

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulations
Department of Health and Mental Hygiene
(DLS Control No. 15-377)**

Overview and Legal and Fiscal Impact

The regulations repeal the Expedited Partner Therapy (EPT) pilot program in the Baltimore City Health Department and set forth the mechanisms for providing EPT in public and private health care settings throughout the State.

The regulations present no legal issues of concern.

There is no fiscal impact on State or local agencies beyond that already estimated in the fiscal and policy note for Senate Bill 599 of 2015 (enacted as Chapter 183).

Regulations of COMAR Affected

Department of Health and Mental Hygiene:

Diseases: Communicable Diseases and Related Conditions of Public Health Importance:
COMAR 10.06.01.02 and .17-1

Sexually Transmitted Infections – Expedited Partner Therapy for Chlamydia and
Gonorrhea: COMAR 10.06.07.01-.09

Legal Analysis

Background

Chapter 146 of 2007 established an EPT pilot program in the Baltimore City Health Department to provide antibiotic therapy to the partner of a patient diagnosed with chlamydia or gonorrhea without making a personal physical assessment of the patient's partner in order to contain and stop further spread of the infection and reduce the likelihood of reinfection in the diagnosed patient. Chapter 183 of 2015 modified the Baltimore City EPT pilot program to make provision of EPT a permanent option and authorize use of EPT throughout the State. Chapter 183 required the Secretary of Health and Mental Hygiene to adopt regulations and implement requirements for practicing EPT in public and private health care settings in the State.

Summary of Regulations

The regulations repeal the EPT pilot program in the Baltimore City Health Department and set forth the mechanisms for providing EPT in public and private health care settings throughout the State. The regulations define "antibiotic therapy" as the oral antibiotic drug regimens currently

recommended by the Centers for Disease Control and Prevention for the treatment of chlamydia and gonorrhea through EPT. Partners eligible for EPT include any partner within 60 calendar days of the patient's diagnosis and the most recent partner of a patient if the patient has not had sex in the 60 days before diagnosis.

The health care providers who are authorized to prescribe and dispense EPT include licensed physicians, physician assistants, and advance practice registered nurses with prescriptive authority acting within their scope of practice. A registered nurse employed by a local health department may also dispense EPT if the nurse complies with certain provisions of law related to formularies, required training, and record keeping. The regulations require, among other things (1) a separate prescription for each partner; (2) the designation "EPT" or "Expedited Partner Therapy" on the face of each prescription; and (3) the partner's name, if known. An EPT prescription may not be refilled. The regulations require a health care provider prescribing or dispensing EPT to provide certain counseling and educational information. In addition, the health care provider must document specified information related to the provision of EPT in the patient's medical chart.

The regulations provide that health care providers or institutions remain required to report to a health officer cases of chlamydia and gonorrhea and the treatment provided to those cases in accordance with COMAR 10.06.01.04. When reporting a case of chlamydia or gonorrhea for which EPT was prescribed or dispensed, a health care provider or institution must report the number of partners for whom prescriptions were provided and medications were dispensed.

Legal Issues

The regulations present no legal issues of concern.

Statutory Authority and Legislative Intent

The department cites §§ 2-104(b), 18-102, 18-105, 18-201, 18-202, 18-205, 18-214.1, 18-307, and 24-101 through 24-110 of the Health – General Article as statutory authority for the regulations. More specifically, the regulations are authorized by §§ 2-104(b) and 18-214.1(d). Section 2-104(b) authorizes the Secretary of Health and Mental Hygiene to adopt regulations to carry out the provisions of law that are within the jurisdiction of the Secretary. Section 18-214.1(d) requires the Secretary to adopt regulations to implement the Expedited Partner Therapy Program as set forth in § 18-214.1 in public and private health care settings in the State. The remaining cited authority is not relevant.

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 estimated in the fiscal and policy note for Senate Bill 599 of 2015 (enacted as Chapter 183).

Agency Estimate of Projected Fiscal Impact

The action repeals regulations relating to the Baltimore City Expedited Partner Therapy (EPT) Pilot Program and establishes new regulations governing the provision of EPT throughout Maryland. The department initially advised that the regulations have an indeterminate fiscal impact on State and local governments, including start-up costs for the department to maintain regulations, develop an EPT website, and provide technical assistance and educational materials. The Department of Legislative Services disagreed with this estimate, noting that the regulations implement Chapter 183 of 2015 (Senate Bill 599). The department has revised its estimate and agrees that the regulations implement Chapter 183.

Chapter 183 makes the provision of EPT permanent and statewide and requires the Secretary of Health and Mental Hygiene to adopt regulations and implement requirements for practicing EPT in public and private health care settings in Maryland. As noted in the fiscal and policy note for Senate Bill 599, any additional expenditures can be handled within existing budgeted resources. Revenues are not affected. To the extent additional local health departments choose to provide EPT, costs may increase minimally. The Department of Legislative Services notes that any impact of the regulations has already been accounted for in the fiscal and policy note for Senate Bill 599.

Impact on Budget

There is no impact on the State operating or capital budget. However, the fiscal 2016 budget includes approximately \$10,000 in federal funds to provide technical assistance, design the EPT website, and prepare educational materials for providers, pharmacists, patients, and sexual partners.

Agency Estimate of Projected Small Business Impact

The department initially advised that the regulations have a meaningful economic impact on small businesses in the State. The Department of Legislative Services disagreed with this estimate, noting that the regulations implement Chapter 183 of 2015; moreover, the fiscal and policy note for Senate Bill 599 assumed a minimal impact on small businesses. The department has revised its estimate and agrees that the regulations likely result in a minimal impact on small businesses.

Contact Information

Legal Analysis: Erin R. Hopwood – (410) 946/(301) 970-5350

Fiscal Analysis: Kathleen P. Kennedy – (410) 946/(301) 970-5510