

**INITIAL RULE IMPACT STATEMENT**

**(This document may be revised based on comment received during the public comment period.)**

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH  
CHAPTER 521. CONTROL AND TREATMENT OF COMMUNICABLE DISEASE**

**1. DESCRIPTION:**

Senate Bill 511, relating to controlled dangerous substances, amended Title 63 O.S. §§ 2-1101 and 2-101, authorizing certain entities to engage in harm-reduction services and requiring registration with the Oklahoma State Department of Health (OSDH) and establishing reporting requirements. The proposed Subchapter 9 rules implement the requirements for harm-reduction services established under Title 63 O.S. §§ 2-101(48) and 2-1101. Until July 1, 2026, this statute permits government entities, religious institutions; nonprofit organizations; for-profit companies; nongovernmental entities partnering with a government agency; and tribal governments to engage in harm reduction services. Any entity offering such services is required to register with OSDH. The measure also requires providers of harm-reduction services to report required information regarding their services and clients served to OSDH at least quarterly.

**2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:**

The Department expects minimal cost impact. These costs are primarily related to processing applications for registration and maintaining an electronic data base for the quarterly reports submitted by harm-reduction service providers. Persons affected by the new rules are those persons who may be at risk for infectious disease due to circumstances such as sharing equipment for injection drug. The rules permit a registered entity to provide access to services that work to reduce the spread of infectious diseases related to injection drug use, reduce drug dependency, overdose deaths and associated complications, and to increase safe recovery and disposal of used syringes and sharp waste.

**3. DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:**

Persons who will benefit from implementation of the proposed rules include persons with substance abuse problems and entities that treat and provide services to reduce drug dependency, overdose deaths and associated complications, and increase safe recovery and provide for the disposal of used syringes and sharp waste.

**4. ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:**

The Department expects minimal costs to implement the rules. There are no fees for registration.

**5. COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:**

There are minimal costs associated with implementation.

**6. IMPACT ON POLITICAL SUBDIVISIONS:**

There will be no impact on political subdivisions and it will not require their cooperation in implementing or enforcing the proposed amendment.

7. **ADVERSE EFFECT ON SMALL BUSINESS:**

There is no known adverse economic effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act.

8. **EFFORTS TO MINIMIZE COSTS OF THE RULE:**

There are no less costly means currently identified.

9. **EFFECT ON PUBLIC HEALTH AND SAFETY:**

This rule will reduce significant risks to the public by reducing the risk of infection and spread of infectious disease through injection drug use and will help to remove used syringes from the community. This rule will reduce health care costs by preventing HIV, viral hepatitis, and other infections.

10. **DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:**

Health care costs will continue to be a burden to the state and the individual by not preventing the spread of HIV, viral hepatitis, and other infections.

11. **PREPARATION AND MODIFICATION DATES:**

This rule impact statement was prepared on October 8, 2021.

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH  
CHAPTER 521. CONTROL AND TREATMENT OF COMMUNICABLE DISEASE**

**RULEMAKING ACTION:**

Notice of proposed PERMANENT rulemaking.

**PROPOSED RULES:**

Subchapter 9. Harm-reduction Services [NEW]

**SUMMARY:**

The proposed Subchapter 9 rules implement the requirements for harm-reduction services established under Title 63 O.S. §§ 2-101(48) and 2-1101. Until July 1, 2026, this statute permits government entities, religious institutions; nonprofit organizations; for-profit companies; nongovernmental entities partnering with a government agency; and tribal governments to engage in harm reduction services. Any entity offering such services is required to register with the Oklahoma State Department of Health. The measure also requires providers of harm-reduction services to report required information regarding their services and clients served to the State Department of Health at least quarterly. These rules establish the registration and reporting requirements for providers of harm-reduction services.

**AUTHORITY:**

Commissioner of Health, Title 63 O.S. § 1-104; Uniform Controlled Dangerous Substances Act, Title 63 O.S. § 2-1101.

**COMMENT PERIOD:**

November 15, 2021 through the close of the Department's normal business hours, 5 PM, on December 15, 2021. Interested persons may informally discuss the proposed rules with the contact person identified below; or may, through the close of the Department's normal business hours, 5 PM, on December 15, 2021, submit written comment to the contact person identified below, or may, at the hearing, ask to present written or oral views.

**PUBLIC HEARING:**

Pursuant to 75 O.S. § 303(A), the public hearing for the proposed rulemaking in this chapter shall be on December 15, 2021 at the Oklahoma State Department of Health Auditorium, 123 Robert S. Kerr Avenue, Oklahoma City, Oklahoma 73102 from 9:30 AM to 12:30 PM. The meeting may adjourn earlier if all attendees who signed up to comment have completed giving their comments. The alternate date and time in the event of an office closure due to inclement weather is January 7, 2022 in the Auditorium, from 9:30 AM to 12:30 PM. Those wishing to present oral comments should be present at that time to register to speak. The hearing will close at the conclusion of those registering to speak. Interested persons may attend for the purpose of submitting data, views or concerns, orally or in writing, about the rule proposal described and summarized in this Notice. Validated parking will be provided for the parking lot located at the east corner of Broadway and Robert S. Kerr Avenue, subject to availability.

**REQUESTS FOR COMMENTS FROM BUSINESS ENTITIES:**

Business entities affected by these proposed rules are requested to provide the agency with information, in dollar amounts if possible, on the increase in the level of direct costs such as fees, and indirect costs such as reporting, recordkeeping, equipment, construction, labor, professional services, revenue loss, or other costs expected to be incurred by a particular entity due to compliance with the proposed rule. Business entities may submit this information in writing through the close of the Department's normal business hours, 5 PM, on December 15, 2021, to the contact person identified below.

**COPIES OF PROPOSED RULES:**

The proposed rules may be obtained for review from the contact person identified below or via the agency website at [www.ok.gov/health](http://www.ok.gov/health).

**RULE IMPACT STATEMENT:**

Pursuant to 75 O.S., § 303(D), a rule impact statement is available through the contact person identified below or via the agency website at [www.ok.gov/health](http://www.ok.gov/health).

**CONTACT PERSON:**

Audrey C. Talley, Agency Rule Liaison, Oklahoma State Department of Health, 123 Robert S. Kerr Avenue, Oklahoma City, OK 73102, phone (405) 426-8563, e-mail [AudreyT@health.ok.gov](mailto:AudreyT@health.ok.gov).

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH  
CHAPTER 521. CONTROL AND TREATMENT OF COMMUNICABLE DISEASE**

**SUBCHAPTER 9. HARM-REDUCTION SERVICES**

**310:521-9-1. Purpose and specific authority**

The purpose of this subchapter is to establish the rules for harm-reduction services. The State Commissioner of Health is authorized pursuant to Title 63 O.S. § 2-1101 to promulgate rules for the implementation of harm-reduction services established under Title 63 O.S. §§ 2-101(48) and 2-1101, the Uniform Controlled Dangerous Substances Act, Article 10. Harm-Reduction Services.

**310:521-9-2. Definitions**

The following words and terms, when used in the Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Administrator" means the director or similarly titled person responsible for the entity providing harm-reduction services through a program registered with the Department.

"Applicant" means the entity in whose name the harm-reduction services program shall be registered.

"AIDS" means Acquired Immunodeficiency Syndrome and is the most severe manifestation of infection with the Human Immunodeficiency Virus (HIV). The Centers for Disease Control and Prevention (CDC) lists numerous opportunistic infections and neoplasms (cancers) that, in the presence of HIV infection, constitute an AIDS diagnosis.

"Client" means a person who receives assistance through a harm-reduction services program.

"Harm-Reduction Services" means programs established to: *reduce the spread of infectious diseases related to injection drug use, reduce drug dependency, overdose deaths and associated complications, and increase safe recovery and disposal of used syringes and sharp waste.* Title 63 O.S. § 2-101(48)

"Hepatitis B (HBV)" means a vaccine-preventable liver infection caused by the hepatitis B virus (HBV). Hepatitis B is spread when blood, semen, or other body fluids from a person infected with the virus enters the body of someone who is not infected.

"Hepatitis C (HCV)" means a liver infection caused by the hepatitis C virus (HCV). Hepatitis C is spread through contact with blood from an infected person.

"Human Immunodeficiency Virus (HIV)" means HIV (human immunodeficiency virus) is a virus that attacks the body's immune system. If HIV is not treated, it can lead to AIDS (acquired immunodeficiency syndrome).

"HIV positive" means a person has tested positive for HIV antibodies, the virus known to cause AIDS.

"Policies and Procedures Manual" means a written manual detailing the policies and procedures for the safe and lawful operation of a harm-reduction services program.

"Program" means harm-reduction services provided by an entity registered to provide such services with the Department.

"Program Site" means the location where harm-reduction services are provided.

"Sharps Waste" means used needles, syringes, or lancets.

"Staff" means any employee, independent contractor, or volunteer adequately educated and trained to provide harm-reduction services on behalf of a program.

**310:521-9-3. Eligible providers**

Harm-reduction services are limited to persons in the following categories:

- (1) Government entities, as provided in Title 63 O.S. § 2-1101;
- (2) Religious institutions or churches;

- (3) Nonprofit organizations;
- (4) For-profit companies;
- (5) Nongovernmental entities partnering with a governmental agency; and
- (6) Tribal governments. Title 63 O.S. § 2-1101(A)

#### **310:521-9-4. Registration requirements.**

No entity may engage in harm-reduction services without first registering with the Department in the form and manner prescribed by the Department.

#### **310:521-9-5. Scope of services**

- (a) Registered programs may engage in harm-reduction services as outlined in 63 O.S. § 2-1101(B) and shall offer such services free of charge.
- (b) Registered programs shall operate and furnish services in compliance with all applicable federal, state, and local laws and regulations.

#### **310:521-9-6. Application for registration**

(a) All entities providing harm-reduction services must complete an application for registration with the Sexual Health and Harm Reduction Service Program at the Department. All applicants must provide the following information:

- (1) The legal name and form of organization registered with the Oklahoma Secretary of State as well as the name under which it will be doing business in the State of Oklahoma.
- (2) The name, address, telephone number, and email address for the administrator of the program and a secondary entity contact, together with:
  - (A) A signed, notarized statement attesting that the applicant accepts full responsibility for ensuring that the program operates in compliance with the provisions of all federal and state laws and regulations;
  - (B) The address and telephone number for each program site, including both fixed locations with permanent structures and venues at which services may be provided by a mobile unit;
  - (C) The scheduled hours of operations for each program site; and
  - (D) A copy of the program's most current version of harm-reduction service policies and procedures, including but not limited to, clear and concise procedures for the safe and secure disposal of sharps waste and any biomedical waste generated by services provided by the program.

(b) Registration applications will be reviewed within sixty (60) days of receipt thereof by the Department. A written correspondence of approval or denial will be sent to the applicant. If an application is denied, a letter of corrective actions may be supplied to the applicant.

(c) Registration shall be valid for one (1) year and shall be renewed by submission of an application for renewal at least thirty (30) days prior to expiration of current registration in the form and manner prescribed by the Department.

#### **310.521-9-7. Quarterly reporting to the Department**

(a) Programs shall submit to the Department electronic reports, in the manner designated by the Department, on the last business day of each calendar quarter, which report the following information for the most recent calendar quarter:

- (1) The number of clients served including basic demographic information;
- (2) Number and type of referrals provided;
- (3) Number of syringes, test kits and antagonists distributed;
- (4) Number of used syringes collected; and
- (5) Number of rapid HIV and viral hepatitis tests performed including the number of reactive test results. Title 63 O.S. § 2-1101(C).

(b) Failure to report data described in Section 310:521-9-7 constitutes grounds for non-renewal of the service provider's registration.