Overview and Legal and Fiscal Impact

The regulations set forth the responsibilities of the Department of Health and Mental Hygiene and local health departments in establishing opioid-associated disease prevention and outreach programs (OADPO programs). Requirements for monitoring and evaluation of OADPO programs and research conducted in collaboration with an OADPO program are also established by the regulations.

The regulations present no legal issues of concern.

There is no fiscal impact on State or local agencies beyond that already assumed in the fiscal and policy note for Senate Bill 97 of 2016 (enacted as Chapter 348).

Regulations of COMAR Affected

Department of Health and Mental Hygiene:
  Preventive Medicine:
    Opioid-Associated Disease Prevention and Outreach Programs:
    COMAR 10.52.01.01-.09

Legal Analysis

Background

Chapter 348 of 2016 authorized a local health department or community-based organization, with the approval of the department and the appropriate local health officer, to establish an opioid-associated disease prevention and outreach program. The programs are required to provide for substance use outreach, education, and linkage to treatment services, including distribution and collection of hypodermic needles and syringes. A local health department or community-based organization must apply to the department and a local health officer for authorization to operate a program. Chapter 348 required the department to adopt regulations that establish:

• procedures for ensuring security of program locations and equipment;
• an appeals process; and:
procedures for data collection and program evaluation.

Summary of Regulations

The regulations set forth the responsibilities of the department and local health departments in establishing OADPO programs. Requirements for monitoring and evaluation of OADPO programs and research conducted in collaboration with an OADPO program are also established by the regulations.

The regulations define, among other terms, “applicant”, “body fluid”, “community-based organized organization”, “harm reduction” education, “infection control”, “injection supplies”, “Naloxone”, “OADPO program”, and “wound care”. Effective October 1, 2016, a local health department or a community-based organization may establish an OADPO program with approval from the department and the local health officer from the county in which the OADPO program operations are proposed. The regulations establish the application process and require an applicant to submit certain information to the department. The department is required to provide the application to the local health officer in each jurisdiction where the OADPO program proposes to operate and to respond in writing to the applicant within 60 calendar days indicating the disposition of the application and explanation of the decision. The department and local health officer are required to jointly review the application, and approve or disapprove the application under certain circumstances. An applicant whose application is disapproved may appeal the decision to the Deputy Secretary for Public Health Services in writing within 30 calendar days of the date postmarked on the notice of disapproval. If an applicant submits an appeal, the Deputy Secretary for Public Health Services shall within 60 days respond in writing to the applicant indicating whether the appeal has been granted or denied and providing an explanation of the decision.

The regulations require the community-based organization or local health department approved to operate an OADPO program to:

- provide certain protocols for the safety and security of OADPO program locations, equipment, and staff;
- offer participants overdose prevention education, access to or a referral to obtain Naloxone, and harm reduction education;
- ensure that all OADPO program staff have appropriate levels of expertise in working with individuals who inject drugs, knowledge of harm reduction strategies, and skills in implementing harm reduction strategies;
- ensure that all OADPO program staff receive certain training;
- ensure that all OADPO program staff demonstrate sensitivity to participant differences;
- ensure that information collected to identify OADPO program participants is kept confidential;
• ensure that there is a method of identification and authorization for OADPO program staff members who have access to hypodermic needles, syringes, and OADPO program records;

• develop and provide a protocol for linking participants to substance use treatment services; testing for HIV, viral hepatitis, and sexually transmitted infections; reproductive health services; wound care; and Naloxone;

• disseminate hypodermic needles or syringes for curtailing the spread of HIV and viral hepatitis at no cost to participants; and

• not discriminate against participants.

In addition, OADPO program staff are required to provide to each participant a certain identification card and to follow certain procedures related to the card.

The regulations establish specified protocols for the safety and security of program locations, equipment, and staff. OADPO program staff must:

• wear suitable clothing, including closed footwear;

• treat all body fluids as potentially infectious and follow infection control protocols at all times;

• have access to a communications system when working offsite to stay in contact with other staff and emergency support;

• obtain consent when entering private property to dispense or collect hypodermic needles; and

• transport biohazardous waste in a certain manner.

In addition, OADPO programs are required to have a critical incident procedure in place that outlines processes and responsibilities of program staff for managing certain incidents, have certain safety equipment available, and have facilities with adequate lighting that are free from clutter.

OADPO program participants, staff, volunteers, and any other individual present at the facility must receive certain education and follow certain procedures to prevent needlestick injuries. Used hypodermic needs, syringes, and injection supplies collected by an OADPO program are to be placed in specified sharps containers. OADPO programs must implement certain protocols for handling needlestick injuries and must designate at least one needlestick manager to assist injured individuals. A needlestick injury must be reported to the onsite needlestick manager immediately and an individual who sustains a needlestick injury shall visit the emergency room or a private physician within 24 hours of the occurrence.
The regulations require OADPO programs to submit certain data to the department on quarterly basis that includes:

- the number of participants served by the OADPO program and new participants registered by the OADPO program;
- certain demographic data of participants served by the OADPO program;
- the number of hypodermic needs and syringes distributed and collected;
- each location where hypodermic needles and syringes were distributed; and
- the number of referrals to certain services provided to participants. OADPO programs must collect data using methods that will not deter participants from using OADPO program services and the department may conduct site visits to monitor and evaluate an OADPO program.

The regulations require an individual researcher or institution to apply for and receive approval from the department before starting research in collaboration with an OADPO program.

The department and the local health officer may revoke the approval of an OADPO program under certain circumstances and shall notify the OADPO program in writing of the revocation of approval and provide an explanation of the decision. 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. If an applicant submits an appeal, the Deputy Secretary for Public Health Services shall within 60 days respond in writing to the applicant indicating whether the appeal has been granted or denied and providing an explanation of the decision.

Legal Issues

The regulations present no legal issues of concern.

Statutory Authority and Legislative Intent

The department cites §§ 24-901 through 24-909 of the Health-General Article as statutory authority for the regulations. More specifically, the regulations are authorized by §24-905 of the Health-General Article. Section 24-905 requires the department to adopt regulations to implement the subtitle in consultation with the Standing Advisory Committee on Opioid-Associated Disease Prevention and Outreach Programs and the Maryland Association of County Health Officers that establish:
procedures for ensuring the security of program locations and equipment;

an appeals process, including the standard of review that the Deputy Secretary for Public Health Services must apply when reviewing a decision of the department and a local health officer; and

procedures for data collection and program evaluation. The remaining authority is not relevant to these regulations.

The relevant cited authority is correct and complete. The regulations comply with the legislative intent of the law.

Fiscal Analysis

There is no fiscal impact on State or local agencies beyond that already assumed in the fiscal and policy note for Senate Bill 97 of 2016 (enacted as Chapter 348).

Agency Estimate of Projected Fiscal Impact

The regulations implement provisions of Chapter 348 of 2016 (Senate Bill 97), which authorized a local health department or a community-based organization to establish an opioid-associated disease prevention and outreach program. Any fiscal impact has already been assumed under the fiscal and policy note for Senate Bill 97 of 2016. The fiscal and policy note estimated that the bill’s requirements could be handled with existing resources and advised that local health department expenditures may increase to the extent the department chooses to implement an opioid-associated disease prevention and outreach program.

Impact on Budget

There is no impact on the State operating or capital budget.

Agency Estimate of Projected Small Business Impact

The department advises that the regulations have minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs, as reflected in the fiscal and policy note for Senate Bill 97.

Contact Information

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