Sexually Transmitted Diseases (STDs)

Effective date: 5/18/16

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 225(4), 2304, 2311 and 2312 of the Public Health Law, Part 23 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:

Section 23.1 is amended as follows:

23.1 List of sexually [transmissible] transmitted diseases.

The following are groups of sexually [transmissible] transmitted diseases (STDs) and shall constitute the definition of sexually [transmissible] transmitted diseases for the purpose of this Part and Section 2311 of the Public Health Law:

Group A

[Treatment] Facilities referred to in section 23.2 of this [p]Part must provide diagnosis and treatment [free of charge] as provided in section 23.2(c) of this Part for the following STDs:

Chlamydia trachomatis infection

Gonorrhea

Syphilis

Non-gonococcal Urethritis (NGU)

Non-gonococcal (mucopurulent) Cervicitis

Trichomoniasis

Lymphogranuloma Venereum

Chancroid

Granuloma Inguinale

Group B

[Treatment facilities] Facilities referred to in section 23.2 of this Part must provide diagnosis [free of charge] and [must provide] treatment as provided in section 23.2(d) of this Part for the following STDs:

[Ano-genital warts]

Human Papilloma Virus (HPV)

Genital Herpes Simplex

Group C

[Treatment facilities] Facilities referred to in section 23.2 of this Part must provide diagnosis [free of charge] and [must provide] treatment as provided in section 23.2(e) of this Part for the following STD:

Pelvic Inflammatory Disease (PID) Gonococcal/Non-gonococcal

Group D

[Treatment facilities] Facilities referred to in section 23.2 of this Part must provide diagnosis [free of charge] and [must provide] treatment as provided in section 23.2(f) of this Part for the following STDs:

Yeast (Candida) Vaginitis

Bacterial Vaginosis

Pediculosis Pubis

Scabies

Section 23.2 is amended as follows:

Section 23.2 [Treatment facilities] Facilities.

Each health district shall provide adequate facilities either directly or through contract for the diagnosis and treatment of persons living within its jurisdiction who are infected or are suspected of being infected with STD as specified in section 23.1 of this Part.

(a) Such persons shall be examined and shall have appropriate laboratory specimens taken and laboratory tests performed for those diseases designated in this Part as STDs for which such person exhibits symptoms or is otherwise suspected of being infected.

(b) The examinations and laboratory tests shall be conducted in accordance with accepted medical procedures as described in the most recent evidence-based STD [clinical guidelines and laboratory] guidelines distributed by the New York State Department of Health.

(c) Any persons diagnosed as having any of the STDs in Group A in section 23.1 of this Part shall be treated directly in the facility with appropriate medication in accordance

with accepted medical procedures as described in the most recent [treatment] evidence-based STD guidelines distributed by the department.

(d) Any persons diagnosed as having any of the STDs in Group B in section 23.1 of this Part must be provided treatment either directly in the [treatment] facility referred to in this section or through a written or electronic prescription or referral. [If treatment is provided directly, it must be provided free of charge.]

(e) Any person diagnosed as having the STD in Group C in section 23.1 of this Part may be managed by immediate referral or if outpatient treatment is appropriate as indicated by evidence-based STD guidelines, the person may be treated directly in the facility. [If outpatient treatment is appropriate as indicated by accepted clinical guidelines and is provided directly in the treatment facility referred to in this section, it must be provided free of charge.]

(f) Any person diagnosed as having any of the STDs in Group D in section 23.1 of this Part may be provided treatment directly within the [treatment] facility referred to in this section or through a written or electronic prescription. [If treatment is provided directly, it must be provided free of charge.]

(g) Health districts shall seek third party reimbursement for these services to the greatest extent practicable; provided, however, that no board of health, local health officer, or other municipal health officer shall request or require that such coverage or indemnification be utilized as a condition of providing diagnosis or treatment services. Health care providers that are permitted by the patient to utilize such coverage or

indemnification may disclose information to third party reimbursers or their agents to the extent necessary to reimburse health care providers for health services.

Section 23.3 is amended as follows:

23.3 Cases treated by other providers.

(a) Every physician, physician assistant, licensed midwife or nurse practitioner providing (as authorized by their scope of practice) gynecological, obstetrical, genito-urological, contraceptive, sterilization, or termination of pregnancy services or treatment, shall offer to administer to every patient treated by such physician, physician assistant, licensed midwife or nurse practitioner, appropriate examinations or tests for STD as defined in this Part.

(b) The administrative officer or other person in charge of a clinic or other facility providing gynecological, obstetrical, genito-urological, contraceptive, sterilization or termination of pregnancy services or treatment shall require staff of such clinic or facility to offer to administer to every resident of the State of New York coming to such clinic or facility for such services or treatment, appropriate examinations or tests [or] for the detection of sexually [transmissible] transmitted diseases.

A new section 23.4 is added as follows:

23.4 Minors.

When a health care provider diagnoses, treats or prescribes for a minor, without the consent or knowledge of a parent or guardian as permitted by section 2305 of the Public Health Law, neither medical nor billing records shall be released or in any manner be

made available to the parent or guardian of such minor without the minor patient's permission. In addition to being authorized in accordance with section 2305 of the Public Health Law to diagnose, treat or prescribe for a person under the age of eighteen years without the consent or knowledge of the parent or guardian of such person where the individual is infected with a sexually transmitted disease, or has been exposed to infection with a sexually transmitted disease, health care practitioners may (as authorized by their scope of practice) render medical care related to other sexually transmitted diseases without the consent or knowledge of the parent or guardian.

Paragraph (2) of subdivision (c) of section 23.5 is amended as follows:

(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 or HIV.

Regulatory Impact Statement

Statutory Authority:

To be consistent with and in conjunction with amendments contained in the 2013-14 enacted State budget which became effective on April 1, 2013 (L. 2013, ch. 56, Part E, §§ 32-41), modifications are needed to relevant sections of 10 NYCRR Part 23 (Sexually Transmissible Diseases). Under sections 225(4), 2311 and 2312 of the Public Health Law, the Commissioner of Health and the Public Health and Health Planning Council have the authority to amend the State Sanitary Code (10 NYCRR Parts 1-24), list the sexually transmitted diseases for which Public Health Law Article 23 is applicable and promulgate rules and regulations concerning expedited partner therapy for chlamydia.

Legislative Objectives:

Laws of 2013, Chapter 56 amended PHL section 2304 to clarify that counties may provide STD diagnosis and treatment not only directly but also "through contract." The Legislature removed the requirement that services must be provided "free" and, further, required municipalities to seek third party coverage (generally Medicaid) reimbursement for such services where appropriate. As amended, PHL section 2304 states that counties must "to the greatest extent possible" seek indemnification from insurance for STD services but shall not "request or require that such coverage or indemnification be utilized as a condition of providing" STD services. This provision allows the counties to bill a third party (usually Medicaid) for the Article 23-required STD services. Counties must seek third party coverage or indemnification if the patient provides evidence of insurance

coverage, but patients can always receive diagnosis and treatment as specified in Part 23 of the health regulations even if they do not provide such evidence.

Laws of 1972, Chapter 244 amended PHL section 2305 to clarify that STD treatment is to be provided not only for an STD "case" but also for any person "exposed to" any STD.

Needs and Benefits:

Changing the word "transmissible" to "transmitted" throughout will conform the regulation to the Public Health Law, as amended, and is consistent with current terminology. Allowing local health departments to provide services through contract, as opposed to only direct provision of these services, gives counties greater flexibility without reducing the level or quality of services provided. Allowing for third party reimbursement will reduce the costs for counties and for the State.

The provisions regarding minors will increase the number of minors who receive treatment for STDs and will prevent the spread of STDs. These provisions will also decrease the number of children who get cancer. National guidelines for adolescent clinical preventive care include immunizations as a key preventive service with a strong evidence basis for effectiveness and safety. Human Papilloma Virus (HPV) represents the first vaccine-preventable sexually transmitted disease with vaccination protecting adolescents from future morbidity and mortality, including from cancer, associated with HPV infection. Section 23.4 permits health care providers to prescribe and administer

HPV vaccine to sexually active minors during confidential sexual and reproductive health care visits without consent or knowledge of the parent or guardian.

HPV is the most common sexually transmitted virus accounting for 79 million infections nationally and 14 million new infections each year. Up to 70 percent of sexually active persons will acquire genital HPV infection at some point in their lives. On an annual basis, young people ages 15-24 who make up 25 percent of the sexually active population, account for 49 percent of new infections.

HPV vaccination prevents 70 percent of cervical cancers, other anogenital and oropharyngeal cancers and over 86 percent of non-cancerous anogenital warts caused by HPV infection. Since HPV vaccine introduction, vaccine-type HPV prevalence has decreased 56 percent among a nationally representative sample of 14-19 year olds in the vaccine era (2007-2010) compared with the pre-vaccine era. A separate study documented a 35 percent decrease in anogenital warts among females younger than 21. Post-licensure monitoring of the HPV vaccine shows that the vaccine continues to be safe and recent data indicates that one dose of vaccine provides 82 percent effectiveness against vaccine type infection.

Finally, contraindication for expedited partner therapy for chlamydia is noted for people who are co-infected with HIV in order to ensure that expedited partner therapy is only provided in appropriate cases consistent with current clinical guidelines.

Costs:

The amendments are intended to ease the cost to local health departments. For those local health departments that do implement a billing system, some may experience associated costs with implementation of the system, however it is anticipated that the ability to bill for rendered services will off-set any up front expense. It is estimated that any county that elects to implement an electronic billing system will incur an estimated cost of $5,000 - $10,000. Costs will vary depending on type of EMR (if used), staffing and whether or not LHDs can leverage existing billing systems for other public health programs. It is noted within the Regulation that the administrative burden of implementing a billing system should not cost the county more than the revenue to be generated by third party payer reimbursement and co-pay. The law only requires billing be pursued in cases where it is practicable.

Local Government Mandates:

Each board of health and local health officer shall ensure that diagnosis and treatment services are available and, to the greatest extent practicable, seek third party coverage or indemnification for such services; provided, however, that no board of health, local health officer, or other municipal officer or entity shall request or require that such coverage or indemnification be utilized as a condition of providing diagnosis or treatments services.

Paperwork:

This rule imposes no new reporting requirements. In order to manage billing operations, forms and paperwork may be necessary for individual local health departments to implement billing systems and contracts with vendors, if any.

Duplication:

There are no relevant rules or other legal requirements of the Federal or State governments that duplicate, overlap, or conflict with this rule.

Alternatives:

The regulations were developed with considerable input from the community, provider groups, and regulated parties, particularly local governments. Input was elicited from the New York State Association of County Health Officials on repeated occasions through in-person meetings as well as telephone conference calls. Existing practices of local health departments that support billing are acceptable. This includes local health departments contracting with local providers and utilizing the contractor's billing infrastructure. Further, the Regulation states that the administrative burden of implementing a billing system should not cost the county more than the revenue to be generated by third party payer reimbursement and co-pay. The law only requires billing be pursued in cases where it is practicable.

Federal Standards:

The rule does not exceed any minimum standards of the Federal government for the same or similar subject area.

Compliance Schedule:

The amendments will be effective upon publication of a Notice of Adoption in the New York State Register. The Department has continued to assist affected entities in compliance efforts.

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Regulatory Flexibility Analysis

for Small Businesses and Local Governments

Effect of Rule:

Modifications to 10 NYCRR Part 23 will impact the existing sixty two local governments. This includes fifty-seven local governments outside of New York City, and the New York City Department of Health and Mental Hygiene.

Compliance Requirements:

State and local public health programs have experienced reductions in discretionary funding for services. Billing public and commercial third party payers may offer LHD STD clinics additional revenue to support direct service delivery and offset budget gaps. However, Public Health Law section 2304 requires LHDs to seek reimbursement "to the greatest extent practicable." LHDs will need to evaluate the costs associated with the development, implementation and maintenance of billing infrastructure and determine if such costs will be offset by the revenue generated. Billing guidance issued by the New York State Department of Health can be found at http://www.health.ny.gov/diseases/communicable/std/docs/billing_guidance.pdf.

Professional Services:

Local governments may seek professional services to develop billing systems if such systems do not exist.

Compliance Costs:

Anticipated capital costs include those associated with the implementation of billing systems and contracts with vendors, if any, to implement and manage billing operations. These costs are anticipated be offset by the revenue generated through reimbursement by third party payers for the clinical services provided. It is estimated that any county that elects to implement an electronic billing system is looking at an estimated cost of $5,000 - $10,000. Costs will vary depending on type of EMR (if used), staffing and whether or not LHDs can leverage existing billing systems for other public health programs. At this time that the great majority of local health departments have some form of a billing system. More than half of local health departments currently contract to a local provider and report utilizing the contractor's billing infrastructure. The 2014 Article 6 State Aid Application included a question to local health departments regarding efforts being made to collect payments from third party payers such a Medicaid and private insurers. Thirty-nine or 68% of LHDs responded "Yes."

Additionally, it is noted within the Regulation that the administrative burden of implementing a billing system should not cost the county more than the revenue to be generated by third party payer reimbursement and co-pay. The law only requires billing be pursued in cases where it is practicable.

Economic and Technological Feasibility:

The New York State Department of Health provides technical assistance to impacted providers regarding economic and technological feasibility. The provision of technical

assistance provides the NYSDOH with the necessary evidence to seek and respond to identified economic issues and technological barriers to compliance with the Law.

Minimizing Adverse Impact:

These amendments are intended to ease the cost to local health departments. However, the administrative burden of implementing billing systems should not cost the county more than the revenue to be generated by third party payer reimbursement and co-pay. The law only requires billing be pursued in cases where it is practicable.

Small Business and Local Government Participation:

Local government had the opportunity to participate in the rule making process through (a) a series of workgroup meetings, (b) participation in regional meeting updates with New York State Association of County Health Officials, and (c) individual local government technical assistance provided by electronic mail, phone and in person as requested.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not necessary.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

Laws of 2013, Chapter 56 amended PHL section 2304 impacts local health departments including those located within rural and urban counties. The proposed regulations provides clarification for the provision of treatment and billing for rendered services.

Reporting, Recordkeeping and Other Compliance Requirements; and Professional Services:

This rule imposes no mandates upon entities in rural areas outside those entities noted within the law. Clarification is made for all counties may provide STD diagnosis and treatment not only directly but also "through contract." The Legislature removed the requirement that services must be provided "free" and, further, required municipalities to seek third party coverage (generally Medicaid) reimbursement for such services where appropriate. As amended, PHL section 2304 states that counties must "to the greatest extent possible" seek indemnification from insurance for STD services but shall not "request or require that such coverage or indemnification be utilized as a condition of providing" STD services. This provision allows the counties to bill a third party (usually Medicaid) for the Article 23-required STD services. Counties must seek third party coverage or indemnification if the patient provides evidence of insurance coverage, but patients can always receive diagnosis and treatment as specified in Part 23 of the health regulations even if they do not provide such evidence. Laws of 1972, Chapter 244

amended PHL section 2305 to clarify that STD treatment is to be provided not only for an STD "case" but also for any person "exposed to" any STD.

Costs:

The amendments are intended to ease the cost to local health departments. For those local health departments that do implement a billing system, some may experience associated costs with implementation of the system; however, it is anticipated that the ability to bill for rendered services will off-set any up front expense. It is estimated that any county that elects to implement an electronic billing system will incur an estimated cost of $5,000 - $10,000. Costs will vary depending on type of EMR (if used), staffing and whether or not LHDs can leverage existing billing systems for other public health programs. It is noted within the Regulation that the administrative burden of implementing a billing system should not cost the county more than the revenue to be generated by third party payer reimbursement and co-pay. The law only requires billing be pursued in cases where it is practicable.

Minimizing Adverse Impact:

These amendments are intended to ease the cost to local health departments. However, the administrative burden of implementing billing systems should not cost the county more than the revenue to be generated by third party payer reimbursement and co-pay. The law only requires billing be pursued in cases where it is practicable.

Rural Area Participation:

Rural area participation was available through (a) a series of workgroup meetings, (b) participation in regional meeting updates with New York State Association of County Health Officials, and (c) individual local government technical assistance provided by electronic mail, phone and in person as requested.

Statement in Lieu of

Job Impact Statement

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendment, that it will not have an adverse impact on jobs and employment opportunities.

Assessment of Public Comment

The public comment period for this regulation ended on January 11, 2016. The Department received a total of fourteen comments, which all expressed support of the proposed amendments to Part 23 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York. Comments were received from the New York City Department of Health and Mental Hygiene (NYCDOHMH), the New York Civil Liberties Union (NYCLU), Family Planning Advocates of New York State (FPA), ACT UP, Physicians for Reproductive Health, New York State Senator Liz Krugger, eight adolescent medicine providers, and the HPV Research Team at the Mount Sinai School of Medicine Adolescent Health Center. In addition, the Department received comments on specific aspects of the regulations which are summarized below, followed by the Department's response.

Comment #1

NYCDOHMH, NYCLU and FPA strongly supported the proposed rules regarding minors consent, in particular, with regard to HPV vaccination. However, each noted that language in the Regulatory Impact Statement specifying that "Section 23.4 permits health care providers to prescribe HPV vaccine to sexually active minors during a visit to diagnose and treat other STDs without the consent of knowledge of the parent or guardian" was inconsistent with the language and purpose of Public Health Law Section 2305. Each commenter requested that the Regulatory Impact Statement be amended to clarify that HPV vaccine may be provided to sexually active minors during

all confidential sexual and reproductive health care visits. Furthermore, the Regulatory Impact Statement states that health care providers may “prescribe” the HPV vaccine while the proposed language in 23.4 permits health care providers to “administer” the HPV vaccine. To avoid confusion among providers, they suggested that the language in the Regulatory Impact Statement be clarified to indicate that providers may both prescribe and administer.

Response:

The Department modified the Needs and Benefits section of the regulatory Impact Statement to state “Section 23.4 permits health care providers to prescribe and administer HPV vaccine to sexually active minors during confidential sexual and reproductive health care visits without consent or knowledge of the parent or guardian.”

Comment #2

Section 23.1 groups the list of sexually transmitted diseases that local health departments have responsibility for diagnosing and treating. The distinction between groups B, C and D is unclear since these diseases can be managed directly by the treatment facility or referred elsewhere for treatment. The recommendation is to consolidate the three groups or make the distinctions clearer.

Response:

In 2011, proposed revisions to Section 23.1 were adopted which established the four groups of STDs for purposes of diagnosis and treatment. No additional revisions are being proposed at this time. Section 23.1 presents the minimum requirements for public health clinics, and the groupings allow flexibility in managing those sexually transmitted diseases that may require the additional expertise available through a routine or urgent referral to manage more severe symptoms or sequelae.

For example, facilities may choose to treat those infections in Groups B and D either directly or through a prescription, but the referral option is only available for Group B. In Group B, Human Papilloma Virus and Herpes Simplex Virus infections may be severe and thus, require referral by the facility to another provider. In Group C, for example, pelvic inflammatory disease is a potentially severe infection with serious complications that may require inpatient therapy and management. As stated in Section 23.2(e), management may be by "immediate referral" which recognizes the severity of PID infection and the need for active referral to another provider. For those patients whose PID infection can be managed on an outpatient basis, the facility has the option to treat directly. In Group D, management of the infections does not include a referral option, as these conditions can be managed appropriately with readily available medications and, thus, the facility should be responsible for ensuring treatment of infected patients. Given these important differences in treatment requirements, the Department is maintaining Groups B, C and D as set forth in the current regulations.

Comment #3

There are references in provisions of Sections 23.2 and 23.3 to "STD clinical guidelines," "most recent treatment guidelines" and "appropriate examinations or tests." It is recommended that applicable sections of Part 23 be modified to refer to an evidence-based set of treatment guidelines.

Response:

The Department agrees that any guidelines required to be used by health departments should be based on scientific evidence and expert opinion. In response, the Department modified the applicable parts of Part 23 to consistently refer to the required use of evidence-based guidelines by health departments for sexually transmitted diseases.

Comment #4

The proposed rules permit local health departments to seek reimbursement for STD services but do not require patients to use insurance in order to receive services. It is recommended that the Department require facilities to clearly communicate their billing policies to patients so as to prevent any possibility of discouraging patients from accessing sexual health services. Communication channels should include print and digital advertisements, clinic brochures, and clinic staff-patient discussions during the clinic visit.

Response:

The Department recognizes the need to educate patients about health department billing practices and has already issued guidance to health departments, which includes messaging for websites and print material, as well as scripts for clinic staff communication with clients around billing. This guidance was disseminated to health departments in May 2014 and is posted on the Department's public website.

Comment #5

Younger adults who are covered by their parents' health insurance need the confidentiality provisions specified in Section 23.4. The comment includes a recommendation to further amend the language in Section 23.4 to state: "Neither medical nor billing records shall be released or in any manner be made available to the parent or guardian of younger people covered by their family health insurance without the patient's permission."

Response:

The first sentence of the proposed section 23.4 is intended to implement the provisions of Public Health Law § 17 that apply to patients under the age of 18. The Department agrees that there may be cases in which a young adult child or spouse of the policy holder does not want to disclose health information to the policy holder. However, the Department believes that existing confidentiality laws, including HIPAA, provide sufficient

confidentiality protection to adults. In addition, the provisions of Insurance Law § 2612 and 11 NYCRR Part 244, where applicable, prevent an explanation of benefits from being sent to the policy holder. The Department believes the first sentence of the proposed section 23.4 is appropriate, and the language remains unchanged in the adopted regulation.