HIV/AIDS Testing, Reporting and Confidentiality of HIV Related Information

Effective date: 2/22/12

SUMMARY OF EXPRESS TERMS

Effective September 1, 2010, Chapter 308 of the Laws of 2010 authorized significant changes in HIV testing in New York State. This law was enacted to increase HIV testing in the State and promote HIV-positive persons entering into treatment. Implementing this legislation is critical, since approximately 20 percent of HIV-positive New Yorkers are unaware of their infection status and 33 percent of persons newly identified with HIV are diagnosed with AIDS within one year.

Key provisions of the legislation and the proposed regulatory changes include:

- HIV testing must be offered to all persons between the ages of 13 and 64 receiving hospital or primary care services, with limited exceptions noted in the law. The offering must be made to inpatients; persons seeking services in emergency departments; persons receiving primary care as an outpatient at a clinic; or from a physician, physician assistant, nurse practitioner or midwife.

- Standardized model forms for obtaining informed consent and providing for disclosure will be developed by the New York State Department of Health and posted on the Department website.

- Consent for HIV testing can be part of a general durable consent to medical care, though specific opt out language for HIV testing must be included.
- Consent for rapid HIV testing can be oral and noted in the medical record, except within correctional facilities.

- Prior to being asked to consent to HIV testing, patients must be provided the seven points of information about HIV required by the Public Health Law.

- Health care and other HIV test providers authorizing HIV testing must arrange an appointment for medical care for persons confirmed positive.

- HIV test requisition forms submitted to laboratories will be simplified.

- Deceased, comatose or persons otherwise incapable of providing consent, and who are the source of an occupational exposure, may now be tested for HIV in certain circumstances without consent.

- Confidential HIV information may be released without a written statement prohibiting re-disclosure when disclosures are made to treating providers or to health insurers to obtain payment.

Pursuant to the authority vested in the Commissioner of Health by section 2786 and 2139 of the Public Health Law of the Law, Part 63 of Title 10 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:

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Section 63.1 Definitions

(a) "HIV-infection" means infection with the human immunodeficiency viruses that are the cause of AIDS or as the term may be defined from time to time by the Centers for Disease Control and Prevention of the United States Public Health Service.

(b) "AIDS" means acquired immune deficiency syndrome, as may be defined from time to time by the Centers for Disease Control and Prevention of the United States Public Health Service.

(c) "HIV-related illness" means any clinical illness that may result from or be associated with HIV infection.

(d) "HIV-related test or HIV-related testing" means any laboratory test, tests or series of tests [for any virus, antibody, antigen or etiologic agent whatsoever, thought to cause or to indicate the presence of HIV infection, HIV-related illness or AIDS] approved for the diagnosis of HIV.

(e) "Rapid HIV test or testing" means any HIV-related test or tests approved for detecting antibodies or antigens to HIV, that produce results in sixty minutes or less, and encompasses a supplemental test to confirm the HIV-related test if the screening test is

reactive. The sixty minutes does not include the time needed for confirmation or delivery of results to the patient.

(f) "Capacity to consent" means an individual's ability, determined without regard to the individual's age, to understand and appreciate the nature and consequences of a proposed health care service, treatment, or procedure, or of a proposed disclosure of confidential HIV-related information, and to make an informed decision concerning the service, treatment, procedure or disclosure.

[(f)] (g) "Protected individual" means a person who is the subject of an HIV-related test or who has been diagnosed as having HIV infection, AIDS or HIV-related illness.

[(g)] (h) "Confidential HIV-related information" means any information, in the possession of a person who provides health or social services or who obtains the information pursuant to a release of confidential HIV-related information, concerning whether an individual has been the subject of an HIV-related test, or has HIV infection, HIV-related illness or AIDS, or information which identifies or reasonably could identify an individual as having one or more of such conditions, including information pertaining to such individual's contacts.

[(h)] (i) "Health or social service" means any care, treatment, clinical laboratory test, counseling or educational service for adults or children, and acute, chronic, custodial, residential, outpatient, home or other health care; public assistance, including disability payments available pursuant to the Social Security Act; employment-related services, housing services, foster care, shelter, protective services, day care, or preventive services; services for the mentally disabled; probation services; parole services; correctional services; detention and rehabilitative services; and the activities of the Health Care

Worker HIV/HBV Advisory Panel (see Public Health Law Article 27-DD), all as defined in section 2780(8) of the Public Health Law.

[(i)] (j) "Health facility" means a hospital as defined in section 2801 of the Public Health Law, blood bank, organ procurement organization, tissue bank, clinical laboratory, or facility providing care or treatment to persons with a mental disability.

[(j)] (k) "Health care provider" or "provider" means any physician, nurse, licensed or certified provider of diagnostic medical services, including a nurse practitioner, a midwife and physician assistant, provider of services for the mentally disabled or other person involved in providing medical, nursing, counseling, or other health care or mental health service, including those associated with, or under contract to, a health maintenance organization or medical services plan. Diagnostic providers include physicians, nurse practitioners, physician assistants and midwives who are authorized to order diagnostic tests and to make clinical diagnoses.

(l) “Primary care” means the medical fields of family medicine, general pediatrics, primary care, internal medicine, primary care obstetrics, or primary care gynecology, without regard to board certification or setting where primary care is provided.

[(k)] (m) "Contact" means an identified spouse or sexual contact of the protected individual or a person identified as having shared hypodermic needles or syringes with the protected individual, or a person whom the protected individual may have exposed to HIV under circumstances that present a risk of transmission of HIV, as noted in section 63.8(m) of this Part.

[(l)] (n) "Contact tracing" shall mean the process of notifying known contacts of protected individuals as reported by the physician or as disclosed by the protected

individuals themselves, and of seeking the cooperation of protected individuals to name contacts, as described in section 63.8 of this Part. For the purposes of this Part, the terms "contact notification", "partner notification", "partner assistance" and "partner counseling and referral services" shall be synonymous with "contact tracing". In all cases of contact tracing authorized in this Part, the name [of] or other identifying information regarding the protected person shall not be disclosed to contacts and the name of contacts shall not be disclosed to other contacts.

[(m)] (o) "Person" includes any natural person, partnership, association, joint venture, trust, public or private corporation or state or local government agency.

[(n)] (p) "Release of confidential HIV-related information" means a written authorization for disclosure of confidential HIV-related information which is signed by the protected individual, or if the protected individual lacks capacity to consent, a person authorized pursuant to law to consent to health care for the individual. Such release shall be dated and shall specify to whom disclosure is authorized, the purpose for such disclosure and the time period during which the release is to be effective. A general authorization for the release of medical or other information shall not be construed as a release of confidential HIV-related information, unless such authorization specifically indicates its dual purpose as a general authorization and an authorization for the release of confidential HIV-related information and complies with this definition.

[(o)] (q) "Insurance institution" means any corporation, association, partnership, reciprocal exchange, interinsurer, fraternal benefits society, agent, broker or other entity in the business of providing health, life and disability coverage including, but not limited to, any health maintenance organization, medical service plan, or hospital plan which:

(1) is engaged in the business of insurance;

(2) provides health services coverage plans; or

(3) provides benefits under, administers, or provides services for, an employee welfare benefit as defined in 29 U.S.C. 1002(1).

[(p)] (r) "Municipal health commissioner" shall mean, for purposes of this Part, a county health commissioner, except, in New York City, the term shall mean the New York City health commissioner. Such county health commissioner and New York City health commissioner shall conduct reporting, counseling and contact notification activities consistent with guidelines acceptable to the commissioner in compliance with Article 21, Title III and Article 27-F of the Public Health Law.

[(q)] (s) "District health officer" shall mean, for the purposes of this Part, the commissioner or his/her designee.

[(r)] (t) For the purposes of this Part, "commissioner" shall mean the New York State Commissioner of Health.

[(s)] (u) For the purposes of this Part, "authorized public health official" shall mean New York State Commissioner of Health, a municipal health commissioner or a district health officer, or their designee.

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Section 63.3 HIV-related testing.

(a) Except as noted in [paragraph (b)(2)] subdivision (d) of this section, no physician or other person authorized pursuant to law may order an HIV-related test without first [obtaining] having obtained written or, where authorized by this section, oral informed

consent. When the test being ordered is a rapid HIV test, such informed consent may be obtained orally, and shall be documented in the subject of the test's record including where a confirmatory test was performed. Oral consent cannot be obtained in facilities operated under the Correction Law. A physician or other person authorized pursuant to law to order an HIV-related test to be used for patient care shall provide to the laboratory the name and address of the person who is the source of the specimen and other such information as specified by the commissioner except in the case of anonymous testing as provided for in this Part. Certification of consent does not have to be provided to the laboratory.

[(1)] (b) Informed consent shall include providing [pre-test counseling] information to the person to be tested or, if such person lacks capacity to consent, to the person lawfully authorized to consent to health care for such person. In situations in which a person other than the test subject consents for the test, [pretest counseling] information shall also be provided to the test subject to the extent that the person responsible for ordering the test deems that the test subject will benefit from [counseling] the information. [Pretest counseling] Information necessary to obtain informed consent may be provided through electronic, written or oral means and shall include:

[(i) explanations regarding the nature of HIV infection and HIV-related illness, an explanation of the HIV-related test, including a description of the procedure to be followed, meaning of the test results, including preliminary positive results obtained prior to confirmation, if applicable, and the benefits of taking the test, including the importance and benefits of early diagnosis and medical intervention] (1) HIV causes AIDS and can

be transmitted through sexual activities and by needle-sharing, by pregnant women to their fetuses, and through breastfeeding infants;

[(ii) an explanation that discrimination problems may result from disclosure of confidential HIV-related information and that legal protections exist which prohibit discrimination (NYC and NYS Human Rights Law) and unauthorized disclosures (PHL article 27-F and/or article 21, Title III)] (2) there is treatment for HIV that can help an individual stay healthy;

[(iii) information on preventing exposure or transmission of HIV infection, including behavior which poses a risk of HIV transmission] (3) individuals with HIV or AIDS can adopt safe practices to protect infected and uninfected people in their lives from becoming infected or multiply infected with HIV;

[(iv) an explanation that the test is voluntary, that consent may be withdrawn at any time, information on the benefits of testing and of early treatment, information that HIV reporting is required by law and that such information must be kept confidential and will be used for the purposes of epidemiologic monitoring of the HIV/AIDS epidemic, that persons who test positive will be requested to cooperate in contact notification efforts, that known contacts will be reported by the physician or other person authorized to order a diagnostic test to the health department for the purposes of contact notification as needed, that anonymous testing is available, including the location and telephone numbers of anonymous test sites, and that for the purpose of insurance coverage, confidential, as opposed to anonymous testing is required; and] (4) testing is voluntary and can be done anonymously at a public testing center;

[(v) information regarding psychological and emotional consequences of receiving the test result] (5) the law protects the confidentiality of HIV-related test results;

(6) the law prohibits discrimination based on an individual's HIV status and services are available to help with such consequences; and

(7) the law allows an individual's informed consent for HIV-related testing to be valid for such testing until such consent is revoked by the subject of the HIV test or expires by its terms.

[(b)(1) Written informed consent must be executed on a form developed by the department or on another form approved specifically by the department. At the time at which informed consent is obtained, the subject must be offered a copy of the informed consent form or a document that provides all pertinent information contained on the informed consent form] (c) In situations where written consent is being obtained, it must be executed on a form that contains information consistent with standardized model forms approved by the department. Such forms based on department models do not require departmental review. General consent forms for medical care may be used to obtain consent, provided that they include information consistent with the state's model forms and a clearly marked place adjacent to the signature where the subject of the HIV-related test, or when the subject lacks the capacity to consent, a person authorized pursuant to law to consent to the health care for such individual, shall be given an opportunity to decline in writing such testing. Consent may be for a single test, for a period of time determined by the subject of the test, or be open-ended, so long as the subject of the test may revoke consent for future tests at any time. Each additional time that an HIV test is being ordered, the physician or other person authorized to order an

HIV test shall orally notify the subject of the test or, if the subject is not able to consent, the person authorized to consent for the subject that the test will be conducted and this notification will be noted in the subject's medical record.

[(2)] (d) Informed consent is not required in the following situations:

[(i)] (1) for court-ordered testing pursuant to Civil Practice Law and Rules, section 3121;

[(ii)] (2) when testing without informed consent is otherwise specifically authorized or required by State or Federal law, including under Public Health Law section 2994-g;

[(iii)] (3) for testing related to procuring, processing, distributing or use of a human body or human body part, including organs, tissues, eyes, bones, arteries, blood, semen or other body fluids for use in medical education, medical research or therapy, or for transplantation to persons, provided that if the test results are communicated to the tested person, post-test [counseling] information for negative results or counseling for positive, indeterminate/inconclusive and preliminary positive results is required;

[(iv)] (4) for research if the testing is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher;

[(v)] (5) for testing of a deceased person to determine cause of death or for epidemiological purposes; [and]

[(vi)] (6) for comprehensive newborn testing pursuant to PHL section 2500-f; and

(7) for anonymous testing of a person who is the source of an occupational exposure under Section 63.8(n) of this Part, who is deceased, comatose, or otherwise unable to provide consent, and no person authorized to consent on behalf of the source patient is immediately available, as provided in Public Health Law section 2781(6)(e).

[(c) A physician or other person authorized pursuant to law to order an HIV-related test shall certify on a laboratory requisition form that informed consent has been obtained, except when not required pursuant to paragraph (b)(2) of this section. In approved anonymous testing sites, authorized employees or agents of the department, may order HIV-related tests and certify that they obtained informed consent in approved anonymous testing sites.

(d) In addition to an explanation of the test result, the person who orders the test shall be responsible for ensuring that post-test counseling or referrals as appropriate with]

(e) With respect to [a] positive[,] and indeterminate/inconclusive results, [negative test result] and for preliminary positive results obtained pursuant to Subpart 58-8 of this Title, [if applicable, shall be provided to the person who consented to the test] in addition to explaining the test result to the person who consented to the test, the person who orders the test shall be responsible, directly or through a representative, for ensuring post-test counseling, referrals and linkage to care as appropriate. Blood banks and tissue banks may report results as specified in [sections] Subparts 58-2[.23] and 52-3[.6] of this Title, respectively. When confirmed positive results are being provided, with the consent of a person who tests positive, or if such person lacks the capacity to consent, with the consent of the person authorized to consent to health care for such person, the person ordering the test or his or her representative shall provide or arrange for an appointment for follow-up care for HIV. In situations in which a person other than the test subject consents for the test, results, post-test counseling and referrals should also be provided to the test subject, to the extent the person responsible for ordering the test deems that the test subject will benefit from counseling. [Such post-test counseling and referrals shall

include specific referral information and] For persons who test positive, post-test counseling shall address:

(1) [(i)] strategies for coping emotionally with the test results;

[(ii)] (2) discrimination issues relating to employment, housing, public accommodations, health care and social services;

[(iii) information on the ability to release or revoke the release of confidential HIV-related information; and] (3) the importance of taking precautions to prevent HIV transmission to others;

[(iv)] (4) the ability to release or revoke the release of confidential HIV-related information [on preventing exposure to or transmission of HIV infection and the availability of medical treatment];

[(2) for persons who test positive, post test counseling shall, in addition, address:]

[(i) that] (5) HIV reporting [is required by law] requirements for the purposes of epidemiologic monitoring of the HIV/AIDS epidemic;

[(ii) that] (6) the importance of contacts' [should be] being notified to prevent transmission, and [to allow] allowing early access of exposed persons to HIV [counseling and] testing, health care, and prevention services, and a description of notification options and assistance available to the protected individual;

[(iii)] (7) an assessment of the risk of domestic violence in conformance with a domestic violence screening protocol developed by the commissioner pursuant to law;

[(iv)] (8) the requirement that known contacts, including a known spouse, will be reported and that protected persons will also be requested to cooperate in contact

notification efforts of known contacts and may name additional contacts they wish to have notified with the assistance of the provider or authorized public health officials;

[(v) that] (9) non-disclosure of the protected individual's name or other information about them [is not disclosed to any person] during the contact notification process;

(10) the provider's responsibility for making an appointment for newly diagnosed persons to receive follow-up HIV medical care;

[(vi) information on] (11) the availability of medical services and the location and telephone numbers of treatment sites, information on the use of HIV chemotherapeutics for prophylaxis and treatment and peer group support, access to prevention, education and support services and assistance, if needed, in obtaining any of these services; and

[(vii) a discussion of] (12) prevention of perinatal transmission.

(f) In the case of a test not indicating evidence of HIV infection, the person who orders the test shall be responsible, directly or though a representative, for providing the result to the subject of the test, or for a person lacking capacity to consent, the person authorized to consent for the health care for the subject. The person ordering the test or his or her representative must also provide, in a manner that may consist of oral or written reference to materials previously provided, information concerning the risks of participating in high risk sexual or needle-sharing behavior. The negative result and required information may be provided in-person, by mail, electronic messaging, or telephone provided that patient confidentiality is reasonably protected.

(g) Every individual between the ages of thirteen and sixty-four years (or younger or older if there is evidence or indication of risk activity) who receives health services as an inpatient or in the emergency department of a general hospital defined in subdivision ten

of section twenty-eight hundred one of the Public Health Law or who receives primary care services in an outpatient department of such hospital or in a diagnostic and treatment center licensed under article twenty-eight of the Public Health Law or from a physician, physician assistant, nurse practitioner, or midwife providing primary care in any office, clinic, facility or other setting shall be offered an HIV-related test unless the health care practitioner providing such services reasonably believes that:

(1) the individual is being treated for a life threatening emergency; or

(2) the individual has previously been offered or has been the subject of an HIV-related test (except that a test shall be offered if otherwise indicated); or

(3) the individual lacks capacity to consent to an HIV-related test.

[(e)] (h) Nothing in this Part or Part 58 of this Title shall be construed to prohibit a person from directly ordering an HIV test on a specimen taken from his/her own body and directly receiving the results of such HIV test. The test must be performed by a New York State licensed laboratory using a specimen collection kit which has been approved for home HIV specimen collection by the U.S. Food and Drug Administration and which is available without a prescription, or as provided by Section 576-b of the Public Health Law.

[(f) In situations when HIV-related testing is intended to aid in clinical disease monitoring, e.g., HIV nucleic acid (RNA or DNA) detection tests, pre- and post-test counseling may be tailored to the needs of the patient.]

Section 63.4 Filing of reports.

(a) (1) All [initial] determinations or diagnoses of Human Immunodeficiency Virus (HIV) infection, HIV-related illness and Acquired Immune Deficiency Syndrome (AIDS) shall be reported to the commissioner by physicians and other persons authorized to order diagnostic tests or make medical diagnoses or their agents as soon as possible after post-test counseling but no later than [21] 14 days after the provider's receipt of a positive laboratory result or after diagnosis, whichever is sooner.

(2) All determinations or diagnoses of HIV, HIV-related illness and AIDS shall be reported to the commissioner by blood banks as defined in Article 5, Title V of the Public Health Law, by tissue banks and organ procurement organizations as defined by Article 43-B of the Public Health Law as soon as possible after post-test counseling but no later than [21] 14 days after receipt of a confirmed positive laboratory result or after diagnosis, whichever is sooner. Such banks and organizations shall report confirmed positive HIV antibody test results.

(3) Pathologists, coroners and medical examiners or other persons determining from examination of a corpse or from the history of the events leading to death, that at the time of death the individual was apparently affected with HIV infection, HIV-related illness or AIDS shall also make such report to the commissioner within [21] 14 days after receipt of a test result or determination.

(4) [(i)] Laboratories performing [diagnostic] tests for screening, diagnosis or monitoring of HIV infection shall report to the Commissioner cases of [initial] determinations or diagnoses of HIV infection, HIV-related illness and AIDS on a schedule to be specified by the Commissioner. Laboratories shall report the following: [confirmed positive HIV antibody test results] any antigen or antibody tests or combination of tests indicative of

HIV infection, HIV nucleic acid (RNA or DNA) detection test results, all CD4 lymphocyte counts unless the test was known to be performed for reasons other than HIV infection or HIV-related illness, HIV subtype and antiviral drug resistance testing in a format designated by the Commissioner, and the results of other tests as may be determined by the Commissioner to indicate a diagnosis of HIV infection, HIV-related illness or AIDS.

[(ii) For the purposes of laboratory reporting, initial diagnosis shall mean the first such test noted in subparagraph (i) of this paragraph which is performed on a specimen submitted after the effective date of these regulations.]

(b) Reports, including names and addresses of the protected individual, all contact and locating information and other information including demographic, and identifying information as may be specified by the commissioner, shall be made in a manner and format as prescribed by the commissioner. Information reported shall also include names and addresses, if available, of contacts, including spouses, known to the physician or other person authorized to order diagnostic tests or make medical diagnoses, or provided to them by the protected person, and the date each contact was notified if contact notification has already been done; and information, in relation to each reported contact, required by an approved domestic violence screening protocol. After receiving the report, the commissioner or his/her authorized representative may request the individual making the report or the person who ordered the diagnostic tests to provide additional information as may be required for the epidemiologic investigation, case finding and analysis of HIV infection, HIV-related illness and Acquired Immune Deficiency Syndrome (AIDS) and to implement Public Health Law Article 21, Title III.

Notwithstanding this subdivision, test results from New York State approved anonymous test sites shall not be reported to the commissioner unless the test subject chooses to supply identification and convert the anonymous test result to a confidential test result.

(c) Confidentiality. Such reports and additional information maintained by the commissioner or his/her designated representative, including all information generated by contact notification and domestic violence screening activities, shall be kept confidential as required by Public Health Law, Article 21, Title III, and shall not be disclosed except when in the judgment of the public health official, necessary to other authorized public health officials for conducting accurate and complete epidemiological monitoring of the HIV/AIDS epidemic and for conducting contact notification activities, except that [contact names and locating] information may be disclosed to public health officials in other jurisdictions when necessary to notify the contact or for purposes of de-duplication; no information about the protected individual will be released to any person in [this] the contact notification process. Reports and information may be used in the aggregate in programs approved by the commissioner for the improvement of the quality of medical care provided to persons with HIV/AIDS; or with patient identifiers when used within the state or local health department by public health disease programs to assess co-morbidity or completeness of reporting and to direct program needs, in which case patient identifiers shall not be disclosed outside the state or local health department. Nothing contained herein shall prevent the department, municipal health commissioner or district health officer from informing physicians and other persons authorized to order diagnostic tests or make medical diagnoses or their agents that there is no need for additional

follow-up by such provider for such individual.

Section 63.5 Disclosure pursuant to a release.

(a) No confidential HIV-related information, including such information as related to domestic violence screening, shall be disclosed pursuant to a general release except to insurance companies as noted in section 63.6(a)(9) of this Part. Disclosure is permitted [for HIV-related information] pursuant to a [specific] release [form for a limited time period which has been developed or approved by the Department] of confidential HIV-related information. The release must be signed by the protected individual, or if the protected individual lacks capacity to consent, by a person [authorized pursuant to law to consent to health care for the individual] specified in section 63.6(a)(1) of this Part.

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(d) The statement required by subdivisions (b) and (c) of this section is not required for [release to the protected person or when a person lacks the capacity to consent, to a person authorized pursuant to law to consent to health care for the person] disclosures made in accordance with paragraphs (1), (4) or (9) of subdivision (a) of section 63.6 of this Part, for releases made by a physician or their agent or public health officer to a contact; or for releases made by a physician or their agent to a person authorized pursuant to law to consent to the health care of the protected person when the person has been counseled and has refused to disclose and the disclosure is medically necessary. For disclosures of confidential HIV-related information from the patient's medical record to

persons who are permitted to access this information pursuant to section 63.6(a)(3), [(4),] (5), (6), (7) [,(9)] and (10) and (e) and (f) of this Part, it shall be sufficient for the statement required by subdivisions (b) and (c) of this section to appear as part of the medical record when a medical record is disclosed.

Section 63.6 Confidentiality and disclosure.

(a) No person who obtains confidential HIV-related information in the course of providing any health or social service or pursuant to a release of confidential HIV-related information may disclose or be compelled to disclose such information, except to the following:

(1) the protected individual or, when the protected individual lacks capacity to consent, a qualified person under section 18 of the Public Health Law, a person the protected individual has authorized to access records relating to the provision of health care under General Obligations Law Article 5, Title 15, or person authorized pursuant to law to consent to health care for the individual;

* * *

(4) (i) a health care provider or health facility when knowledge of the HIV-related information is necessary to provide appropriate care or treatment to the protected individual or a child of the individual;

(ii) a health care provider or health facility when knowledge of HIV-related information is necessary to provide appropriate care or treatment to a contact or exposed individual,

provided the requirements in section 63.8(m) of this Part are followed for disclosures involving exposures in risk situations;

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(16) a law guardian, appointed to represent a minor pursuant to the social services law or the family court act, for the purpose of representing that minor. If the minor has the capacity to consent, the law guardian may not redisclose confidential HIV-related information without the minor's permission. If the minor lacks capacity to consent, the law guardian may redisclose confidential HIV-related information for the purpose of representing the minor; or

(17) an executor or administrator of an estate of a deceased person as needed to fulfill his or her responsibilities/duties as an executor or administrator.

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(e) Confidential HIV-related information of a protected person may be disclosed to authorized employees or agents of a governmental agency pursuant to the regulations of the governmental agency when the person providing health or social services is regulated, supervised or monitored by the governmental agency or when the governmental agency administers the health program or a social service program and when such employees or agents have access to records in the ordinary course of business and when access is reasonably necessary for regulation, supervision, monitoring, administration or provision of services. Such authorized employees or agents may include attorneys authorized by a

government agency when access occurs in the ordinary course of providing legal services and is reasonably necessary for supervision, monitoring, administration or provision of services. Such authorized employees or agents may also include public health officers as [required] needed for conducting epidemiological or surveillance investigations pursuant to [the State Sanitary Code or this Part] applicable law, rule or regulation. Such surveillance or investigational data shall also be disclosed by the public health officer to the State Department of Health as required by the State Sanitary Code or this Part.

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§ 63.8 Contact notification.

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(j) Municipal health commissioners must provide HIV contact notification services and shall forward to the department, summary data and all identifiable information related to notification activities upon completion of such activity unless otherwise determined by the commissioner. Information identifying the contact collected in the course of contact notification activities by authorized public health officials shall not be maintained at the state or local level for more than [one year] three years following completion of such activity.

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(m) When the requirements of this section have been met, physicians and other diagnostic providers may disclose HIV-related information, without a release of confidential HIV-related information, to physicians or other diagnostic providers of persons whom the protected individual may have exposed to HIV under the circumstances noted below that present a risk of transmission of HIV, except that disclosures related to exposures of emergency response employees governed by federal law shall continue to be governed by such law:

(1) the incident must involve exposure to blood, semen, vaginal secretions, breast milk, tissue or the following body fluids: cerebrospinal, amniotic, peritoneal, synovial, pericardial and pleural;

* * *

[(6) the medical provider of the exposed person or the medical officer designated by the facility reviews, investigates and evaluates the incident and certifies that:

(i) the information is necessary for immediate decisions regarding initiation or continuation of post-exposure prophylactic treatment for the exposed person;

(ii) the exposed person's status is either HIV negative or unknown and that if the person's status is unknown, the person has consented to an HIV test; and

(iii) if such test result becomes known as positive prior to the receipt of the source's HIV status, no disclosure of the source's HIV status will be made to the person;]

[(7)] (6) documentation of the request is placed in the medical record of the exposed person; and

[(8)] (7) if the provider of the source or the medical officer designated by the facility determines that a risk of transmission has occurred or is likely to have occurred in the reasonable exercise of his/her professional judgment, the provider or medical officer may release the HIV status of the source, if known. The provider or medical officer may consult with the municipal health commissioner or district health officer to determine whether a risk of transmission exists. If consultation occurs, both the provider and the local health officer must be in agreement if the HIV information is to be disclosed. In the disclosure process the name of the source shall not be provided to the exposed person. Redisclosure of the HIV status of the source is prohibited except when made in conformance with Public Health Law Article 21, Title III.

(n) In cases of anonymous testing of an occupational exposure source patient who is deceased, comatose or otherwise unable to provide consent, and no person authorized to consent on behalf of the source person is immediately available, as provided for in Public Health Law Section 2781(6)(e), the results of such anonymous test, but not the identity of the source person, shall be disclosed only to the attending health care professional of the exposed person solely for the purpose of assisting the exposed person in making appropriate decisions regarding post-exposure medical treatment. The results of the test shall not be disclosed to the source person or placed in the source person's medical record.

§ 63.9 Health care provider and health facility policy and procedures.

Each health care provider and health facility employing persons or contracting with persons to perform any activity related to such provider's or facility's rendering of health services shall develop and implement policies and procedures to maintain the confidentiality of confidential HIV-related information. Such policies and procedures shall assure that such information is disclosed to employees or contractors only when appropriate under this Part. Such policies and procedures shall include:

(a) initial employee education [and annual] inservice education of employees regarding the legal prohibition against unauthorized disclosure in Public Health Law Article 27-F and provisions of Article 21, Title III. Updates should be provided to all employees in cases of changes to relevant laws or regulations. A list of all employees who have had such training must be maintained by health care providers and health facilities. Health care providers and health facilities contracting with others for services in which HIV-related information may be disclosed to such contractors, must document evidence that such contractors have been informed of the confidentiality and disclosure requirements of this Part;

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§ 63.10 Significant risk.

(a) The three factors necessary to create a significant risk of contracting or transmitting HIV infection are:

(1) the presence of a significant risk body substance;

(2) a circumstance which constitutes significant risk for transmitting or contracting HIV infection; and

(3) the presence of an infectious source and [a noninfected] another person.

(b) "Significant risk body substances" are blood, semen, vaginal secretions, breast milk, tissue and the following body fluids: cerebrospinal, amniotic, peritoneal, synovial, pericardial, and pleural.

(c) Circumstances which constitute "significant risk of transmitting or contracting HIV infection" are:

(1) sexual intercourse (e.g., vaginal, anal, oral) which exposes [a noninfected] another individual to blood, semen or vaginal secretions of an infected individual;

(2) sharing of needles and other paraphernalia used for preparing and injecting drugs between infected and [noninfected] other individuals;

(3) the gestation, birthing or breast feeding of an infant when the mother is infected with HIV;

(4) transfusion or transplantation of blood, organs, or other tissues from an infected individual to [an uninfected individual] another, provided such blood, organs or other tissues have not tested conclusively for antibody or antigen and have not been rendered noninfective by heat or chemical treatment;

(5) other circumstances not identified in paragraphs (1) through (4) of this subdivision during which a significant risk body substance (other than breast milk) of an infected individual contacts mucous membranes (e.g., eyes, nose, mouth), non-intact skin (e.g., open wound, skin with a dermatitis condition, abraded areas) or the vascular system of [a noninfected] another person. Such circumstances include, but are not limited to

needlestick or puncture wound injuries and direct saturation or permeation of these body surfaces by the infectious body substance.

* * *

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for this regulation is contained in Public Health Law (PHL) Article 21, Title III, Sections 2130(1); 2135; and 2139: and Article 27-F Sections 2780(4); 2781; 2781-a ; 2782(1); 2782(5)(a); and 2786(1) to be consistent with and in conjunction with implementing Chapter 308 of the Laws of 2010, the HIV Testing Law. PHL Section 2786 authorizes the Commissioner of Health to promulgate rules and regulations concerning implementation of Article 27-F for health facilities, health care providers, and other persons to whom this article is applicable. Section 2786 further authorizes the Commissioner to develop standardized model forms for informed consent for HIV testing, for the release of confidential HIV-related information, and materials for pre-test and post-test counseling. The Commissioner is also authorized to promulgate regulations, in consultation with the AIDS Advisory Council, to identify significant risk of contracting or transmitting HIV infection provided, however, that such regulations not be determinative of any significant risk of contracting or transmitting risk determined pursuant to paragraph (a) of subdivision 4 of Section 2782 or Section 2785 of Article 27-F. The commissioner is also authorized by PHL Section 2139 to promulgate rules and regulations as shall be necessary and proper to effectuate HIV reporting.

Legislative Objectives:

In enacting Chapter 308 of the Laws of 2010, the Legislature found that mandating a broad range of health facilities and practitioners to offer HIV diagnostic testing to adolescent and adult patients and streamlining consent, counseling, and

information handling practices were important for addressing the ongoing challenge of the HIV epidemic. The legislative objective of the amendments contained in this law is to encourage HIV testing among a broad range of persons as a means of identifying HIV-infected persons as early as possible in the course of their infection and to link them into care. Chapter 308 maintains the informed consent requirement for HIV testing and protection of confidential HIV-related information while removing numerous barriers that are inherent in a broad-based mandated offer of screening. Chapter 308 allows for enhanced use of patient specific and non-patient specific HIV information to improve patient medical care and to assess co-morbidity or completeness of reporting and to direct program needs.

Needs and Benefits:

According to the federal Centers for Disease Control and Prevention (CDC) at the end of 2006, an estimated 1,106,400 persons (range: 1,056,400 – 1,156,400) in the United States were living with HIV. CDC estimates that 56,300 new HIV infections occurred in the United States in 2006. Each year, approximately 16-22 million persons in the United States are tested for HIV, with 2 million of those persons being New Yorkers.

By 2002, an estimated 38%-44% of all adults had been tested nationally for HIV. In 2009, approximately half of all New Yorkers age 18 to 64 reported having ever been tested; however, one-third of persons newly diagnosed with HIV were identified so late in the course of their infection they progressed to AIDS within one year. At the end 2006, approximately 1 in 5 of persons nationally with HIV (21%, or 232,700 persons) did not know they were infected.

In September 2006, CDC released *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*. These recommendations, which replaced CDC's 1993 *Recommendations for HIV Testing Services for Inpatients and Outpatients in Acute-Care Hospital Settings*, advise routine HIV screening of adults, adolescents, and pregnant women in health care settings in the United States. They also recommend reducing barriers to HIV testing. People who are infected with HIV but not aware of it are not able to take advantage of the therapies that can keep them healthy and extend their lives, nor do they have the knowledge to protect their sex or drug-use partners from becoming infected. Knowing whether one is positive or negative for HIV confers great benefits in health-related decision making.

Cohort studies have demonstrated that many infected persons decrease behaviors that transmit infection to sex or needle-sharing partners once they are aware of their positive HIV status. HIV-infected persons who are unaware of their infection tend to continue their high risk behaviors, therefore increasing the likelihood of transmitting HIV to partners. Medical treatment lowers HIV viral load and reduces risk for transmission to others, and early referral to medical care can prevent HIV transmission in communities and reduce a person's risk for HIV-related illness and death.

Chapter 308 of the Laws of 2010 brings New York State closely into alignment with CDC's 2006 recommendations while reducing barriers to HIV testing. Chapter 308 eases current written consent requirements by providing an option for a durable written general consent that specifically includes HIV testing, or a documented oral consent when the test being ordered is a rapid HIV test. Chapter 308 also makes a corresponding technical change to the law requiring that the Commissioner develop forms to be used for

informed consent purposes. Specifically, Chapter 308 designates such forms as "standardized model" forms, and providers no longer need to obtain prior authorization for the use of alternative forms that contain information consistent with the standardized model forms. Similarly, Chapter 308 removes the requirement that physicians confirm to laboratories that informed consent has been obtained before ordering HIV-related testing.

Previously, state law required post-test counseling which was the same regardless of the test's results. This legislation requires that counseling be tailored based on whether the HIV test indicates infection. Counseling for positive results will remain consistent with existing law with a requirement added to make an appointment for the infected person to receive follow-up HIV medical care. For negative results, education will emphasize risks associated with participating in high risk behavior and may be accomplished by oral or written reference to information previously provided. Interactive counseling for HIV negatives is no longer necessary.

Chapter 308 also requires physicians to report HIV data obtained through laboratory tests conducted in conjunction with periodic monitoring of HIV infection, which will enable NYS DOH to monitor the spread of HIV/AIDS and to target program initiatives. This provision reflects the availability of data from HIV tests which was not available when Article 21, Title III and Article27-F were originally enacted. Chapter 308 makes similar technical changes to various provisions of law to update references to testing in accordance with newer testing technologies. In addition, Chapter 308 protects individuals who are at risk of acquiring HIV infection due to an occupational exposure by permitting anonymous HIV testing if the source patient is incapable of providing consent.

Finally, Chapter 308 changed confidentiality provisions, first by allowing limited access to confidential HIV information to the executor or administrator of an estate when needed by such persons to fulfill their responsibilities. Second, under the previous law, disclosure of HIV-related information had to be accompanied by a written statement regarding confidentiality and re-disclosure. It is appropriate to exempt from these requirements routine disclosures of information which are made to providers for purposes of treatment and to third party payers for reimbursement purposes.

Costs:

Chapter 308 of the Laws of 2010 created the requirements for the mandated offer of HIV testing for persons between the ages of 13 and 64 and other activities addressed in recommended revisions to Part 63. The proposed regulations add no further costs. The Department took steps in constructing the regulations to incorporate suggestions from regulated parties to minimize the financial burden. It is estimated that the implementation and administration of other requirements of this rule will not impose any costs upon this agency, New York State, or its local governments.

The law and proposed regulations can actually decrease long term costs. By increasing access to HIV testing and requiring a referral to care for HIV infected persons, there is the potential to lower individual and community level exposure to HIV, and also to potentially intervene at an earlier stage of disease (HIV vs. AIDS). Earlier medical intervention may lessen the degree of medical care therefore potentially decreasing costs (HIV treatment vs. AIDS treatment).

The costs associated with Chapter 308 mainly include offering tests to all persons between the ages of 13 and 64 receiving primary care in county operated sites, screening those that accept testing, and linking those found to be positive to HIV medical care. HIV testing can cost between $10 for a rapid screening test and up to $100 for confirmatory for the 1 out of 100 persons on average who have a preliminary positive test and need to have it confirmed with a western blot test. Early identification of HIV reduces medical costs for the identified person who can be treated with medicine rather than in-patient hospital stays and more expensive medical treatment. The infected person can also be educated how not to pass the virus to others. Each new case averted saves $367,134 in projected lifetime medical costs of an HIV infection. Neither the law nor the regulations require additional data reporting.

This rule mitigates costs by streamlining the consent process from a counseling model to one that can be accomplished by the provision of information in written, oral or electronic form. Consent can be obtained orally when a rapid test is being used and written consent can be incorporated into a facilities general medical consent. Similarly, post-test counseling has been eliminated as a requirement except in those instances in which a person is diagnosed with HIV.

Local Government Mandates:

This rule imposes no mandates upon any county, city, town, village, school district, fire district, or other special district other than those required under Chapter 308 of the Laws of 2010 for any entity operating a general hospital or providing primary care. The major mandate of the law is the required offer of HIV testing to all persons between

the ages of 13 and 64 who are receiving primary care services. County clinics providing primary care must comply with the requirement to offer HIV testing. Similar to other entities covered under the law, steps were taken in drafting the regulations to minimize the impact by streamlining consent, pre-test, and post-test negative practices. Chapter 308 mandates an appointment for HIV medical care be made with any new positive identified. Posted to the NYSDOH website is contact information for Designated AIDS Centers across the state at which such appointments can be made.

Paperwork:

This rule imposes no new reporting requirements, forms, or other paperwork upon regulated parties.

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 after considerable input from the community, provider groups, and regulated parties. All day regional meetings were held in Buffalo, Syracuse, Albany and New York City that had over 400 in-person participants, with others connected through telephone conference calls. Input was also elicited from the Healthcare Association of New York State, Greater New York Hospital Association, New York State Academy of Family Physicians, Medical Society of the State of New

York, New York City Department of Health and Mental Hygiene, New York State Association of County Health Officials, Community Health Care Association of New York State, New York State AIDS Advisory Council, and the New York State HIV Prevention Planning Group. Alternative approaches were considered with a number of these already being reflected in the Department's publicly available materials for implementation of Chapter 308, as well as in the proposed regulations.

Examples of alternative approaches the Department has included in the proposed regulations include allowing pre-test information to be provided by oral, written, or electronic means. Similarly, negative test results and negative post-test information can be provided by mail, phone, or electronic means as long as the patient's confidentiality is protected. Previously, these would have involved potentially time consuming in-person interactions, which in settings such as emergency rooms are not feasible.

Federal Standards:

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

Compliance Schedule:

Chapter 308 of the Laws of 2010 had an effective date of September 1, 2010 for all provisions relating to regulated parties. The Department has continued to assist affected entities in compliance efforts.

Contact Person: Katherine Ceroalo
New York State Department of Health
Bureau of House Counsel, Regulatory Affairs Unit
Corning Tower Building, Rm. 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.state.ny.us

REGULATORY FLEXIBILITY ANALYSIS

FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

Chapter 308 of the Laws of 2010 will impact the existing sixty two local governments. This includes New York City and the fifty-seven counties outside of New York City. Also impacted would be all health care facilities with fewer than 100 employees that use certain licensed professionals to provide primary care such as private medical practices, community health centers, urgent care clinics, employee health services, retail health clinics, and student health services. Chapter 308 requires that all physicians, physician assistants, nurse practitioners, and midwives providing primary care make the offer of HIV testing, and the regulations clarify the mandate is in force regardless of the setting in which primary care is being provided.

Compliance Requirements:

This rule imposes no mandates upon any small business or local government except for those required under Chapter 308 of the Laws of 2010 for any entity operating a general hospital or providing primary care. A major mandate of the law is the required offer of HIV testing to all persons between the ages of 13 and 64 who are receiving primary care services. County clinics providing primary care must comply with the requirement to offer HIV testing. Similar to other entities covered under the law, steps were taken in drafting the regulations to minimize the impact by streamlining consent, pre-test, and post-test negative practices. Chapter 308 mandates an appointment for HIV

medical care be made with any new positive identified. Posted to the NYSDOH website is contact information for Designated AIDS Centers across the state at which such appointments can be made.

Professional Services:

The Law does not require any significant changes to existing professional services.

Compliance Costs:

There are no capital costs incurred as a result of this Law. Costs associated with the implementation of this Law may be offset (to some degree) with existing grant and/or State funding. These funding sources include (a) Federal (Ryan White and Centers for Disease Control) and (b) State (Medicaid). Some small businesses may be directly impacted by now, under Chapter 308, having to offer and conduct HIV testing, a service they may not have offered in the past. While the state as a whole may benefit from the early detection of previously undiagnosed cases of HIV in terms of overall treatment cost savings, the individual small business will not directly participate in the benefits.

Economic and Technological Feasibility:

New York State Department of Health provides technical assistance to impacted providers regarding economic and technological feasibility. Providers covered under the law are by definition offering primary care services to patients, and most are providing HIV testing already. For those that must newly add screening services required by

Chapter 308, rapid test technology is available that is reasonably priced (approximately $15 per test) and CLIA waived as a point of care device. Additional costs would be incurred in cases of persons testing positive by a rapid screening test (on average 1 in 100). Other point of care specimen collection devices are available for confirming results if the provider does not have phlebotomy capacity.

Minimizing Adverse Impact:

Chapter 308 of the Law of 2010 is intended to ease the compliance requirement of HIV Testing providers through, (a) a streamlined consent process, (b) the delivery of post-test negative test results through a variety of approaches including electronic mail, postal mail or phone.

The regulations were developed after considerable input from the community, provider groups, and regulated parties. All day regional meetings were held in Buffalo, Syracuse, Albany and New York City that had over 400 in-person participants, with others connected through telephone conference calls. Input was also elicited from the Healthcare Association of New York State, Greater New York Hospital Association, New York State Academy of Family Physicians, Medical Society of the State of New York, New York City Department of Health and Mental Hygiene, New York State Association of County Health Officials, Community Health Care Association of New York State, New York State AIDS Advisory Council, and the New York State HIV Prevention Planning Group. Alternative approaches were considered with a number of these already being reflected in the Department's publicly available materials for implementation of Chapter 308, as well as in the proposed regulations.

Examples of alternative approaches the Department has included in the proposed regulations include allowing pre-test information to be provided by oral, written, or electronic means. Similarly, negative test results and post-test information can be provided by mail, phone, or electronic means as long as the patient's confidentiality is protected. Previously, these would have involved potentially time consuming in-person interactions, which in setting such as emergency rooms are not feasible.

Small Business and Local Government Participation:

Small businesses and local governments had the opportunity to participate in the rule making process through (a) a series of New York statewide stakeholder meetings, (b) participation in regional meeting updates with New York State Association of County Health Officials (c) individual local government technical assistance provided by electronic mail, phone and in person as requested, and (d) discussions with the Academy of Family Physicians, the Greater New York Hospital Association, and the Healthcare Association of New York State. Groups have generally acknowledged that the Department has taken substantial steps to accommodate the legitimate concerns of providers by streamlining processes and not creating new requirements for data collection or reporting.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

Chapter 308 of the Laws of 2010 is a statewide mandate including rural and urban counties. This would include any general hospital or provider of primary care. The proposed regulations do not expand the type of facilities to which the law applies, but do clarify that the mandated offer of HIV must be made by any physician, physician assistant, nurse practitioner or midwife providing primary care regardless of setting.

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

This rule imposes no mandates upon entities in rural areas except those required under the law for any entity operating a general hospital or providing primary care. The major mandates of the law are the required offer of HIV testing to all persons between the ages of 13 and 64 who are receiving primary care services. Steps were taken in drafting the regulations to minimize the impact by streamlining consent, pre-test, and post-test negative practices. Chapter 308 mandates an appointment for HIV medical care be made with any new positive identified. Posted to the NYSDOH website is contact information for Designated AIDS Centers across the state at which such appointments can be made.

Costs:

There are no capital costs associated with Chapter 308 of the Laws of 2010. Costs associated with the implementation of this Law may be offset (to some degree) with

existing grant and/or State funding. These funding sources include (a) Federal (Ryan White and Centers for Disease Control) and (b) State (Medicaid). HIV testing and counseling are covered benefits in Medicaid managed care, Family Health Plus and Medicaid fee-for-service. Some entities in rural areas may be directly impacted by now, under Chapter 308, having to offer and conduct HIV testing, a service they may not have offered in the past. While the state as a whole may benefit from the early detection of previously undiagnosed cases of HIV in terms of overall treatment cost savings, the individual small business will not directly participate in the benefits.

Minimizing Adverse Impact:

There are no capital costs associated with Chapter 308 of the Laws of 2010. Costs associated with the implementation of this Law may be offset (to some degree) with existing grant and/or State funding. These funding sources include (a) Federal (Ryan White and Centers for Disease Control) and (b) State (Medicaid). HIV testing and counseling are covered benefits in Medicaid managed care, Family Health Plus and Medicaid fee-for-service.

The regulations were developed after considerable input from the community, provider groups, and regulated parties. All day regional meetings were held in Buffalo, Syracuse, Albany and New York City that had over 400 in-person participants, with others connected through telephone conference calls. Input was also elicited from the Healthcare Association of New York State, Greater New York Hospital Association, New York State Academy of Family Physicians, Medical Society of the State of New York, New York City Department of Health and Mental Hygiene, New York State

Association of County Health Officials, Community Health Care Association of New York State, New York State AIDS Advisory Council, New York State HIV Prevention Planning Group. Alternative approaches were considered with a number of these already being reflected in the Department's publicly available materials for implementation of Chapter 308, as well as in the proposed regulations.

Examples of alternative approaches the Department has included in the proposed regulations include allowing pre-test information to be provided by oral, written, or electronic means. Similarly, negative test results and post-test information can be provided by mail, phone, or electronic means as long as the patient's confidentiality is protected. Previously, these would have involved potentially time consuming in-person interactions, which in setting such as emergency rooms are not feasible.

Rural Area Participation:

Rural area participation was available through (a) New York State Department of Health statewide stakeholder meetings, (b) an ongoing mechanism for email inquiries and (c) individual technical assistance available through electronic mail, phone or in person as requested.

JOB IMPACT STATEMENT

Nature of Impact:

There is no anticipated loss of jobs due to the implementation of Chapter 308 of the Laws of 2010.

Categories and Numbers Affected:

The requirement for the offering of HIV testing applies to persons receiving inpatient or emergency department services at hospitals and persons receiving primary care services through hospital outpatient clinics, diagnostic and treatment centers, and persons receiving primary care services from physicians, physician assistants, nurse practitioners and midwives.

Regions of Adverse Impact:

An adverse impact is not anticipated in any region of the state due to the implementation of Chapter 308 of the Laws of 2010.

Minimizing Adverse Impact:

N/A

Self-Employment Opportunities:

N/A

Assessment of Public Comment

Public comments were submitted to the NYS Department of Health (DOH) in response to this regulation from the Greater New York Hospital Association, the HIV Law Project, the New York City HIV Planning Council, and others. In all, five comments were received, with two of them offering their support for the proposed changes. These comments and the Department of Health's responses are summarized below.

Comment:

One commenter found language in the proposed regulations that defines the length of time for which a person's informed consent to an HIV test is valid to be unnecessarily confusing and insufficiently clear.

Response:

The language cited comes directly from the statute. In working with persons consenting to a test, health care providers may use other language that will clarify, if necessary, that the consent may be withdrawn at any time.

Comment:

One commenter noted that adding medical education to the list of circumstances where consent is not required for HIV testing related to procuring and processing of human body parts might have broader implications than intended and, if such unconsented testing is done at all, should be done anonymously.

Response:

The addition of medical education to the consent exemption is a clarification of existing practice allowed under the law.

Comment:

Occupational exposure testing should only be allowed in cases where there is a significant risk of exposure to the health care worker. Also, allowing anonymous unconsented testing when no person authorized to consent on behalf of the source is immediately available unreasonably constricts the timeframe for locating such a person.

Response:

The regulations are clear that occupational exposure HIV testing without consent is limited to circumstances provided for in PHL section 2781(6)(e), which specifically states there must be a significant risk of contracting or transmitting HIV infection. In terms of allowing unconsented HIV testing if no person authorized to provide consent is immediately available, this approach is consistent with CDC guidelines for management of occupational exposures. In order to minimize the chances of disease transmission, the health care worker may need to begin post-exposure prophylaxis immediately, and stop if the source test is determined to be negative. The decision making timeframes require rapid access to key information. It should be noted that under the Family Health Care Decisions Act, the number of persons authorized to consent on behalf of a patient have been broadened considerably, which should decrease the likelihood that no one will be immediately available to authorize or decline the occupational exposure source test.

Comment:

The regulations do not provide guidance on post-test counseling for persons with indeterminate/inconclusive HIV test results.

Response:

Consistent with the law, the regulations require post-test counseling for persons with indeterminate/inconclusive results but do not prescribe specific content for such counseling; rather, they allow for clinical judgment to be used. Frequently Asked Questions and other guidance documents from DOH will reiterate current recommendations for persons with inconclusive/indeterminate results to be retested and avoid risk behaviors as dictated by the circumstances of the individual patient.

Comment:

Section 63.3(e)(8) would be clearer if it stated directly that the requirement for known contacts be documented and reported is the responsibility of health care providers and not that of the person receiving the positive test result.

Response:

Since the proposed regulations do not change the wording that is already in the regulations, this is really a new proposal to amend the regulations, not a comment on DOH's proposed amendments. It is not necessary to change the wording that is already in the regulations, and DOH declines to amend the current wording as the commenter proposes.

Comment:

The proposed wording that allows for HIV negative results to be provided by mail or electronic means as long as the person's confidentiality is reasonably protected undermines confidentiality protections.

Response:

The law makes several important advances in routinizing HIV testing, including mandating the offer of such testing to millions of New Yorkers 13 years of age and older who seek health care. Consistent with this is the need to streamline the provision of anti-body negative results, which will represent over 99% of the total from tests conducted. The proposed language in the regulation continues to provide protection of confidentiality while recognizing the realities of health care facilities needing to find efficient mechanisms to provide negative results and the other required information to thousands of patients each year.

Comment:

The proposed regulations are too vague in terms of how often the mandatory offer of a test should be made: it should be an annual offer for sexually active persons, in addition to offers that would be otherwise indicated.

Response:

The law does not require an annual offer of an HIV test. It requires the test to be offered at least once and then subsequently depending on indication of risk. The proposed language maintains the flexibility in the law to ensure every one has the offer made once,

and then additional offers made based on the individual circumstances of the patient. For some persons, this would be more frequently than once per year.

Comment:

The law says that the offer of the test must be culturally and linguistically appropriate, but the proposed regulations do not.

Response:

The statutory requirement around cultural and linguistic competence of the testing offer will be reinforced through DOH materials and forms that operationalize the law.

Comment:

Hospitals that provide care to a large number of cancer patients will have a difficult time meeting the new requirement that new HIV diagnoses be reported within 14 days after the provider's receipt of a positive laboratory result or after diagnosis, whichever is sooner. This is because cancer hospitals will have many patients with low CD3 and CD4 counts who are not HIV-infected, and it is a painstaking process to sort through these cases to identify those that are truly HIV-related.

Response:

The proposed regulations require that physicians and other persons authorized to order diagnostic tests or make medical diagnoses report persons with established new diagnoses within 14 days. The proposed regulations, however, do not change the amount of time that hospitals and laboratories have to report HIV-related tests. The commenter will not need to report any sooner than what is current practice.

Comment:

Two commenters expressed concern that proposed changes to rules for confidential information obtained by DOH through HIV reporting were unnecessary and intrusive. Specifically noted were expansion of requirements for providing DOH identifying/locating information on diagnosed persons; use of patient information for assessing co-morbidity; use of identifying information for deduplication of cases across jurisdictions; and contacting physicians when DOH is aware that a person may be unavailable for clinical follow-up.

Response:

The proposed regulations maintain the significant confidentiality protections afforded to HIV-infected persons and HIV-related information through Article 27-F of the Public Health Law. The changes in language will improve DOH's ability to carry out its statutorily mandated role in documenting the epidemic and conducting disease control activities, including contact notification. With the high volume of HIV-related lab reports received each year, having as much identifying information as possible allows for more efficient determination as to whether the case is in fact new or previously reported and for locating persons who are newly diagnosed. De-duplication across jurisdictions is a federally mandated effort that allows for an accurate case count by determining whether cases reported from multiple states are different individuals or the same person living in and seeking care in a variety of places. Assessing co-morbidities is an important public health function specifically allowed for in the law using patient identifiers to enable the appropriate level of analysis. Informing physicians that no further public health reporting

follow-up is needed for a patient does not interfere with the doctor/patient relationship, but rather allows for efficient use of limited DOH and clinical resources.

Comment:

Removal of the phrase “for a limited time period” from the section that describes the amount of time a release of confidential of HIV-related information is valid for should be changed to make it clear that the person granting the release can revoke their consent at any time.

Response:

The statute does not require that the release be time limited, only that the time period be specified, which would include an open ended release. The changes provide the flexibility allowed for under Public Health Law 2780(9) and clarify what is required.

Comment:

Two commenters felt having the state retain information about named contacts of HIV-infected persons for three years instead of one is unnecessary and would increase the likelihood that the information would be misused.

Response:

The additional time is necessary to do thorough disease investigation. Oftentimes, contact information is inaccurate or incomplete, especially in the current environment where people meet for sex through anonymous social media. It may take multiple reports received over time to piece together enough information to identify a particular person who can be located in the community. Patients voluntarily provide information on

contacts, so much of the information that would be retained would be that which infected persons divulged because they agreed to help ensure their partners were informed of a possible exposure to HIV. The additional time will make it more likely such notification will happen.

Comment:

DOH should not reduce the steps required prior to confidential HIV information about a source patient being released in cases of an occupational exposure.

Response:

Significant protections remain in the relevant section of the regulations that address occupational exposure for ensuring that confidential HIV information is released only under circumstances that present a risk of transmission to another person. The language that was removed imposed potentially time-consuming barriers to rapid treatment of an exposed worker and excluded HIV-infected health care workers from determining if an occupational exposure posed a risk to them for infection with a different strain of the disease.

For the reasons noted above, the Department is adopting the amendments as proposed.