - 5.3. 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;
 - 5.4. A proposed prototyping, use case, or scaling plan, including a statement of arranged capital;
 - 5.5. 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;
 - 5.6. A description of the business entity's plan to test, monitor, and assess the innovative medical digital assessment product or service;
6. STAFFING

- 6.1. A summary of the experiences and qualifications of the personnel who will test, monitor, and assess the innovative medical digital assessment product or service;
- 6.2. A statement whether any person substantially involved in the development, operation, or management of the innovative medical digital assessment product or services has been convicted of or is currently under investigation for federal or state crimes; or had any professional license revoked or suspended;

7. BUSINESS INFORMATION

- 7.1. Proof that the business entity is a domestic corporation or other organized domestic entity;
- 7.2. Proof that the business entity has a physical presence, other than that of a registered office or agent, in Wyoming;
- 7.3. 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

8. FEE

- 8.1. Applications must include a five hundred dollar (\$500) application fee.