

Sexually Transmitted Disease Reporting and Treatment Requirements

Effective date: 7/6/11

Pursuant to the authority vested in the Public Health and Health Planning Council by Public Health Law, Section 225 and the Commissioner of Health by Sections 206(1) and 2311 of the Public Health Law, Sections 2.10, 23.1, 23.2, 23.3 and 23.4 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State *Register*, to read as follows:

Section 2.10 is amended as follows:

Section 2.10 Reporting cases or suspected cases or outbreaks of communicable disease by physicians.

It shall be the duty of every physician to report to the city, county or district health officer, within whose jurisdiction such patient [is] resides, the full name, age and address of every person with a suspected or confirmed case of a communicable disease, any outbreak of communicable disease, any unusual disease or unusual disease outbreak and as otherwise authorized in section 2.1 of this Part, together with the name of the disease if known, and any additional information requested by the health officer in the course of an investigation pursuant to this Part, within 24 hours from the time the case is first seen by him, and such report shall be by telephone, facsimile transmission or other electronic communication if indicated, and shall also be made in writing, except that the written notice may be omitted with the approval of the State Commissioner of Health. [(a) Cases in State institutions and facilities licensed under article 28 of the Public Health Law.] When a case which is required to be reported under section 2.1 of this Part occurs in a State institution or a facility licensed under Article 28 of the Public

Health Law, the person in charge of the institution or facility shall report the case to the State Department of Health and to the city, county or district health officer, in whose jurisdiction such institution is located.

[(b) Cases of sexually transmitted diseases. Provided further that cases of gonorrhea, chlamydia trachomatis infection and syphilis shall be reported in writing, and that the patient's initials may be given in lieu of the patient's name. The physician shall keep a record of each case reported by initials and the corresponding name of the patient together with his address. The name and address of the patient shall be reported to the local or State health official to whom the attending physician is required to report such case, upon the special request of such official.]

Section 23.1 is amended as follows:

Section 23.1 List of sexually transmissible diseases.

The following [is a list] are groups of sexually transmissible diseases [(STD)] (STDs) and shall constitute the definition of sexually transmissible diseases for the purposes of this Part and

Section 2311 of the Public Health Law:

[Chlamydia trachomatis infection*

Gonorrhea*

Syphilis*

Non-gonococcal Urethritis (NGU)*

Non-gonococcal (mucopurulent) Cervicitis*

Trichomoniasis*

Genital Herpes Simplex*

PID Gonococcal/Non-gonococcal

Lymphogranuloma Venereum*

Chancroid*

Ano-genital warts

Granuloma Inguinale*

Yeast Vaginitis

Gardnerella Vaginitis

Pediulosis Pubis

Scabies

Treatment facilities referred to in section 23.2 of this part must provide diagnosis and treatment for those STD designated by.]

Group A

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

Ano-genital warts

Human Papilloma Virus (HPV)

Genital Herpes Simplex

Group C

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

Pelvic Inflammatory Disease (PID) Gonococcal/Non-gonococcal

Group D

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

Yeast (Candida) Vaginitis

Bacterial Vaginosis

Pediculosis Pubis

Scabies

Section 23.2 is amended as follows:

23.2 Treatment facilities.

Each health district shall provide adequate facilities[, without charge,] 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.

(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 [sexually transmissible diseases] 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 STD clinical guidelines and laboratory guidelines distributed by the New York State Department of Health.

(c) Any persons diagnosed as having [syphilis or gonorrhea, or those who have been exposed to syphilis or gonorrhea,] any of the STDs in Group A in section 23.1 of this Part shall be treated with appropriate medication in accordance with accepted medical procedures as described in the most recent treatment [schedule] guidelines distributed by the department [of health].

[(d) Because antiviral therapy is rapidly evolving, the choice of therapy for persons having herpes (hominis) infection shall be in accordance with established medical procedure as described in the STD clinical guidelines distributed by the New York State Department of Health.

(e) Any person diagnosed as having the other sexually transmissible diseases (Non-gonococcal Urethritis, Non-gonococcal (mucopurulent) Cervicitis, Trichomoniasis, Lymphogranuloma Venereum, Chancroid, and Granuloma Inguinale) designated for the purposes of this section shall be treated by means of a written prescription issued in accordance with accepted medical

procedure as described in the STD clinic guidelines distributed by the New York State Department of Health.]

(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. 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.

Section 23.3 is deleted:

[23.3 STD reporting.

(a) The reporting obligations of this section shall not affect the obligation to report individual cases of syphilis and gonorrhea imposed by section 2.10(b) of this Chapter.

(b) Cases of STD diagnosed in public health clinics operated by, and for, a health district must be reported by mail to the New York State Department of Health, Empire State Plaza, Tower Building, Albany, N.Y. 12237, by the 15th of the month following the month in which the case is diagnosed. Such reports shall be made on a standard form provided by the Department of Health.

(c) Cases of STD diagnosed by health providers other than those specified in subdivision (b) of this section may be tabulated and reported as described in that subdivision.]

Section 23.4 is renumbered as section 23.3, and a new Section 23.3 is added as follows:

[23.4] 23.3 Cases treated by other providers.

(a) Every physician, 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, 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 the 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 for the detection of sexually transmissible diseases.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Sections 225(4) and 225(5) (a), (h), and (i) of the Public Health Law (PHL) authorize the Public Health and Health Planning Council to establish and amend State Sanitary Code provisions relating to the designation of communicable diseases dangerous to public health, and the nature of information required to be furnished by physicians in each case of communicable disease. PHL Section 206(1) (d) authorizes the commissioner to “investigate the causes of disease, epidemics, the sources of mortality, and the effect of localities, employments and other conditions, upon the public health.” PHL Section 206(1) (e) permits the commissioner to “obtain, collect and preserve such information relating to marriage, birth, mortality, disease and health as may be useful in the discharge of his duties or may contribute to the promotion of health or the security of life in the state. . .”

Article 23 of the PHL provides the authority for the control of sexually transmissible diseases (STDs) by local health officers. Section 2304 outlines the responsibility of each board of health of a health district “to provide adequate facilities for the free diagnosis and treatment of persons living within its jurisdiction who are suspected of being infected or are infected with” an STD; that the health officer “shall administer these facilities and shall promptly examine or arrange for the examination of persons suspected of being infected...”; and that these facilities “shall comply with the requirements of the commissioner” of the New York State Department of Health (NYSDOH).

Section 2.10 of the State Sanitary Code codified in Title 10 (Health) of the Codes, Rules, and Regulations of the State of New York requires the reporting of cases or suspected cases or outbreaks of communicable disease, including chancroid, chlamydia, gonorrhea,

lymphogranuloma venereum, hepatitis B virus and syphilis, as outlined in Section 2.1, by physicians.

The part of the State Sanitary Code codified in Sections 23.1 through 23.4 of Title 10 outlines the list of STDs, the rules for the examination by the health department of persons infected or suspected of being infected with STD; the reporting obligations for STD, and the requirement that either physicians or clinics providing gynecological, obstetrical, genito-urinary, contraceptive, sterilization, or termination of pregnancy shall offer every patient appropriate examination or tests for STD.

Legislative Objectives:

The following are proposed changes to Sections 2.10, 23.1, 23.2, 23.3 and 23.4 that deal with the reporting of cases or suspected cases or outbreaks of communicable disease by physicians, list of sexually transmitted diseases, treatment facilities, and STD reporting. These regulations meet the legislative objective of protecting the public health by removing archaic language, which requires the filing of written reports. In addition, language allowing reporting using patient's initials is equally archaic and is being removed. HIPAA regulations (45 CFR Parts 160 and 164) as well as other confidentiality protections currently make reporting by initials unnecessary. Further, the proposed legislation updates the list and the terminology used for conditions in Section 23.1 designated as requiring free diagnosis and treatment in Section 23.2 (c): specifically chlamydia, gonorrhea, syphilis, non-gonococcal urethritis, mucopurulent cervicitis, trichomoniasis, lymphogranuloma venereum, chancroid and granuloma Inguinale.

The syndromal condition, pelvic inflammatory disease (PID) is being added to the list of STDs requiring free diagnosis, but free on-site treatment is not required for PID. The NYSDOH

will promulgate diagnostic criteria for PID. Outpatient treatment may be offered by local health department STD clinics or a managed referral to another health care provider should take place. Local health departments should be able to confirm the follow-up of PID patients if requested by the NYSDOH. Confirmation includes facilitating the referral to another medical provider, ensuring that the patient attended the referral appointment, and verifying that treatment was provided. Facilities described in Section 23.2 (local health department clinics) must provide treatment for genital herpes simplex, ano-genital warts, and human papilloma virus on-site or by means of a written or electronic prescription or by referral to another provider. Yeast (candida) vaginitis, bacterial vaginosis, pediculosis pubis and scabies may be treated on site by the Section 23.2 facility or by means of a written or electronic prescription.

The proposed changes are consistent with the current guidance from the Centers for Disease Control and Prevention (CDC) as to what conditions constitute sexually transmitted diseases. The changes also clarify disease reporting requirements for medical providers and medical management requirements for local health departments.

Needs and Benefits:

A. Background

Proposed changes to Section 23.1 clarify and update the official list of STDs in NYS including NYC based on current medical technology and understanding. Proposed changes to Sections 23.1 and 23.2 also clarify and simplify local health department service responsibilities relating to STD control.

The CDC's Program Operations Guidelines for STD Prevention states "Medical services at the public STD clinic should be low or no cost, confidential, and convenient to avoid creation

of barriers between the patient and the accessibility of services.” Recommendations regarding the range of services include at a minimum that clinics should have the capacity to: accurately diagnose and treat bacterial STDs and to distribute medications for diseases diagnosed in the clinic. Medications “must be available for locally prevalent STDs, with prescriptions available for diagnosed diseases not prevalent in the community.” The proposed regulations are consistent with these federal guidelines.

Modification of the treatment requirements for pelvic inflammatory disease in Section 23.2(e) will permit the local health department to either treat the patient on site free of charge OR immediately refer the individual for out-patient management to another medical facility.

The list of conditions in Sections 23.2 (d) and 23.2 (f) designated as requiring free diagnosis, permits the local health department to either treat the patient on site free of charge OR to treat with either prescription or referral. This list includes: genital herpes, ano-genital warts, human papilloma virus, yeast (candida) vaginitis, bacterial vaginosis, pediculosis pubis, and scabies. For genital herpes, free diagnosis would not include a requirement for providing antibody serologic testing as this is not considered a diagnostic test for acute or recurrent infection, but rather a screening test for past exposure that is useful for counseling purposes. Language relating to therapy for herpes infection is being updated since the preferred therapy is now firmly established. Section 23.2 facilities will have a choice of providing on-site treatment for herpes or providing a prescription.

If the local health department selects to treat with either prescription or referral for conditions listed in 23.2(d) or (f), or chooses the referral option for conditions listed in 23.2(e), they are absolved of the cost for treatment and will not be responsible for any residual costs of treatment that are not covered by the patient or insurance carriers.

In addition, for the purpose of these regulations, the cervical Papanicolaou (Pap) test, while an indirect indicator of human papilloma virus infection, is a screening test for cervical cancer rather than an STD. Thus, local health departments would not be required to offer cervical Pap tests free of charge. These changes are recommended based on the positive fiscal impact they will have on the local health department's provision of STD clinical services.

Section 23.3 has been eliminated since it is inconsistent with the reporting requirements of communicable diseases as written in Section 2.10. In addition, laboratories currently report test results electronically to the health departments. The counties are required to complete a case investigation and report morbidity to the state using the Communicable Disease Electronic Surveillance System (CDESS) or an alternative reporting mechanism approved by the State Commissioner of Health.

COSTS:

Costs to Regulated Parties:

The deletion of Sections 2.10(b) and 23.3 updates the Sanitary Code to reflect accepted practice, reporting by name only. There will be no increased costs to physicians as a result of this change.

Costs to Local and State Governments:

There would be no increased costs incurred from the changes to Part 23 to local health department facilities. Changes in the official list of STDs will have minimal cost impact on local health departments as most have already adopted the updated STD nomenclature. Clearly identifying those STDs that must be diagnosed and treated on site at local health departments,

diseases diagnosed and referred for treatment, and diseases treated by prescription, will clarify vagaries of the regulations as currently written. These clarifications have been requested by local health department officials.

Local health departments are already required to provide free diagnosis of all the listed STD conditions. In fact, the proposed changes would actually serve to lessen the burden of costs to local health departments associated with the treatment of some selected conditions by permitting either referral or use of a written or electronic prescription. In addition, the local health departments may realize some increased revenues by having the ability to bill third parties for selected screening services which are considered “non-diagnostic” tests for the purposes of this section (i.e., herpes simplex antibody serology), a practice which is currently permitted for HIV antibody serologic testing.

Increased costs for services under Public Health Law section 602(3)(b) - disease control and 10 NYCRR sections 40-2.80 and 2.81 are expected to be negligible, in the \$25,000 - \$50,000 annual range statewide, as county health departments already have the diagnostic capability required in the proposed changes. Treatment costs are expected to remain stable since the medications recommended are inexpensive and more conditions can now be treated through prescription. In addition, clarifying which STDs can be treated by prescription or by referral may reduce overall costs thereby potentially lessening Article 6 costs to the state.

Costs to the Department of Health:

There would be no increased costs to the Department of Health as a result of these regulatory changes. The infrastructure of the state DOH to manage the proposed changes is in place. Medicaid costs for STDs are typically associated with care for complications of untreated

disease. The proposed changes should decrease Medicaid costs by encouraging patients to visit local health departments for free diagnosis and treatment, thereby reducing complications which would normally require hospitalization. The Department of Health will maintain its commitment to assist counties with disease intervention activities including interviewing patients and partner notification.

Paperwork:

There will be no new paperwork associated with these changes. The proposed changes will result in decreased paperwork since written reporting is no longer required.

Local Government Mandates:

There are no new mandates associated with these regulatory changes. Current mandates are clarified, simplified, and worded in such a way as to eliminate additional financial burden on local governments.

Duplication:

There is no duplication of these regulatory changes in existing State or federal law.

Alternatives:

The Department considered no action to update these regulations, but determined that the proposed revisions would be more prudent.

The deletion of Section 2.10(b) and Section 23.3 removes archaic language in order to make the regulations consistent with current reporting practices.

The proposed changes to Part 23 clarify existing responsibilities of the local health department in providing diagnostic and treatment services for STD. Variations in the nomenclature of STDs and the diagnosis and treatment requirements reflect the most recent Program Operations Guidelines promulgated by CDC. For the most part, these changes are in place in local health departments and clarify vague language that has previously existed.

Federal Standards:

The proposed regulations are consistent with federal guidelines. The regulatory changes recommended are consistent with federal standards as promulgated in the CDC Program Operations Guidelines.

Compliance Schedule:

Compliance with these revisions of the Sanitary Code will be mandated upon filing of a Notice of Adoption of this regulation in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

The regulatory changes apply to reporting of STD by health care providers and to the responsibilities of local health departments in providing clinical services for the diagnosis and treatment of persons with STD or suspected STD infection within their jurisdiction. There will be no effect on small businesses since the reporting language changes are designed to reflect what is currently existing practice. Local governments with health departments that directly provide or contract for the provision of STD clinical services have always been required to provide free diagnosis and treatment of STDs. The proposed revisions clarify what constitutes a sexually transmitted disease and when alternatives to treatment such as referral and prescription can be used. This may result in a decrease of treatment costs for several STDs. These recommended changes will affect local health departments.

Compliance Requirements:

There are no new compliance requirements associated with these proposed changes.

Professional Services:

No additional professional services will be required. The local health departments are currently reporting using the Communicable Disease Electronic Surveillance System (CDESS) or an alternative reporting mechanism approved by the State Commissioner of Health. Any additional needed training (i.e. CDESS updates) will be offered by the New York State Department of Health.

Compliance Costs:

No additional costs will be incurred as a result of these revisions to the Sanitary Code. Due to rising costs and decreased revenues, local health departments are struggling to maintain services as required by the Public Health Law and Sanitary Code. These proposed revisions should actually lessen the burden of costs associated with treatment for some conditions by allowing the use of prescriptions to meet the “treatment” requirement.

Minimizing Adverse Impact:

There will be no adverse impacts on reporting or clinical services as a result of these changes. The changes will likely enhance screening and have the potential for actually enhancing the scope of services for county residents who receive STD care through local health departments.

Feasibility Assessment:

There will be no increased workload associated with these revisions.

Small Business and Local Government Participation:

Local governments have been consulted in the process through communication with local health departments and the New York State Association of County Health Officers. Individually and collectively, local health departments support all of these changes and many have provided letters to the Department attesting to their support.

RURAL AREA FLEXIBILITY ANALYSIS

Effect on Rural Areas:

The proposed regulatory changes will apply statewide and will affect reporting of STD by health care providers in the same manner across the state. The effect on rural health departments in the provision of services for the diagnosis and treatment of persons with STD or suspected STD infection within their jurisdiction will also be similar to the rest of the state. Analysis of STD data statewide shows that rural areas do not have a disproportionate number of STD cases.

Compliance Requirements:

There are no new compliance requirements associated with these proposed changes.

Professional Services:

No additional professional services will be required. Any additional needed training on reporting will be provided by the New York State Department of Health in multi-county meetings or on an individual basis as necessary or as requested. Clinical training will be made available by the Montefiore Medical Center STD Center for Excellence, a contractor for the Bureau of STD Prevention and Epidemiology.

Compliance Costs:

No additional costs will be incurred as a result of these revisions to the Sanitary Code.

Due to rising costs and decreased revenues, local health departments are struggling to maintain services as required by the Public Health Law and Sanitary Code. These proposed

revisions should actually lessen the burden of costs associated with treatment for some conditions by allowing the use of prescriptions to meet the “treatment” requirement.

Minimizing Adverse Impact:

There will be no adverse impacts on reporting or clinical services as a result of these changes. The changes will likely enhance screening and have the potential for actually enhancing the scope of services for county residents who receive STD care through the local health department.

Feasibility Assessment:

There will be no increased workload associated with these revisions.

Rural Area Participation:

Local governments have been consulted in the process through communication with local health departments and the New York State Association of County Health Officers.

JOB IMPACT STATEMENT

The proposed regulatory change will not increase demands on existing staff nor increase the need to hire additional staff for providers or local health departments. The NYSDOH has determined that this regulatory change will not have a substantial adverse impact on jobs and employment.

Assessment of Public Comment

The New York State Department of Health (DOH) received comments from the New York City Department of Health and Mental Hygiene on the proposed amendments to Part 23 of Title 10 of the New York Code, Rules and Regulations. A summary of each comment is provided followed by the DOH response.

Comment #1:

The regulation states that local health facility clinics may refer patients with the STDs in Groups B and D to another provider for treatment; such facilities may also treat those patients with STDs in Group C by prescription. We are seeking clarification on the local health department facility's responsibility for paying for treatment under these circumstances, as the regulation does not clearly identify such responsibility.

Response:

The Needs and Benefits section of the Regulatory Impact Statement specifically states "If the local health department selects to treat with either prescription or referral for conditions listed in 23.2(d) or (f), or chooses the referral option for conditions listed in 23.2 (e), they are absolved of the cost for treatment and will not be responsible for residual costs of treatment that are not covered by the patient or insurance carriers."

Comment #2:

The regulation states in Section 23.2 (d), (e) and (f), “If treatment is provided directly, it must be provided free of charge.” We recommend that the regulation be clarified to specify that “a local health department clinic” is responsible for providing free treatment.

Response:

DOH agrees and proposes to amend the language in Section 23.2 (d), (e), and (f) to read “in the treatment facility referred to in this section” in order to specifically assign such responsibility to the treatment facilities defined in Section 23.2.

Comment #3:

The proposed changes to section 23.1 are intended to clarify and update the official reportable STDs in New York State, including New York City. The title of this section is list of sexually transmitted diseases. Public Health Law Section 2311 provides that the Commissioner of DOH shall promulgate a list of sexually transmitted diseases for the purposes of Article 23 of the Public Health Law. We recommend that the opening sentence of this section be amended to also reference PHL § 2311 as follows “The following are groups of sexually transmitted diseases (STDs) and shall constitute the definition of sexually transmitted diseases for the purposes of this Part and § 2311 of the Public Health Law:”

Response:

DOH agrees with the proposed amendment and has revised the language in § 23.1 as suggested by the commenter.

Comment # 4:

The references to Part 23.2 should be amended to ‘Section 23.2’ throughout the document.

Response:

The language has been updated to accurately reflect the titling of the subparts.

Comment #5:

The regulatory language in § 23.2 (e) and the regulatory impact statement are in conflict with respect to requirements for managed referral of patients diagnosed with pelvic inflammatory disease and should be reconciled. The regulatory impact statement mandates follow up by local health department facilities of persons with PID who have been referred to another provider for care when the language in § 23.2 (e) promotes but does not require such managed referral by health departments. The regulatory impact statement cannot impose requirements when such language is not included in the regulation itself.

Response:

DOH proposes to amend the language in the Legislative Objectives of the Regulatory Impact Statement to encourage rather than require health department STD clinics to follow patients diagnosed with PID by replacing ‘must’ with ‘should’. Federal recommendations stress early administration of appropriate therapy for PID in order to prevent long-term sequelae.

Consequently, health departments are still strongly encouraged to ensure that patients who are referred for care and treatment maintain follow up appointment(s) with the referral provider as a best practice.

Comment #6:

The Needs and Benefits section of the Regulatory Impact Statement states that the counties are required to complete a case investigation and report morbidity to the State using the Communicable Disease Electronic Surveillance System (CDESS). In addition, the Regulatory Flexibility Analysis states that one hundred percent of local health departments are currently using CDESS. It should be noted that New York City does not use CDESS for reporting but has established an alternative system for providing the State with line-listed STD morbidity. The language in these sections needs to be reconciled to reflect this difference.

Response:

DOH proposes to amend the appropriate references in both the Needs and Benefits section of the Regulatory Impact Statement as well as the Professional Services section of the Regulatory Flexibility Analysis section to clarify that local health departments use CDESS “or an alternative reporting mechanism approved by the State Health Commissioner.”

Comment #7:

The Regulatory Impact Statement indicates that local health departments may realize some increased revenues by having the ability to bill third parties for selected screening services which are non-diagnostic including Pap smears. The Department seeks clarification as to how this proposal impacting Pap smears relates to DOH regulations regarding Ambulatory Payment Groups (APGs) in 10 NYCRR Subpart 86-8. Specifically, Pap smears would be ineligible for reimbursement under the APG regulation when they are the only reason for a visit as a Pap smear is not a carve-out under APG. We believe the proposed regulatory amendment should be

reconciled to permit reimbursement for Pap smears on a fee-for-service basis when provided by the health department.

Response:

Separate regulations have been established for APGs and amendments to those regulations, or associated policy, would be necessary to achieve an APG carve out for Pap smears rather than changes to Part 23.

DOH proposes to revise the Costs to Local and State Governments section of the Regulatory Impact Statement to remove Pap smears as an example of a non-diagnostic test for which local health departments may obtain reimbursement.

Comment #8:

It is recommended that the statement in the Legislative Objectives section of the Regulatory Impact Statement, which reads “but free treatment is not required for PID” should be changed to “but direct on-site treatment is not required for PID” to align with the regulatory language in § 23.2 (e).

Response:

DOH agrees and proposes to modify the language in the Legislative Objectives section to reflect the proposed revision.