

DEPARTMENT OF HEALTH AND HUMAN SERVICES
MAINE CENTER FOR DISEASE CONTROL AND PREVENTION

Chapter 720: RULES GOVERNING THE IMPLEMENTATION OF EXPEDITED
PARTNER THERAPY

SUMMARY: Pursuant to the authority granted by Title 22 MRSA ch. 251 §1242, the Maine Center for Disease Control and Prevention (Maine CDC) is required to adopt rules to implement Expedited Partner Therapy. Expedited Partner Therapy facilitates the treatment and prevention of sexually transmitted infections by prescribing, dispensing, furnishing, or otherwise providing prescription antibiotic drugs to the sexual partner(s) of persons clinically diagnosed with sexually transmitted infections without physical examination of the partner(s). Maine Center for Disease Control and Prevention herein limits Expedited Partner Therapy to be used for the treatment and prevention of infection with chlamydia (*Chlamydia trachomatis*) and/or gonorrhea (*Neisseria gonorrhoeae*).

Section I. General Definitions

- A. The following terms used in these regulations shall have the meaning specified.
1. **Department** means the Department of Health and Human Services, Maine Center for Disease Control and Prevention.
 2. **Expedited Partner Therapy (EPT)** means prescribing, dispensing, furnishing, or otherwise providing prescription antibiotic drugs to the sexual partner(s) of a person clinically diagnosed with a sexually transmitted disease without physical examination of the partner(s).
 3. **Health Care Professional** means an
 - a. *allopathic physician* licensed pursuant to Title 32, chapter 48;
 - b. an *osteopathic physician* licensed pursuant to Title 32, chapter 36;
 - c. a *physician assistant* who has been delegated the provision of sexually transmitted disease therapy or expedited partner therapy by that physician assistant's supervising physician;
 - d. an *advanced practice registered nurse* who
 - (1) has a written collaborative agreement with a collaborating physician that authorizes the provision of sexually transmitted disease therapy or expedited partner therapy, or
 - (2) who possesses appropriate clinical privileges in accordance with Title 32, chapter 31.

4. **Patient** means an individual presenting signs of infection with a sexually transmitted disease eligible for Expedited Partner Therapy.
5. **Sex Partner(s) or Partner(s)** means a person who has engaged in vaginal, anal or oral sex with the patient eligible for Expedited Partner Therapy.
6. **Sexually transmitted disease (STD)** means a bacterial, viral, fungal, or parasitic disease determined by rule of the department to be sexually transmitted, to be a threat to the public health and welfare, and to be a disease for which a legitimate public interest will be served by providing for its regulation and treatment.

Section II. Expedited Partner Therapy Guidelines

A. Expedited Partner Therapy Clinical Eligibility

1. Appropriate patients for Expedited Partner Therapy are those with a clinical diagnosis of sexually transmitted chlamydia (*Chlamydia trachomatis*) and/or gonorrhea (*Neisseria gonorrhoeae*) infection, preferably with laboratory confirmation. All such cases must be reported to the Maine Center for Disease Control pursuant to the *Rules for the Control of Notifiable Diseases and Conditions*, 10-144 CMR Chapter 258.

Laboratory confirmation of the diagnosis may include:

- a. a positive culture test for chlamydia and/or gonorrhea;
 - b. a positive nucleic acid amplification test (NAAT) for chlamydia and/or gonorrhea. Because of their high sensitivity, NAATs are the tests of choice for chlamydia and gonorrhea screening and testing; or
 - c. a gram stain of male urethral exudate showing gram negative intracellular diplococci indicative of gonorrhea.
2. Expedited Partner Therapy can be provided to patients without laboratory confirmation of a sexually transmitted chlamydia and/or gonorrhea infection if the health care professional makes a clinical diagnosis of chlamydia and/or gonorrhea infection in the index case and there is concern about loss of follow-up.
 3. Expedited Partner Therapy should not be offered to patients who are:
 - a. Not clinically diagnosed with chlamydia and/or gonorrhea;
 - b. co-infected with sexually transmitted diseases not covered by EPT medication (e.g. co-infection of gonorrhea and syphilis); or
 - c. in the health care professional's estimation, if the patient is in a situation in which the patient's safety is in doubt.

B. Expedited Partner Therapy Eligibility of Sex Partner(s)

1. Patients most appropriate for Expedited Partner Therapy are those whose partners in the judgment of the health care professional are unable or unlikely to seek prompt clinical services that the patient feels comfortable contacting. EPT is recommended for all of the patient's sex partners in the 60 days prior to diagnosis of chlamydia/gonorrhea. Expedited Partner Therapy should be used as a last resort option.

Factors to consider are that the partner:

- a. is uninsured,
 - b. lacks a primary care provider,
 - c. faces significant barriers to accessing clinical services, or
 - d. is reportedly unwilling to seek care.
2. Health Care Professionals should interview the patient to assess the partner's:
 - a. symptom status, particularly symptoms indicative of a complicated infection;
 - b. risk for severe medication allergies;
 - (1) For partners with known severe allergies to antibiotics, EPT should not be used .
 - c. pregnancy status;
 - d. and status as a man who has sex with men (MSM).
 - (1) If the partner is a MSM, the Health Care Professional should advise the patient that EPT is not routinely recommended for MSM because of a high risk for coexisting infections, especially undiagnosed HIV infection, in their partners.
 3. Even if EPT is provided, the sex partner(s) should be encouraged to seek follow-up care as soon as possible.

C. Expedited Partner Therapy Counseling

1. Health care professionals must provide patients infected with chlamydia and/or gonorrhea counseling and written materials developed by the Maine CDC HIV, STD, & Viral Hepatitis Program for their partners who will receive EPT either as a prescription to be filled or medication to be taken. Materials are available at the Maine CDC HIV, STD, & Viral Hepatitis website (<http://mainepublichealth.gov/std>).

2. Required patient counseling and written materials for EPT partners include:
 - a. A warning that a woman who is pregnant or might be pregnant should not take certain antibiotics and should immediately contact a health care professional for an examination;
 - b. Information about the antibiotic and dosage provided or prescribed; clear and explicit allergy and side effect warnings, including a warning that a sexual partner who has had a history of allergy to the antibiotic or the pharmaceutical class of antibiotic should not take the antibiotic and should be immediately examined by a health care professional;
 - c. Information about the treatment and prevention of STDs;
 - d. The requirement of abstinence for seven days after the initiation of treatment to prevent infecting others;
 - e. Notification of the importance of sex partners to receive examination and testing for HIV and other STDs and information on available resources;
 - f. Notification of the risk to the sexual partner, others, and the public health if the STD is not completely and successfully treated;
 - g. The responsibility of the sex partner to inform his/her sexual partners of the risk of STDs and importance of prompt examination and treatment;
 - h. Advice to symptomatic patients, especially women with symptoms of pelvic inflammatory disease, to seek medical attention; and
 - i. Other information deemed necessary by Maine CDC, such as prevention strategies to reduce the risk of acquiring or transmitting sexually transmitted diseases.
3. Health care professionals should advise patients that if their partners have symptoms of a more serious infection (e.g., fever, pelvic pain in women, testicular pain in men), then the partners should not take the EPT medications and should seek care as soon as possible.
4. Health care professionals should counsel and provide written materials to patients who have a history of two or more sexually transmitted diseases concerning the increased risks related to re-infection and subsequent complications, such as pelvic inflammatory disease, ectopic pregnancy, etc., and increased risk of HIV acquisition/transmission.
5. Health care professionals should advise patients that if their partner is being treated for gonorrhea, oral medications are not as effective at treating pharyngeal gonorrhea infection compared to the preferred treatment for gonorrhea infection.
6. It also is recommended that sex partners who receive EPT be re-tested for chlamydia and/or gonorrhea three months after treatment.

7. Pregnant patients and/or partners who receive EPT need a test-of-cure in three weeks after treatment.

D. Recommended Treatment Regimens

1. Recommended antibiotic regimens for EPT for chlamydia include:
 - a. Azithromycin, 1 gram orally once; or
 - b. Doxycycline, 100mg orally twice daily for 7 days.
 - (1) Doxycycline is not recommended during pregnancy or lactation.
2. Recommended antibiotic regimens for EPT for gonorrhea of the cervix, urethra, and/or rectum include:
 - a. Cefixime, 400mg orally once, plus
 - (1) Azithromycin, 1 gram orally once; or
 - (2) Doxycycline, 100mg orally twice daily for 7 days.
 - i. Doxycycline is not recommended during pregnancy or lactation
 - b. The EPT regimen for gonorrhea may not be as effective at treating pharyngeal gonorrheal infection.
 - (1) Providers who are concerned that the partner is at risk for pharyngeal infection should advise the patient that oral treatment may not cure pharyngeal gonorrhea in all patients; and
 - (2) The partner should still seek care to receive first-line therapy.
3. Although side effects are mild and adverse reactions are rare, health care professionals should mitigate the risk of allergy and adverse reactions by providing educational materials that accompany the medication, which include explicit warnings and instructions for partners who may be allergic to penicillin, cephalosporins, macrolides, minocycline, tetracyclines, or sulfites to seek medical advice before taking the medication.
4. If changes are made to recommended treatment regimens by Maine CDC after this rule is adopted, Maine CDC shall publish updated recommendations with the materials referred to in Section II(C). Health Care Professionals should use the most current Maine CDC recommended treatment regimens for EPT for chlamydia and gonorrhea.

E. Options for Delivery of Antibiotics to Sex Partner(s)

1. Authorized health professionals may engage in the following alternative methods for delivering antibiotics to sex partners.

- a. Dispense medication directly to the patient for delivery to partner(s).
 - (1) The patient should be given enough doses to treat each sex partner in the past 60 days whom the patient feels confident contacting, and who are unable or unlikely to seek medical care.
 - (2) There is no limit to the number of partners that may be treated through EPT.
 - (3) Medication packets should only contain drugs recommended by the Maine CDC for the treatment of chlamydia and/or gonorrhea.
 - (4) Labeling of medication packets should adhere to *Maine Pharmacy Practice Act* stipulations.
 - i. Pursuant to 32 M.R.S.A. §§ 13701 *et seq.*, the *Maine Pharmacy Act* was amended to allow drugs to be dispensed without the name of the patient's sexual partner on the label, provided that the drugs were dispensed in accordance with Maine EPT rules.
- b. Dispense prescription to the patient to be delivered to partner(s) who is unable or unlikely to seek medical care. Partner(s) presents the prescription to a pharmacy of his/her choice to be filled.
 - (1) The patient should be given one prescription for each sex partner in the past 60 days whom the patient feels confident contacting and who is unable or unlikely to seek medical care.
 - (2) Medication prescriptions should only list drugs recommended by the Maine CDC for the treatment of chlamydia and/or gonorrhea.
 - (3) When available, the patient partner's name should be on the prescription.
 - i. If the patient's partner's name is unavailable, in lieu of the name, the prescribing health care professional should write "Expedited Partner Therapy" or "EPT."
 - ii. A drug dispensed in accordance with Maine EPT regulations does not require the name of the patient's sexual partner on the label.
- c. A combination of partner strategies also may be used, for example, a patient with several partners may refer one partner to a health care professional but take EPT for other partners.

F. Patient Follow-Up

1. To ensure the effectiveness of EPT, providers should schedule both male and female patients to return for re-testing for chlamydia and/or gonorrhea three months after treatment.
2. Pregnant patients should be scheduled for a test-of-cure three weeks after treatment.

G. Immunity for Health Care Professional and Pharmacist or Pharmacy

1. Health care professionals (allopathic physicians, osteopathic physicians, physician assistants, and advance practice registered nurses and nurse practitioners) who provide Expedited Partner Therapy in good faith without fee or compensation, and provide counseling and written materials as required in this rule, are immune from civil and/or professional liability, except in cases of willful and wanton misconduct.
2. A health care professional (allopathic physicians, osteopathic physicians, physician assistants, and advance practice registered nurses and nurse practitioners) shall not be subject to civil or professional liability for choosing not to provide Expedited Partner Therapy.
3. A pharmacist or pharmacy is not subject to civil or professional liability for choosing not to fill a prescription that would cause that pharmacist or pharmacy to violate any provision of the *Maine Pharmacy Act*, 32 M.R.S.A. §§ 13701 *et seq.*

STATUTORY AUTHORITY:

Pursuant to 22 MRSA §42(1) and 22-A MRSA §205(2), the Department has general authority to adopt rules considered to be necessary and proper for the protection of life, health and welfare, and the successful operation of the health and welfare statutes. Furthermore, 22 MRSA §1242 (2010) requires the Maine Center for Disease Control and Prevention (Maine CDC) to implement statutory provisions governing the practice of expedited partner counseling for the treatment of sexually transmitted infections.

EFFECTIVE DATE:

November 4, 2015 – filing 2015-205