

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 225(4) and 2312 of the Public Health Law, section 23.5 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

23.5 Expedited [p]Partner [t]Therapy for [chlamydia trachomatis infection] sexually transmitted infections.

(a) Definitions. As used in this section:

(1) “Expedited Partner Therapy” or “EPT” means a practice whereby a health care practitioner chooses to provide a patient with either antibiotics intended for the patient’s sexual partner or partners or a written prescription for antibiotics for the sexual partner or partners to be delivered by the patient to the sexual partner or partners for treatment of exposure to [Chlamydia trachomatis] sexually transmitted infections (STIs).

(2) “Health care practitioner” means a physician, midwife, nurse practitioner, physician assistant, or other person who is authorized under Title 8 of the Education Law to diagnose and prescribe drugs for [Chlamydia trachomatis] STIs, acting within [his or her] their lawful scope of practice.

(b) Liability. A health care practitioner who reasonably and in good faith renders expedited partner therapy in accordance with section 2312 of the Public Health Law and this section, and a pharmacist who reasonably and in good faith dispenses drugs pursuant to a prescription written in accordance with section 2312 of the Public Health Law and this section, shall not be subject to civil or criminal liability or be deemed to have engaged in unprofessional conduct.

(c) Eligibility criteria for EPT. EPT shall:

(1) [be provided only for the partner or partners of a patient diagnosed with Chlamydia trachomatis infection] be provided for sexual partner(s) of patients diagnosed (either through laboratory confirmation or clinical diagnosis) with an STI for which EPT is recommended by the Federal Centers for Disease Control and Prevention (CDC). The department shall list which STIs are eligible for EPT on the department's website and shall promulgate guidelines that include partner eligibility criteria. If the patient's sexual partner(s) are pregnant or there is a suspicion of possible pregnancy, some EPT medications are not recommended, and the partner(s) should seek medical care as soon as possible; and

(2) not be provided [for any partner or partners, when the patient with Chlamydia trachomatis infection seen by the health care practitioner is found to be concurrently infected with gonorrhea, syphilis or HIV] in cases involving suspected or confirmed child abuse, sexual abuse/assault, or where the diagnosed patient's safety may be impacted.

(d) Educational material requirements for patients provided with EPT. Each patient provided with antibiotics or a prescription in accordance with this section must be given informational materials for the patient to give to [his or her] their sexual partner or partners. Each patient shall be counseled by [his or her] the patient's health care practitioner to inform [his or her] the patient's partner or partners that it is important to read the information contained in the materials prior to the partner or partners taking the medication.

The materials shall:

- (1) encourage the partner to consult a health care practitioner for a complete [sexually transmitted infection] sexual health evaluation, including HIV testing, as a preferred alternative to EPT and regardless of whether they take the medication;
- (2) disclose the risk of potential adverse drug reactions, including allergic reactions, and the possibility of dangerous interactions between the patient-delivered therapy and other medications that the partner may be taking;
- (3) inform the partner that [he or she] they may be affected by other [sexually transmitted infections] STIs that may be left untreated by the delivered medicine;
- (4) inform the partner that if symptoms of a more serious infection are present (such as abdominal, pelvic, or testicular pain, fever, nausea or vomiting) [he or she] they should seek medical care as soon as possible;
- (5) recommend that a partner who is or could be pregnant should consult a health care practitioner as soon as possible;
- (6) instruct the patient and the partner to abstain from sexual activity for at least seven days after treatment of both the patient and the partner in order to [decrease the risk of recurrent infection] reduce the likelihood of reinfection;
- [(7) inform a partner who is at high risk of co-morbidity with HIV infection that he or she should consult a health care practitioner for a complete medical evaluation including testing for HIV and other sexually transmitted infections] and
- [(8)] (7) inform the patient and the partner how to prevent [repeated chlamydia infection] and reduce the likelihood of reinfection.

(e) Prescription format. Whenever a health care practitioner provides EPT through the use of a prescription:

(1) the designation “EPT” must be written in the body of the prescription form above the name of the medication and dosage for all prescriptions issued;

(2) if the name, address, and date of birth of the sexual partner are available, this should be written in the designated area of the prescription form; and

(3) if the sexual partner’s name, address, and date of birth are not available, the written designation “EPT” shall be sufficient for the pharmacist to fill the prescription.

(f) Reporting of cases of [Chlamydia trachomatis] STIs by health care providers.

(1) This section shall not affect the obligation to report individual cases and suspected cases of [Chlamydia trachomatis] STIs imposed by Part 2 of this [Chapter] Title.

(2) Reports of cases of [Chlamydia trachomatis] STIs who are provided with EPT shall include the added designation of “EPT” plus the number of sexual partners for whom a prescription or medication was provided.

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

Pursuant to sections 225(4) and 2312 of the Public Health Law (PHL), the Commissioner of Health and the Public Health and Health Planning Council have the authority to adopt regulations concerning Expedited Partner Therapy for Chlamydia Trachomatis Infection and Other Sexually Transmitted Infections.

### **Legislative Objectives:**

Laws of 2008, Chapter 577, allowed health care providers with prescriptive privileges to provide Expedited Partner Therapy (EPT) for Chlamydia when the prescriber's judgment is that the partner(s) will not seek a personal medical visit. This law has helped improve treatment rates for partners and decrease re-infection rates for partners. Laws of 2019, Chapter 298, amended PHL section 2312 to expand the use of EPT for other sexually transmitted infections (STIs) that the Centers for Disease Control and Prevention (CDC) recommends for EPT, in addition to Chlamydia.

EPT helps physicians and other health care providers decrease rates of STIs. While EPT in no way replaces a face-to-face interaction with a health care provider, it can help patients who otherwise would not reach out for treatment.

The CDC has found through randomized controlled tests that EPT has the potential for the same success that it has shown with Chlamydia with other STIs. EPT can be highly effective in decreasing infection rates with other STIs, such as gonorrhea, that can be cured by taking antibiotics by mouth.

**Needs and Benefits:**

EPT is the clinical practice of providing individuals with medication or a prescription to deliver to their sexual partner(s) as treatment for a presumptive STI, without completing a clinical assessment of those partners.

On January 1, 2020, Chapter 298 of the Laws of 2019 went into effect, expanding PHL section 2312 to permit expedited treatment for STIs for which the CDC recommends the use of expedited therapy. Prior to this change, EPT was allowable in New York State for chlamydia only. In addition to supporting EPT for chlamydia, at this time the CDC also supports or lists EPT as a strategy for partner management for persons diagnosed with either gonorrhea or trichomoniasis.

Chlamydia, gonorrhea, and trichomoniasis are STIs that are transmitted by sexual contact with a penis, vagina, mouth, or anus of an infected sex partner; these STIs can result in adverse health effects if left untreated. According to the 2019 national STI surveillance report released by CDC, both chlamydia and gonorrhea diagnoses have continued to rise, with 19% and 56% increases, respectively since 2015. New York State has mirrored the national increases in both chlamydia and gonorrhea with 20% and 60% increases, respectively, since 2015. Additionally, though trichomoniasis is not a reportable STI both nationally and in New York State, the CDC estimates that nationally there are around 6.9 million (diagnosed or undiagnosed) new infections.

With respect to EPT, three US clinical trials involving heterosexually active males and females with chlamydia or gonorrhea all show that more sexual partners were treated when the patients were offered EPT. Two out of those three trials showed a significant reduction in re-infection of the patients, and the third noted a decreased risk of recurrent infection that was not significant. One trial show that there was a reduction in prevalence as high as 10% in females

when EPT was provided free of charge. Though trials and meta-analyses conducted on EPT differ in findings with respect to the magnitude of the reduction in re-infection, all show a reduction in prevalence in chlamydia and gonorrhea at follow up. Though data on EPT for trichomoniasis is limited, EPT may have a role in partner management, and it should remain an option when treatment of partners cannot otherwise be assured.

The CDC, along with several national professional organizations, recommend EPT as an effective and practical strategy for treating the sex partners of people diagnosed with chlamydia and/or gonorrhea. The New York State Department of Health (NYSDOH) previously released a position statement strongly encouraging providers to utilize EPT as a strategy to treat the sex partner(s) of persons diagnosed with chlamydia. In consideration of the expansion of the law, and of what is a larger shift toward a comprehensive sexual health framework, the position statement was revised to: expand the use of EPT to include gonorrhea and trichomoniasis, remove exclusionary language, and include updated treatment guidelines.

Current New York Codes, Rules, and Regulations (NYCRR) section 23.5, of Title 10 provides definitions, and eligibility specific to EPT for chlamydia only. Given the expansion of PHL section 2312 to include additional STIs beyond chlamydia alone, the regulation needs to be modified as follows: 1) rather than defining EPT as a strategy for treating chlamydia, EPT needs to be defined as a strategy more generically for STIs and be integrated with other sexual health services, 2) rather than stating eligibility is limited to persons diagnosed with chlamydia who are not co-infected with gonorrhea or HIV, the regulation should state persons eligible for EPT are those diagnosed with an STI for which the CDC recommends the use of EPT for partner management, and 3) an addendum to the eligibility section should include language permitting the Commissioner of Health to designate which STIs are eligible in the department's website.

Additional proposed modifications to the current regulation specific to the educational material requirements include: shifting from the use of binary language (“his/her”) to gender neutral language (“their”) to ensure inclusivity and removing specific language stating persons at high risk of co-morbidity with HIV should seek medical evaluation, as HIV testing for all persons receiving EPT educational materials is already included as a recommendation in a previous section and this additional callout can be deemed stigmatizing.

**Costs:**

**Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:**

An estimated \$850 million is spent annually treating chlamydia and gonorrhea in the US. EPT can decrease these costs by reducing the spread of infections and re-infections by reducing the reliance on public services to treat STIs. If left untreated, chlamydia and gonorrhea can progress to pelvic inflammatory disease (PID) in females, resulting in additional treatment costs of \$1,167 per case of PID. Both infections are also a common cause of infertility; and because EPT increases STI treatment rates and reduces prevalence of chlamydia and gonorrhea, infertility and PID resulting from such infections will likely decline. Both chlamydia and gonorrhea change the immune system and may increase a person’s chances of contracting HIV if exposed to the virus. Data related to costs for screening and treatment of trichomoniasis are limited. Integrating EPT into a broader sexual health approach can have significant public health benefits, including lowering overall STI rates and reducing healthcare costs associated with untreated infections.

**Costs to State and Local Governments:**

This regulation imposes no costs on State and local governments. It expands the use of EPT.

**Costs to the Department of Health:**

The additional costs to the NYSDOH will be related to additional data collection burden and follow up; such costs are expected to be minimal and easily accommodated within existing infrastructure.

**Local Government Mandates:**

This proposal has no local mandates.

**Paperwork:**

The existing electronic data collection mechanism was revised when the law was changed such that local health departments could start reporting provision of EPT for the other STIs.

**Duplication:**

These regulations will not conflict with any State or federal rules.

**Alternatives:**

The alternative to this regulatory amendment would be to not conform the regulation to PHL section 2312, as amended by Laws of 2019, Chapter 298. This is not a viable alternative as

the Department of Health is obligated to execute the PHL. This regulation is further necessary to expand the availability EPT to reduce the rates of sexually transmitted infections.

**Federal Standards:**

The Centers for Disease Control and Prevention has recommendations related to expedited partner therapy. This regulation is consistent with federal standards.

**Compliance Schedule:**

This regulation is effective upon the publication of the Notice of Adoption in the State Register. This regulation permits, but does not require, EPT for STI.

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**STATEMENT IN LIEU OF  
REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

**STATEMENT IN LIEU OF  
RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

**STATEMENT IN LIEU OF  
JOB IMPACT STATEMENT**

A Job Impact Statement for these amendments is not being submitted because the New York State Department of Health has determined that these regulatory changes will not have a substantial adverse impact on jobs and employment, based upon its nature and purpose.

## ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (Department) received two comments, which both expressed support for the proposed amendments to Section 23.5 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York. The comments were submitted by a local health department and an association of county health officials.

**Comment:** The local health department asked why this regulation deletes language in § 23.5(c)(2) that states that Expedited Partner Therapy may not be provided for a patient's partners when the patient diagnosed with a sexually transmitted infection is also found to have syphilis infection.

**Response:** Under § 23.5(c)(1), the Department shall list which sexually transmitted infections are eligible for Expedited Partner Therapy on the Department's website and shall promulgate guidelines that include partner eligibility criteria. The Department agrees with the local health department that under the Department's guidelines, patients known to have syphilis in addition to gonorrhea, chlamydia, and trichomoniasis are ineligible for Expedited Partner Therapy. No changes to the regulation have been made in response to this comment.

**Comment:** The local health department also pointed out two drafting errors in § 23.5(c)(1).

**Response:** The Department thanks the local health department, and the final regulation amends the second and third sentences of § 23.5(c)(1) in the proposed regulation to read (in a single sentence) as follows: "If the patient's sexual partner(s) are pregnant or there is a suspicion of

possible pregnancy, some Expedited Partner Therapy medications are not recommended, and the partner(s) should seek medical care as soon as possible.”

**Comment:** The association of county health officials supports updating the regulation in alignment with CDC guidance. The association of county health officials requested guidance regarding the use of Expedited Partner Therapy. The commenter also asserted that Expedited Partner Therapy is often not documented in the patient medical record, making it difficult to know when and how Expedited Partner Therapy has been used. The commenter asked the Department to consider strategies to improve Expedited Partner Therapy documentation and reporting, both to evaluate impact and to inform public health follow up.

**Response:** Department’s guidance regarding the use of Expedited Partner Therapy is available on the Department’s website. See [Expedited Partner Therapy landing page](#), [Expedited Partner Therapy Brochures](#) (available for ordering at no cost); and [Expedited Partner Therapy Information for Providers and Pharmacists](#). The Department will publish additional guidance as needed. No changes to the regulation have been made in response to this comment.