

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	11/24/2015	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 1/8/2016

2. COMAR Codification

Title	Subtitle	Chapter	Regulation
10	06	01	02 and .17-1
10	06	07	01-.09

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator	Telephone Number
Michele Phinney	410-767-5623

Mailing Address

201 W. Preston Street

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Baltimore	MD	21201

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5. Name of Person to Call About this Document	Telephone No.
Alexis Moss	410-767-4071

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6. Check applicable items:

- New Regulations

- Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: October 16, 2015.

- Repeal of Existing Regulations

Recodification

Incorporation by Reference of Documents Requiring DSD Approval

Reproposal of Substantively Different Text:

: Md. R

(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

Yes - No

8. Incorporation by Reference

Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Claire Pierson, Assistant Attorney General, (telephone #410-767-6526) on November 23, 2015. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Van T. Mitchell

Title

Secretary

Telephone No.

410-767-6500

Date

November 24, 2015

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Subtitle 06 DISEASES

10.06.01 Communicable Diseases and Related Conditions of Public Health Importance

Subtitle 06 DISEASES

10.06.07 Sexually Transmitted Infections - Expedited Partner Therapy for Chlamydia and Gonorrhea

Authority: See proposal.

Notice of Proposed Action

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The Secretary of Health and Mental Hygiene proposes to :

- (1) Amend Regulation .02 and repeal Regulation .17-1 under COMAR 10.06.01 Communicable Diseases and Related Conditions of Public Health Importance; and
- (2) Adopt new Regulations .01—.09 under a new chapter, COMAR 10.06.07 Sexually Transmitted Infections - Expedited Partner Therapy for Chlamydia and Gonorrhea.

Statement of Purpose

The purpose of this action is to repeal regulations related to the Expedited Partner Therapy (EPT) Pilot Program in Baltimore City Health Department under COMAR 10.06.01, and add a new chapter of regulations for EPT for chlamydia and gonorrhea in Maryland under COMAR 10.06.07. Pursuant to Health-General Article, §18-214.1, Annotated Code of Maryland, (Chapter 183 of the Acts of 2015), this proposal creates regulations for certain health care providers and pharmacists, within their existing scopes of practice, to prescribe or dispense antibiotic therapy to any partner of a patient diagnosed with chlamydia or gonorrhea without making a personal physical assessment of the partner, and without having a previous provider-patient relationship with the partner. This proposal expands EPT permissibility throughout Maryland in order to help reduce the likelihood of repeat infection in a patient diagnosed with chlamydia or gonorrhea. Specifically, this proposal outlines: eligibility; prescribing and dispensing authority; counseling and educational requirements; documentation; and reporting. This proposal also expands EPT permissibility throughout Maryland and helps to reduce the likelihood of repeat infection in a diagnosed patient.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.

This proposal will result in an indeterminate impact to the Department of Health and Mental Hygiene (Department), local health departments (LHDs), pharmacists, insurers, and health care providers. As permitted in statute, EPT is a voluntary practice of treating chlamydia or gonorrhea in a sex partner or partners of an infected patient; therefore, there is no way to determine how many: health care providers (including LHDs) will offer EPT to their patients or need training from the Department; patients will accept EPT for their sex partner or partners; sex partners will accept EPT medication or fill their prescription for the medication; pharmacists will fill EPT prescriptions; and repeat infections will be avoided. The impact of this proposal on insurers including Medicaid, is indeterminate because of the unknown number of EPT prescriptions that will be given to an insured sex partner or partners.

It is anticipated that the Department, LHDs, insurers, health care providers, and the public will benefit from a reduction in repeat infections. Pharmacists will incur minor costs associated with providing educational information to accompany EPT medications and health care providers who provide EPT will likewise incur minor costs associated with counseling patients and providing educational information for their partner or partners. Insurers will incur reimbursement costs for EPT medications given to a sex partner or partners who are their enrollees, but will also benefit from a reduction in costs associated with untreated infections in their enrollees.

II. Types of Economic Impact.	Revenue (R+/R-)	Magnitude
	Expenditure (E+/E-)	
A. On issuing agency:	(E+)	Indeterminate
B. On other State agencies:	NONE	
C. On local governments:	(E+)	Indeterminate
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:		
(1) Pharmacies	(-)	Indeterminate
(2) Insurers	(-)	Indeterminate
(3) Health Care Providers	(-)	Indeterminate
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	(+)	Indeterminate

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. The Department will incur operational costs as a result of start-up costs during the first year, including maintaining newly developed regulations, developing the EPT website, and providing technical assistance and educational materials. Additionally, the

Department will expend existing federal funding to educate pharmacists and health care providers about EPT. This funding amount is indeterminate because the number of health care providers who will need training from the Department is unknown.

C. LHD Sexually Transmitted Infection (STI) and Family Planning programs may incur the cost of prescribing or dispensing medications and providing educational information for the patient's sex partner or partners. LHDs may also see a reduction in costs associated with providing services for repeat infection in a patient.

D(1). Pharmacies will incur minor operational costs associated with filling EPT prescriptions and providing educational information for the patient's sex partner or partners. Additionally, pharmacies will generate revenue by filling EPT prescriptions at an indeterminate amount as it will depend on the insurance plan coverage of the patient and the patient's partner or partners, along with the varying reimbursement rates.

D(2). Insurers will incur the cost of EPT medications for patient's partner or partners enrolled in their insurance plan. This may also result in lower costs overall if patients experience lower rates of repeat infections and fewer patients seek care.

D(3). Health care providers will incur costs associated with counseling patients and providing educational information for a patient's sex partner or partners and possibly for adapting Electronic Medical Records software to accommodate EPT documentation. Health care providers may also see a reduction in costs associated with providing fewer clinical services once their patients' partner or partners are treated.

F. It is anticipated that the public will benefit from reduced rates of chlamydia and gonorrhea and costs associated with repeat infection.

Economic Impact on Small Businesses

The proposed action has a meaningful economic impact on small business. An analysis of this economic impact follows.

Small businesses that could be potentially be impacted by this proposal include independent pharmacists and small health care practices who provide EPT. Health care providers will incur costs associated with providing counseling and educational information, and can anticipate a reduction in costs associated with providing services for repeat infection in a patient. Additionally, independent pharmacists will incur costs associated with providing educational information and will generate revenue with each prescription filled. However, the actual impact of this proposal on independent pharmacists and small health care practices cannot be determined at this time, so it is unclear whether this proposal will have a meaningful impact on small businesses or not.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through February 8, 2016. A public hearing has not been scheduled.

Economic Impact Statement Part C

- A. Fiscal Year in which regulations will become effective: FY 2016
- B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?
Yes
- C. If 'yes', state whether general, special (exact name), or federal funds will be used:
Federal funds
- D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

- E. If these regulations have no economic impact under Part A, indicate reason briefly:

- F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

- G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 06 DISEASES

10.06.01 Communicable Diseases and Related Conditions of Public Health Importance

Authority: Health-General Article, §§2-104(b), 18-102, 18-105, 18-201, 18-202, 18-205, 18-214.1, 18-307, and 24-101—24-110,
Annotated Code of Maryland

10.06.01 (10/16/15)

.02 Definitions.

- A. (text unchanged)
- B. Terms Defined.
 - (1)—(9) (text unchanged)

[(10) "Expedited partner therapy" means the treatment under the Expedited Partner Therapy Pilot Program of a sex partner of a patient with a sexually transmitted infection of gonorrhea or chlamydia without previous medical evaluation or prevention counseling of the sex partner.

(11) "Expedited Partner Therapy Pilot Program" means a program to conduct and evaluate expedited partner therapy in the Baltimore City Health Department pursuant to Health-General Article, §18-214.1, Annotated Code of Maryland.]

[(12)] (10)—[(31)] (29) (text unchanged)

10.06.07 Sexually Transmitted Infections - Expedited Partner Therapy for Chlamydia and Gonorrhea

Authority: *Health General Article, §§2-104(b), 18-102, 18-201, 18-202, and 18-214.1, Annotated Code of Maryland*

.01 Purpose and Scope.

A. *The purpose of Expedited Partner Therapy in Maryland is to:*

(1) *Provide antibiotic therapy to any partner of a patient diagnosed with chlamydia or gonorrhea without a personal physical assessment of the partner, and without having a previous provider-patient relationship with the partner;*

(2) *Contain and stop the further spread of chlamydia and gonorrhea; and*

(3) *Reduce the likelihood of reinfection in the diagnosed patient.*

B. *This chapter applies to the provision of Expedited Partner Therapy, as described in §A of this regulation, in public and private health care settings.*

.02 Definitions.

A. *In this chapter, the following terms have the meanings indicated.*

B. *Terms Defined.*

(1) *"Antibiotic therapy" means the oral antibiotic drug regimens currently recommended by the Centers for Disease Control and Prevention for the treatment of chlamydia and gonorrhea through Expedited Partner Therapy.*

(2) *"Department" means the Department of Health and Mental Hygiene.*

(3) *"Expedited Partner Therapy (EPT)" means the prescribing or dispensing of antibiotic therapy to any partner of a patient diagnosed with chlamydia or gonorrhea by certain health care providers without making a personal physical assessment of the partner, and without having a previous provider-patient relationship with the partner, in order to contain and stop the further spread of the infection and reduce the likelihood of reinfection in the diagnosed patient.*

(4) *"Health officer" means the health officer in each of the 23 counties and the Commissioner of Health in Baltimore City, or the duly designated representative of the health officer, or both.*

(5) *"Partner" means an individual with whom one has, or has had, oral, anal or vaginal sexual contact.*

.03 Partners Eligible for EPT.

Partners eligible for EPT are:

A. *Any partner within 60 calendar days of the patient's diagnosis; or*

B. *The most recent partner of a patient if the patient has not had sex in the 60 days before diagnosis.*

.04 Health Care Providers Authorized to Prescribe and Dispense EPT.

Notwithstanding any other provision of law, and only in accordance with their current scope of practice, EPT may be prescribed or dispensed by the following health care providers:

A. *A physician licensed under Health Occupations Article, Title 14, Annotated Code of Maryland;*

B. *An authorized physician assistant licensed under Health Occupations Article, Title 15, Annotated Code of Maryland, acting in accordance with Health Occupations Article, §15-302.2, Annotated Code of Maryland;*

C. *An advanced practice registered nurse with prescriptive authority licensed under Health Occupations Article, Title 8, Annotated Code of Maryland, acting in accordance with Health Occupations Article, §8-508, Annotated Code of Maryland; and*

D. *A registered nurse employed by a local health department who complies with:*

(1) *The formulary developed and approved under Health-General Article, §3-403(b), Annotated Code of Maryland; and*

(2) *The requirements established under Health Occupations Article, §8-512, Annotated Code of Maryland.*

.05 Prescribing and Dispensing EPT Medications.

A. *Antibiotic therapy prescribed or dispensed for EPT shall be in accordance with recommendations from the Centers for Disease Control and Prevention.*

B. *Prescribing.*

(1) *A separate prescription shall be issued for each partner;*

(2) *The designation "EPT" or "Expedited Partner Therapy" shall be included on the face of the prescription for each prescription issued;*

(3) *If the partner's name is known, the prescription shall be issued in the partner's name;*

(4) If the partner's name is unknown, the written designation "EPT" or "Expedited Partner Therapy" shall be sufficient for the pharmacist to fill the prescription; and

(5) An EPT prescription may not be refilled.

C. Dispensing.

(1) Each EPT medication label shall:

(a) Include the designation "EPT" or "Expedited Partner Therapy"; and

(b) Include the partner's name, if known; and

(2) Comply with Health Occupations Article, §12-505, Annotated Code of Maryland.

.06 Counseling and Educational Information Requirements.

A. A health care provider prescribing or dispensing EPT to a patient shall:

(1) Counsel the patient to encourage each partner to seek a personal physical assessment; and

(2) Provide the patient with educational information for each partner, in accordance with §C of this regulation.

B. A pharmacist dispensing EPT shall provide educational information for each partner, in accordance with §C of this regulation.

C. The educational information, that is available or comparable to that available on the Department's website, shall include:

(1) Advice for the partner to seek a medical evaluation;

(2) Information about chlamydia and gonorrhea;

(3) Medication instructions;

(4) Warnings about adverse drug or allergic reactions; and

(5) Advice to abstain from sexual activity as required during treatment.

.07 Documenting EPT in a Medical Chart.

A. A health care provider prescribing or dispensing EPT shall document the provision of EPT in the patient's chart.

B. Documentation shall include the:

(1) Number of EPT prescriptions or medications provided to the patient for each partner; and

(2) Medication and dosage being provided to the patient for each partner.

.08 Reporting of Chlamydia and Gonorrhea by a Health Care Provider or Institution.

A. This chapter may not affect the obligation of a health care provider or institution 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.

B. When reporting a case of chlamydia or gonorrhea for which EPT was prescribed or dispensed, a health care provider or institution shall report the number of partners for whom:

(1) Prescriptions were provided; and

(2) Medications were dispensed.

VAN T. MITCHELL

Secretary of Health and Mental Hygiene