

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulations
Department of Health and Mental Hygiene
(DLS Control No. 16-077)**

Overview and Legal and Fiscal Impact

The regulations implement provisions of Chapter 356 of 2015, which altered the Overdose Response Program. The regulations also repeal the requirement for an individual to pay any fee required by the Department of Health and Mental Hygiene to obtain a certificate to administer naloxone.

The regulations present no legal issues of concern.

There is no fiscal impact on State or local agencies.

Regulations of COMAR Affected

Department of Health and Mental Hygiene:

Alcohol and Drug Abuse Administration: Overdose Response Program:
COMAR 10.47.08.02-.12

Legal Analysis

Background

Chapter 299 of 2013 established the Overdose Response Program within the department to authorize certain individuals (through the issuance of a certificate) to administer naloxone to an individual experiencing, or believed to be experiencing, opioid overdose to help prevent a fatality when medical services are not immediately available.

Summary of Regulations

The regulations implement provisions of Chapter 356 of 2015, which altered the Overdose Response Program. In accordance with Chapter 356, the regulations authorize an advanced practice registered nurse or pharmacist to conduct educational training programs, or supervise an employee or a volunteer of a private or public entity to conduct educational training programs, for applicants seeking to obtain a certificate to administer naloxone. The regulations also authorize a licensed physician or an advanced practice registered nurse with prescribing authority to prescribe and dispense naloxone to a certificate holder by issuing a standing order, if the licensed physician or advanced practice registered nurse:

- is employed by the department or a local health department; or
- supervises or conducts an educational training program under the Overdose Response Program.

Additionally, the regulations authorize a licensed physician or an advanced practice registered nurse with prescribing authority who issues a standing order to delegate to specified individuals the authority for dispensing naloxone to a certificate holder. A licensed health care provider who has dispensing authority is authorized to dispense naloxone to a certificate holder in accordance with a standing order issued by a licensed physician.

In accordance with Chapter 356, the regulations offer protection to health care providers who comply with the requirements of the Overdose Response Program. More specifically, the regulations:

- prohibit disciplinary action, solely for the act of prescribing or dispensing naloxone to a certificate holder, against an advanced practice registered nurse with prescribing authority who prescribes or dispenses naloxone to the certificate holder in a manner consistent with the protocol established by the authorized private or public entity;
- prohibit a cause of action arising against any licensed physician, advanced practice registered nurse with prescribing authority, or pharmacist for any act or omission when the physician, advanced practice registered nurse with prescribing authority, or pharmacist in good faith prescribes or dispenses naloxone and the necessary paraphernalia for the administration of naloxone to a certificate holder or patient under the law; and
- provide immunity from liability to an individual who administers naloxone to an individual who is or in good faith is believed to be experiencing an opioid overdose.

The regulations also repeal the requirement for an individual to pay any fee required by the department to obtain a certificate to administer naloxone.

Legal Issues

The regulations present no legal issues of concern.

Statutory Authority and Legislative Intent

The department cites Title 13, Subtitle 31 of the Health – General Article as statutory authority for the regulations. As described above under “*Background*”, Subtitle 31 establishes the Overdose Response Program within the department to authorize certain individuals (through the issuance of a certificate) to administer naloxone to an individual experiencing, or believed to be experiencing, opioid overdose to help prevent a fatality when medical services are not immediately available. The changes enacted by Chapter 356 authorized an advanced practice nurse with prescribing authority or a licensed physician to prescribe and dispense naloxone to a certificate

holder either directly or, under specified circumstances, under a standing order. A licensed physician or an advanced practice nurse with prescribing authority who issues a standing order may also delegate to specified persons the authority for dispensing naloxone to certificate holders. Chapter 356 also authorized any licensed health care provider with prescribing authority to prescribe naloxone to a patient who is believed to be at risk of experiencing an opioid overdose or in a position to assist an individual at risk of experiencing an opioid overdose. Chapter 356 established legal and civil immunity for specified individuals.

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

Technical Corrections and Special Notes

The regulations include the defined term “advanced practice registered nurse”, which not only differs from the defined term “advanced practice nurse” in statute but also conflicts with the statutory definition. The department will change the regulations to use the defined term in statute.

Fiscal Analysis

There is no fiscal impact on State or local agencies.

Agency Estimate of Projected Fiscal Impact

The regulations implement provisions of Senate Bill 516 of 2015 (enacted as Chapter 356), which altered the Overdose Response Program by (1) authorizing advanced practice nurses with prescribing authority or licensed physicians to prescribe and dispense naloxone directly or under a standing order and to delegate authority to dispense naloxone to specified persons; (2) authorizing advanced practice nurses and pharmacists to conduct educational training programs; and (3) establishing legal and civil immunity for specified individuals who prescribe and dispense naloxone. The regulations also implement, in part, provisions of Senate Bill 626 of 2015 (enacted as Chapter 44), which, among other things, authorized registered nurses who comply with a specific formulary and other specified requirements to personally prepare and dispense prescription drugs and devices in a local health department in accordance with the Overdose Response Program. That legislation also established the Committee on Registered Nurses Personally Preparing and Dispensing Drugs and Devices in Local Health Departments to develop, approve, and annually review a formulary for use by registered nurses. Any fiscal impact has already been assumed under the fiscal and policy notes for Senate Bill 44 and Senate Bill 516 of 2015.

In addition to several procedural and conforming changes, the regulations also repeal the requirement that an individual pay any fee required by the department in order to receive an initial or renewal certificate to administer naloxone from an authorized private or public entity. The department advises that a fee has never been required; therefore, there is no fiscal impact. The Department of Legislative Services concurs.

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.

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