

## Department of Health

### NOTICE OF ADOPTION

#### Expedited Partner Therapy to Treat Chlamydia Trachomatis

**I.D. No.** HLT-14-10-00005-A

**Filing No.** 1008

**Filing Date:** 2010-09-28

**Effective Date:** 2010-10-13

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

**Action taken:** Addition of section 23.5 to Title 10 NYCRR.

**Statutory authority:** Public Health Law, section 2312

**Subject:** Expedited Partner Therapy to Treat Chlamydia Trachomatis.

**Purpose:** Use of expedited partner therapy to treat the partner of persons infected with Chlamydia Trachomatis.

**Text of final rule:** Pursuant to the authority vested in the Commissioner of Health by Section 2312 of the Public Health Law, Part 23 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended, by adding a new Section 23.5, to read as follows:

*Section 23.5 Expedited Partner Therapy for Chlamydia trachomatis Infection*

(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.

(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, acting within his or her 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; 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 or syphilis.*

(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 sexual partner or partners. Each patient shall be counseled by his or her health care practitioner to inform his or her 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 evaluation 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 may be affected by other sexually transmitted infections 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 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;*

(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) *inform the patient and the partner how to prevent repeated chlamydia infection.*

(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 by health care providers.*

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

(2) *Reports of cases of Chlamydia trachomatis 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.*

**Final rule as compared with last published rule:** Nonsubstantive changes were made in section 23.5.

**Text of rule and any required statements and analyses may be obtained from:** Katherine Ceroalo, DOH, Bureau of House Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqa@health.state.ny.us

**Revised Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement**

Changes made to the last published rule do not necessitate revision to the previously published Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis or Job Impact Statement.

#### Assessment of Public Comment

The NYS Department of Health (NYSDOH) received written comments on the proposed amendment to Part 23 of Title 10 of the New York Code, Rules and Regulations from Stony Brook University Hospital and an anonymous entity. A summary of each comment is provided followed by the DOH response.

##### Comment # 1

Guidance is sought from NYSDOH to assist local health departments in targeting those Chlamydia cases who should receive partner services, including patients diagnosed in public STD clinics, as well as those Chlamydia cases to whom expedited partner therapy should be offered.

##### Response:

The NYSDOH Bureau of STD Prevention and Epidemiology has previously provided the federal Centers for Disease Control and Prevention Program Operations Guidelines as well as its own Field Manual to assist local health departments in establishing partner services policies for Chlamydia but also permits flexibility in developing policies that are consistent with local resources. The regulation for expedited partner therapy provides another option for local health departments to use in Chlamydia partner management. However, the regulations do not require local health departments to use EPT. If they prefer to provide partner services for Chlamydia, they still have that option. NYSDOH will be issuing educational materials to assist providers in using EPT.

##### Comment # 2

The regulation states that Chlamydia case reports must indicate if EPT was provided and the number of partners for whom a prescription or medication was provided. NYSDOH should provide guidance to local health departments on how to utilize EPT data.

##### Response:

It is the responsibility of the local health departments to enter the number of partners for whom expedited partner therapy is provided on the case report form in the Communicable Disease Electronic Surveillance System for Chlamydia cases meeting the federal case definition. Local health departments may use these data to monitor the usage of expedited partner therapy.

##### Comment # 3

The Bureau of Sexually Transmitted Disease Control (BSTDC) has negotiated contracts and work plans with individual local health districts which include deliverables related to partner services for Chlamydia cases. To the extent that expedited partner therapy for Chlamydia cases replaces partner services for Chlamydia cases, local health districts will fail to meet some of their grant deliverables for Chlamydia disease intervention. Guidance regarding the funding consequences of this change in practice would be appreciated.

## Response:

As stated previously, expedited partner therapy is an option for Chlamydia partner management and NYSDOH expects that partner services activities will continue to be performed for Chlamydia. Consequently, the existing county contracts for disease intervention services will still be enforced. As noted in the comment, these contracts and work plans are negotiated between the BSTDC and the county and therefore counties may request to re-negotiate these plans taking into consideration the impact of expedited partner therapy on partner services activities.

## Comment # 4

To the extent that providers adopt expedited partner therapy for Chlamydia, partners will present to local health districts with prescriptions labeled 'E.P.T.' requesting free medication. Some of these partners will not be interested in an STD examination or in an interview by nurses or STD partner services staff. Few, if any, local health districts in NYS have the ability to operate a free retail pharmacy operation.

## Response:

It should be noted that currently, partners exposed to a sexually transmitted infection present to local health department clinics for treatment and may refuse an examination and/or interview. Treatment on the basis of exposure is a critical public health strategy for preventing disease transmission. The cost of treatment with azithromycin is minimal and local health departments may realize additional savings in the cost of purchasing azithromycin through federal programs that provide access to public health pricing, e.g. Office of Pharmacy Affairs 340B program. Finally, New York State Public Health Law, Article 6 funding enables local health departments to recover some of the costs of treatment.

## Comment # 5

NYSDOH should have consulted with more local health districts in drafting this regulation.

## Response:

NYSDOH broadly solicited comments on the proposed regulations. As stated in the regulatory impact statement, NYSDOH consulted with a number of professional organizations, including the New York State Association of County Health Officers, as well as local governments to seek input during the drafting of these regulations.

## Comment # 6

It is recommended that NYSDOH post all comments in real-time in order to permit greater transparency in NYS governmental operations, reduce potential for duplicate comments, and improve the quality of the regulations.

## Response:

NYSDOH consulted widely in the development of these regulations in order to ensure representation of those consumers and stakeholders who would be impacted by the proposed rules. This consultation process promoted transparency, discussion, and quality of the regulations. Finally, this Assessment of Public Comment serves to inform all parties of the comments that were submitted in response to these regulations and the NYSDOH response.

## Comment # 7

Expedited Partner Therapy should apply to Neisseria gonorrhoeae as well as Chlamydia trachomatis infections as has been implemented in other states.

The proposed regulation protects pharmacists who dispense medication for EPT but does not specifically include language that affords the same protection to health department officials who provide EPT. It is recommended that the proposed regulation be amended to include protection for state and local health departments against liability.

## Response:

The legislation does not provide an option to use EPT for gonorrhea.

The regulations state that health care practitioners and pharmacists who comply with the requirements of section 2312 shall not be subject to civil or criminal liability under these regulations. A health care practitioner is defined as a physician, midwife, nurse practitioner, physician assistant or other person authorized under Title 8 of the Education Law to diagnose and treat Chlamydia infections. Such health care practitioners who work in state and local health departments are also protected from civil and criminal liability. Public health officials who are not licensed health care practitioners, such as public health advisors, are not permitted by Title 8 of the State Education law to prescribe or dispense drugs and therefore are not permitted to practice expedited partner therapy.

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## Insurance Department

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### EMERGENCY RULE MAKING

#### Standards for the Management of the New York State Retirement Systems

**I.D. No.** INS-11-10-00002-E

**Filing No.** 976

**Filing Date:** 2010-09-23

**Effective Date:** 2010-09-23

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

**Action taken:** Amendment of Part 136 (Regulation 85) of Title 11 NYCRR.

**Statutory authority:** Insurance Law, sections 201, 301, 314, 7401(a) and 7402(n)

**Finding of necessity for emergency rule:** Preservation of general welfare.

**Specific reasons underlying the finding of necessity:** The Second Amendment to Regulation 85 (11 NYCRR 136), effective November 19, 2008, established new standards of behavior with regard to investment of the Common Retirement Fund's assets, conflicts of interest, and procurement. In addition, it created new audit and actuarial committees, and greatly strengthened the investment advisory committee. The Second Amendment also set high ethical standards, strengthened internal controls and governance, enhanced the operational transparency of the Fund, and strengthened supervision by the Insurance Department.

Nevertheless, recent events surrounding how placement agents conduct business on behalf of their clients with regard to the Fund compel the Superintendent to conclude that the mere strengthening of the Fund's control environment is insufficient to protect the integrity of the state employees' retirement systems. Rather, only an immediate ban on the use of placement agents will ensure sufficient protection of the Fund's members and beneficiaries and safeguard the integrity of the Fund's investments.

This regulation was previously promulgated on an emergency basis on June 18, 2009, September 16, 2009, January 5, 2010, April 2, 2010, May 28, 2010, and July 29, 2010. A public hearing was held on April 28, 2010. Comments were received from two entities recommending that the total ban on the use of placement agents be modified. The Department will continue to assess the comments that have been received and any others that may be submitted.

Regulation No. 85 needs to remain effective for the general welfare.

**Subject:** Standards for the management of the New York State Retirement Systems.

**Purpose:** To ban the use of placement agents by investment advisors engaged by the state employees retirement system.

**Text of emergency rule:** Section 136-2.2 is amended to read as follows:  
§ 136-2.2 Definitions.

The following words and phrases, as used in this Subpart, unless a different meaning is plainly required by the context, shall have the following meanings:

[(a) Retirement system shall mean the New York State and Local Employees' Retirement System and the New York State and Local Police and Fire Retirement System.]

[(b) Fund shall mean the New York State Common Retirement Fund, a fund in the custody of the Comptroller as trustee, established pursuant to Section 422 of the Retirement and Social Security Law, which holds the assets of the retirement system.]

[(c)](a) Comptroller shall mean the Comptroller of the State of New York in his capacity as administrative head of the Retirement System and the sole trustee of the [fund] Fund.

[(d) OSC shall mean the Office of the State Comptroller.]

[(e)](b) Consultant or advisor shall mean any person (other than an OSC employee) or entity retained by the [fund] Fund to provide technical or professional services to the [fund] Fund relating to investments by the [fund] Fund, including outside investment counsel and litigation counsel, custodians, administrators, broker-dealers, and persons or entities that identify investment objectives and risks, assist in the selection of [money] investment managers, securities, or other investments, or monitor investment performance.

(c) Family member shall mean any person living in the same household