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### [.01 Purpose and Scope.](#)

This chapter:

A. Defines an opioid-associated disease prevention and outreach program; and

B. Sets forth:

(1) The responsibilities of the Maryland Department of Health and local health departments in establishing opioid-associated disease prevention and outreach programs; and

(2) Requirements for:

(a) Monitoring and evaluating opioid-associated disease prevention and outreach programs; and

(b) Research conducted in collaboration with an opioid-associated disease prevention and outreach program.

### [.02 Definitions.](#)

A. In this chapter, the following terms have the meaning indicated.

B. Terms Defined.

(1) "Applicant" means a local health department or community-based organization seeking to establish an opioid-associated disease prevention and outreach program.

(2) Body Fluid.

(a) "Body fluid" means any fluid containing visible blood, semen, or vaginal secretions.

(b) "Body fluid" does not include cerebrospinal fluid, synovial fluid, breast milk, amniotic fluid, saliva, stool, nasal secretions, sputum, tears, urine, or vomitus.

- (3) "Community-based organization (CBO)" means a public or private organization that:
- (a) Is representative of a community or significant segments of a community; and
  - (b) Provides educational, health, or social services to individuals in the community.
- (4) "Department" means the Maryland Department of Health.
- (5) "Harm reduction education" means education on practical strategies:
- (a) To reduce negative consequences associated with drug use; and
  - (b) That reflect specific individual and community needs.
- (6) "HIV" means the human immunodeficiency virus that causes acquired immune deficiency syndrome (AIDS).
- (7) "Infection control" means infection prevention and control measures that ensure the protection of individuals who are vulnerable to acquiring an infection both in the general community and while receiving health care services in a range of settings.
- (8) "Injection supplies" means materials used to inject drugs including, but not limited to:
- (a) Cookers;
  - (b) Water; and
  - (c) Cotton.
- (9) "Naloxone" means an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory or central nervous system depression.
- (10) "OADPO program" means an opioid-associated disease prevention and outreach program established by a local health department or community-based organization that provides services including:
- (a) Dissemination of hypodermic needles or syringes and other preventive means for curtailing the spread of HIV and viral hepatitis;
  - (b) Overdose prevention education; and
  - (c) Harm reduction education.
- (11) "Participant" means an individual who has registered with an OADPO program.
- (12) "Sexually transmitted infection (STI)" means an infection passed from one person to another person through sexual contact.
- (13) "Viral hepatitis" means inflammation of the liver caused by the hepatitis A, B, C, D, and E viruses.
- (14) "Wound care" means treatment of the symptoms of infections that may result from using drugs.

### **.03 Program Establishment.**

A. Effective October 1, 2016, a local health department or CBO may establish an OADPO program with approval from the:

(1) Department; and

(2) Local health officer of the county in which OADPO program operations are proposed.

B. When proposing an OADPO program, a local health department may collaborate with:

(1) A CBO; or

(2) Another local health department.

C. A CBO may operate an OADPO program in multiple counties if approved by the local health officer in each county where the OADPO program proposes to operate.

## **.04 Application Process.**

A. An applicant:

(1) Shall submit an application to establish an OADPO program to the Department that includes:

(a) Responses to all applicable questions; and

(b) Any supporting documentation indicated on the application;

(2) May voluntarily withdraw an application at any time; and

(3) May submit a new application at any time.

B. The Department shall:

(1) Distribute the application to establish an OADPO program to the local health officer in each jurisdiction where the OADPO program proposes to operate;

(2) Request additional information or changes to the application if necessary; and

(3) Respond in writing to the applicant within 60 calendar days indicating the disposition of the application and explanation of the decision.

C. The Department and the local health officer in each jurisdiction where the OADPO program proposes to operate shall jointly:

(1) Review the application; and

(2) Either:

(a) Approve the application if the:

(i) Application is complete; and

(ii) OADPO program meets the requirements of Regulations .05 and .06 of this chapter; or

(b) Disapprove the application if the:

(i) Application does not provide sufficient information or documentation on the OADPO program; or

(ii) OADPO program does not meet the requirements of [Regulations .05](#) and [.06](#) of this chapter.

D. An applicant whose application is disapproved may appeal the decision to the Deputy Secretary for Public Health Services by submitting the request in writing to the Deputy Secretary for Public Health Services within 30 calendar days of the date postmarked on the notice of disapproval.

E. If an applicant submits an appeal, the Deputy Secretary for Public Health Services shall within 60 days:

- (1) Grant or deny the appeal; and
- (2) Respond in writing to the applicant:
  - (a) Indicating whether the appeal has been granted or denied; and
  - (b) Providing an explanation of the decision.

## **.05 Program Design and Operation.**

A. The CBO or local health department approved to operate an OADPO program:

- (1) Shall provide protocols for the safety and security of OADPO program locations, equipment, and staff in accordance with Regulation .06 of this chapter that:
  - (a) Control the dissemination of hypodermic needles and syringes; and
  - (b) Allow for a full accounting of the number of hypodermic needles and syringes managed by the program;
- (2) Shall offer participants:
  - (a) Overdose prevention education;
  - (b) Access to or a referral to obtain naloxone; and
  - (c) Harm reduction education;
- (3) Shall ensure that all OADPO program staff have:
  - (a) Appropriate levels of expertise in working with individuals who inject drugs;
  - (b) Knowledge of harm reduction strategies; and
  - (c) Skills in implementing harm reduction strategies;
- (4) Shall ensure that all OADPO program staff receive training approved by the Department to work with injection drug users and to provide referrals to:
  - (a) Community services;
  - (b) Counseling; and
  - (c) Preventative education;
- (5) Shall ensure that all OADPO program staff demonstrate sensitivity to participant differences including:

- (a) Cultural;
  - (b) Behavioral; and
  - (c) Values;
- (6) Shall ensure that information collected to identify OADPO program participants is kept confidential according to:
- (a) Health-General Article, [§24-906](#)(b), Annotated Code of Maryland; and
  - (b) [42 CFR Part 2](#);
- (7) Shall ensure that there is a method of identification and authorization for OADPO program staff members who have access to:
- (a) Hypodermic needles;
  - (b) Syringes; and
  - (c) OADPO program records;
- (8) Shall develop and provide a protocol for linking participants to:
- (a) Substance abuse treatment services;
  - (b) Testing for:
    - (i) HIV;
    - (ii) Viral hepatitis; and
    - (iii) STIs;
  - (c) Reproductive health services;
  - (d) Wound care; and
  - (e) Naloxone;
- (9) Shall disseminate hypodermic needles or syringes and other preventive means for curtailing the spread of HIV and viral hepatitis at no cost to participants, including but not limited to:
- (a) Injection supplies; and
  - (b) Safer sex supplies; and
- (10) May not discriminate against participants based on factors including but not limited to:
- (a) Culture;
  - (b) Language;
  - (c) Ability;
  - (d) Socioeconomic status;

- (e) Sexual orientation;
- (f) Gender identity;
- (g) Age;
- (h) Religion;
- (i) Race; and
- (j) Ethnicity.

B. Identification Card. OADPO program staff shall:

- (1) Give each participant an identification card that includes the participant's OADPO program identification number;
- (2) Advise participants to carry the identification card with them at all times; and
- (3) If the identification card is lost by a participant, re-issue an identification card to the participant.

C. The CBO or local health department approved to operate an OADPO program may offer other services to OADPO program participants, including:

- (1) Testing for:
  - (a) HIV;
  - (b) Viral hepatitis; and
  - (c) STIs;
- (2) Wound care;
- (3) Reproductive health services; and
- (4) Substance abuse counseling, treatment, and recovery services.

## **.06 Program Security.**

A. An OADPO program shall implement protocols for the safety and security of program locations, equipment, and staff.

B. OADPO program staff shall:

- (1) Wear suitable clothing, including closed footwear, at all times;
- (2) Treat all body fluids as potentially infectious and follow infection control protocols at all times including:
  - (a) Use of barriers including gloves;
  - (b) Immediate washing of hands and other skin surfaces after contact with body fluids; and
  - (c) Careful handling and disposal of sharp instruments during and after use;

(3) When working off-site, have access to a communications system that allows staff to stay in contact with:

(a) Other staff; and

(b) Emergency support;

(4) Obtain consent of the owner or occupier of private property to enter the property to dispense or collect syringes or hypodermic needles; and

(5) Transport biohazardous waste to the disposal facility using a method that does not put any individuals at risk.

C. OADPO programs shall:

(1) Have a critical incident procedure that outlines processes and responsibilities of program staff for managing incidents including:

(a) Participant aggression;

(b) Threats of violence; and

(c) Other hazardous situations;

(2) Have available the following safety equipment during program operations:

(a) Puncture resistant utility gloves;

(b) Bleach; and

(c) Forceps or tongs;

(3) Have facilities that:

(a) Have adequate lighting; and

(b) Are free from clutter; and

(4) Have a:

(a) Contract with a licensed biohazardous waste disposal facility to receive biohazardous waste; or

(b) Written agreement that authorizes the OADPO program to drop off used syringes contained in a locked sharps container for safe disposal with a:

(i) Hospital;

(ii) Doctor's office;

(iii) Pharmacy;

(iv) Medical testing facility; or

(v) Other facility that already receives and safely disposes of hazardous waste.

D. To prevent needlestick injuries, OADPO program participants, staff, volunteers, and any other individuals present at the facility in an occupational capacity shall:

- (1) Receive education on safety protocols for:
  - (a) Carrying and handling:
    - (i) Syringes;
    - (ii) Hypodermic needles; and
    - (iii) Other sharps;
  - (b) The transport and disposal of biohazardous waste; and
  - (c) Infection control;
- (2) Refrain from touching, without safety equipment, used:
  - (a) Hypodermic needles;
  - (b) Syringes; and
  - (c) Injection supplies; and
- (3) Be encouraged to wear clothing at all times that provides protection against needlestick injuries including:
  - (a) Long pants; and
  - (b) Long-sleeved shirts.

E. Use of Sharps Containers.

- (1) Used hypodermic needles, syringes, and injection supplies collected by the program from participants shall be placed in sharps containers.
- (2) Sharps containers:
  - (a) Shall be leak proof;
  - (b) Shall be rigid;
  - (c) Shall be puncture resistant;
  - (d) Shall be labeled as containing sharps;
  - (e) Shall be placed on a level, secure surface that is a safe distance between participants and staff or volunteers during syringe exchange transactions; and
  - (f) May not be more than 75 percent full.
- (3) Participants shall:
  - (a) Place into the sharps container all used:
    - (i) Hypodermic needles;
    - (ii) Syringes; and

- (iii) Injection supplies;
- (b) When possible, retrieve supplies that fall outside of the sharps container, including:
  - (i) Hypodermic needles;
  - (ii) Syringes; and
  - (iii) Injection supplies; and
- (c) When possible, cover supplies used by the participant including:
  - (i) Hypodermic needles;
  - (ii) Syringes; and
  - (iii) Injection supplies.

F. Needlestick Injuries.

- (1) OADPO programs shall implement protocols for handling needlestick injuries.
- (2) OADPO programs shall designate at least one needlestick manager who shall:
  - (a) Assist injured individuals present at the facility including:
    - (i) Participants;
    - (ii) Staff;
    - (iii) Volunteers; and
    - (iv) Any other individuals present in an occupational capacity;
  - (b) Follow established procedures for accident or incident reporting; and
  - (c) Immediately notify the ranking supervisor of any needlestick injuries.
- (3) Participants, staff, volunteers, and any other individuals present at the facility in an occupational capacity shall:
  - (a) Report a needlestick injury to the on-site needlestick manager immediately; and
  - (b) Visit the emergency room or a private physician within 24 hours of the occurrence.

G. Post-Exposure Management. OADPO programs shall implement protocols for post-exposure management including:

- (1) Testing; and
- (2) Post-exposure prophylaxis.

## **.07 Monitoring and Evaluation.**

A. OADPO programs shall:

(1) Submit all data for each reporting period on a quarterly basis as required by the Department, including:

(a) The number of:

(i) Participants served by the OADPO program;

(ii) New participants registered by the OADPO program;

(b) Demographic data of participants served by the OADPO program, including:

(i) Age;

(ii) Gender identity;

(iii) Sexual orientation;

(iv) Race;

(v) Ethnicity;

(vi) Zip code; and

(vii) Types of drugs the participant reports using;

(c) The number of hypodermic needles and syringes distributed and collected;

(d) Each location where hypodermic needles and syringes were distributed; and

(e) The number of referrals to services provided to participants listed in Health-General Article, [§24-903](#)(A)(6), Annotated Code of Maryland, and [Regulation .05A\(4\)](#) of this chapter; and

(2) Collect data using methods that will not deter participants from utilizing OADPO program services.

B. The Department may conduct site visits to monitor and evaluate an OADPO program.

## **.08 Research.**

A. An individual researcher or institution shall apply for and receive approval from the Department before starting research in collaboration with an OADPO program.

B. The Department shall:

(1) Review each request; and

(2) Approve or disapprove the proposed research based on whether the proposed research:

(a) Advances scientific knowledge or practice related to opioid-associated disease prevention and outreach;

(b) Has approaches, aims, and methods that will allow the researcher to perform descriptive analyses or test hypotheses;

(c) Has one or more investigators who have training and experience with the approaches and methods;

(d) Will impede or interfere with the operations of the OADPO program;

(e) Is approved by the Department's Institutional Review Board to ensure that the research will be conducted according to established ethical guidelines for research in the field of opioid-associated disease prevention and outreach; and

(f) Will keep any data used for the research confidential as required by:

(i) Health-General Article, [§24-906](#)(B), Annotated Code of Maryland;

(ii) [42 U.S.C. §290dd-2](#); and

(iii) [42 CFR Part 2](#).

## **.09 Revocation of Approval and Appeals.**

A. The Department and the local health officer may revoke the approval of an OADPO program if the OADPO program does not:

(1) Meet the requirements of [Health-General Article, Title 24, Subtitle 9, Annotated Code of Maryland](#); or

(2) Operate in accordance with the requirements of [Regulations .05](#) and [.06](#) of this chapter.

B. The Department shall:

(1) Notify the OADPO program in writing of the revocation of approval; and

(2) Provide an explanation of the decision.

C. An OADPO program may appeal the decision to revoke approval to the Deputy Secretary for Public Health Services by submitting the request in writing to the Deputy Secretary for Public Health Services within 30 calendar days of the date postmarked on the notice of revocation of approval.

D. If an applicant submits an appeal, the Deputy Secretary for Public Health Services shall within 60 days:

(1) Grant or deny the appeal; and

(2) Respond in writing to the applicant:

(a) Indicating whether the appeal has been granted or denied; and

(b) Providing an explanation of the decision.