

## **HIV/AIDS Testing, Reporting and Confidentiality of HIV-Related Information**

**Effective date: 5/17/17**

### **SUMMARY OF EXPRESS TERMS**

Effective April 1, 2014, amendments contained in the 2014-15 enacted New York State budget authorized certain changes to HIV testing in New York State. These amendments simplified HIV testing as part of routine medical care, improved linkage to care, and made New York State law consistent with Centers for Disease Control and Prevention (CDC) recommendations for routine HIV screening in healthcare settings.

Effective April 1, 2015, amendments contained in the 2015-16 enacted New York State budget authorized the elimination of the requirement of written consent for HIV testing in New York State correctional facilities.

Effective November 28, 2016, amendments contained in Chapter 502 of the Laws of 2016 require that, at a minimum, the individual be advised that an HIV-related test is going to be performed, that no such test be performed if the individual objects, and that any objection by the individual be noted in the individual's medical record. Chapter 502 also expands the requirement to offer HIV testing to individuals over the age of 64.

Effective March 28, 2017, Chapter 461 of the Laws of 2016 allows disclosure of confidential HIV-related information to qualified researchers for medical research purposes upon the approval of a research protocol under applicable State or federal law.

Key provisions of these regulation amendments implementing the legislation include:

- Removing the requirement for informed consent prior to ordering an HIV-related test, including elimination of written consent for HIV testing in New York State correctional facilities, and removing references to consent forms.
- Adding a provision stating that performing an HIV test as part of routine medical care requires at a minimum advising that an HIV-related test is being performed, prior to ordering an HIV-related test.
- Removing the reference to expiration of an individual's informed consent.
- Adding a provision authorizing local and state health departments to share HIV surveillance information with health care providers, including entities engaged in care coordination, for purposes of patient linkage and retention in care.
- Clarifying language pertaining to reporting by blood and tissue banks.
- Inserting updates to the list of reportable HIV-related test results that need to be reported. These updates are consistent with CDC and Association of Public Health Laboratories guidance related to the diagnosis of HIV infection. Additionally, reporting of results for NYS residents and NYS-located clinicians is explicitly required. This change was designed to address known gaps in reporting.
- Including language specifically stating that reports must include the requesting provider and facility. The requirement is expected to improve the quality of provider data and lead to more complete data. This should improve accuracy of the Department's surveillance data and, consequently, the National HIV/AIDS Strategy retention and care measures.

- Removing the requirement that the information on HIV provider reporting forms associated with newly diagnosed cases of HIV infection be reported within 60 days.
- Adding individuals who were previously diagnosed as HIV positive, and who are at elevated risk of transmitting HIV to others, to the contact notification prioritization process.
- Removing the requirement that data on the partners of HIV cases be destroyed after three years, and stating that the Department will establish a policy for “record retention and schedule for disposition.”
- Eliminating the upper age limit of 64 for the offering of HIV testing.
- Allowing the disclosure of HIV related information to qualified researchers in compliance with State and federal law.

Pursuant to the authority vested in the Commissioner of Health by Sections 2786 and 2139 of the Public Health 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:

Subdivisions (a), (b), (c), (d), (e) and (g) of section 63.3 are amended to read as follows:

Section 63.3 HIV-related testing.

(a) Except as noted in subdivision ([d]c) of this section, no physician or other person authorized pursuant to law may order an HIV-related test without first 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] advised the individual, or, when the individual lacks capacity to consent, a person authorized to consent to health care for such individual, that an HIV-related test will be performed. The physician, or other person authorized pursuant to law, may not order the HIV-related test over the objection of the individual, or person authorized to consent to health care for such individual, except as authorized or required by law. A physician or other person authorized pursuant to law to order an HIV-related test to be used for [patient] the individual's care shall provide to the laboratory the name, [and address] addresses, and date of birth of the [person] individual who is the source of the specimen and other such information as specified by the [commissioner] 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.

(b) [Informed consent shall include providing 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, 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 the information. Information necessary to obtain informed consent may be provided through electronic, written or oral means and shall include] The advisement, and any objection to testing, shall be noted in the individual's medical record. Before ordering an HIV-related test, the physician or other person authorized by law to order such test, or such person's representative, shall make the following information available:

- (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;
- (2) there is treatment for HIV that can help an individual stay healthy;
- (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;
- (4) testing is voluntary and can be done anonymously at a public testing center;
- (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] requires that an individual be advised before an HIV-related test is performed, and that no test shall be performed over the individual's objection except as authorized or required by law.

(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.

(d) Informed consent] Advising that an HIV-related test is being performed is not required in the following situations:

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

(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 information for negative results or counseling for positive, indeterminate/inconclusive and preliminary positive results is required;

(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;

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

(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).

(d) The Commissioner may appoint and designate, from time to time, persons to review regulated facilities to determine compliance with this Part.

(e) With respect to positive and indeterminate/inconclusive results, and for preliminary positive results obtained pursuant to Subpart 58-8 of this Title, in addition to explaining the test result to the person [who consented to the test] lawfully authorized to consent to health care, 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 Subparts

58-2 and 52-3 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] is lawfully authorized to consent to health care, 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. For persons who test positive, post-test counseling shall address:

- (1) strategies for coping emotionally with the test results;
- (2) discrimination issues relating to employment, housing, public accommodations, health care, public benefits and social services;
- (3) the importance of taking precautions to prevent HIV transmission to others;
- (4) the ability to release or revoke the release of confidential HIV-related information;
- (5) HIV reporting requirements for the purposes of epidemiologic monitoring of the HIV/AIDS epidemic;
- (6) the importance of contacts' being notified to prevent transmission, and allowing early access of exposed persons to HIV testing, health care, and prevention services, and a description of notification options and assistance available to the protected individual;
- (7) an assessment of the risk of domestic violence in conformance with a domestic violence screening protocol developed by the [commissioner] Commissioner pursuant to law;

(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;

(9) non-disclosure of the protected individual's name or other information about them 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;

(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]

(12) prevention of perinatal transmission[.]; and

(13) the importance of remaining in care to maintain good health and reduce the likelihood of transmission to others, and that if protected individuals appear not to be receiving HIV medical care, health care providers, entities engaged in care coordination or local and state health departments may contact them to help address any challenges or barriers that may be affecting their ability to initiate and remain in care.

\* \* \*

(g) Every individual [between the ages of] age 13 and [64 years] older (or younger [or older] than thirteen 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 in accordance with subdivision (a) of this section 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.

Section 63.4 is amended to read as follows:

Section 63.4 Filing of reports.

(a)(1) All determinations or diagnoses of Human Immunodeficiency Virus (HIV) infection, HIV-related illness and acquired immune deficiency syndrome (AIDS) shall be reported to the [commissioner] 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 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 infection, HIV-related illness and AIDS shall be reported to the [commissioner] 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 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 and reactive nucleic acid 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] Commissioner within 14 days after receipt of a test result or determination.

(4) Laboratories performing tests for screening, diagnosis or monitoring of HIV infection for New York State residents and/or New York State health care providers shall report to the Commissioner cases of 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: any reactive test result from an antigen or antibody [tests or combination of tests indicative of HIV infection,] test performed as an initial screen for HIV infection and the results from all supplemental tests performed to verify HIV infection, all HIV nucleic acid (RNA or DNA) [detection] test results, all CD4 lymphocyte counts and percents 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.

(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] Commissioner, shall be made in a manner and format as prescribed by the [commissioner] Commissioner. For the requesting provider and facility, the following information shall be included: provider and facility name, complete provider and facility address and telephone number, and provider and facility National Provider Identification. 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] individual, 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] Commissioner or [his/her authorized] designated 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] Article 21, [title] Title III. Notwithstanding this subdivision, test results from New York State approved anonymous test sites shall not be reported to the [commissioner] 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] 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] Article 21, [title] 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 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 the contact notification process. Reports and information may be used in the aggregate in programs approved by the [commissioner] Commissioner (1) for the improvement of the quality of medical care provided to persons with HIV/AIDS; [or] (2) 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; or (3) when used for purposes of linkage to and retention in care, in which case the protected individual's individually identifiable health information may be shared among state health departments, local health departments, health care providers as defined in section 63.1(k) of this Part, and entities engaged in care coordination that have a clinical, diagnostic, or public health interest in the patient. For purposes of this section, care coordination shall mean managing, referring to, locating, coordinating, and monitoring health care services for the individual to assure that all medically necessary health care services are made available to and are effectively used by the individual in a

timely manner, consistent with patient autonomy. Care coordination shall be conducted by or with the participation of the individual's health care provider to the extent possible.

[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.]

Paragraphs (16) and (17) of subdivision (a) of section 63.6 are amended and a new paragraph (18) is added to read as follows:

(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[.]; or

(18) qualified researchers for medical research purposes upon the approval of a research protocol by a human research review committee established and approved under the provisions of article 24-A of the Public Health Law or by an institutional review board established and approved under applicable provisions of federal law, for the purpose of reviewing and monitoring research involving human subjects, provided that in no event

shall any qualified researcher disclose information tending to identify the subjects of the research.

Paragraph (1) of subdivision (a) of section 63.8 is amended to read as follows:

(1) Physicians and other persons required to report as provided for in section 63.4 of this Part must indicate on the reporting form whether they have conducted post-test counseling and an assessment of the risk of domestic violence in conformance with a domestic violence screening protocol developed by the [commissioner] Commissioner, whether they plan to undertake contact notification activities, have completed notification of contacts or are making a referral for partner notification assistance to authorized public health officials. If the physician or other mandated reporter chooses to conduct notification, the results of those activities, including information specified by the [commissioner] Commissioner on forms supplied by the [commissioner] Commissioner, or their equivalent, must be forwarded to the appropriate authorized public health official [within 60 days of the initial report], pursuant to section 63.4 of this Part.

Subdivision (b) of section 63.8 is amended to read as follows:

(b) Authorized public health officials shall consider the following as important factors in determining the priority for which cases merit contact notification in order to protect the public health:

(1) reported contacts, including spouses known to the reporting physician or other

diagnostic provider, or who the protected [person] individual wishes to have notified, unless the provider certifies that these known contacts have already been notified; [and] (2) protected [persons] individuals who are newly diagnosed with HIV infection[.]; and (3) protected individuals who were previously diagnosed with HIV infection, and who show evidence of: being out of medical care; not being virally suppressed; recent sexually transmitted diseases; or having recently moved into New York State.

Subdivision (j) of section 63.8 is amended to read as follows:

(j) Municipal health commissioners must provide HIV contact notification services and shall forward to the [department,] Department summary data and all identifiable information related to notification activities upon completion of such activity unless otherwise determined by the [commissioner] 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 three years following completion of such activity] longer than administratively necessary. The Department or local health department shall establish a records retention and disposition schedule for destruction of these records.

Subparagraph (ii) of paragraph (3) of subdivision (m) of section 63.8 is amended to read as follows:

(ii) in a facility regulated, authorized or supervised by the Department of Health, Office of Mental Health, Office [of Mental Retardation and] for People With Developmental Disabilities, Office of Children and Family Services, Office of Alcoholism and Substance Abuse Services, Department of [Correctional Services] Corrections and Community Supervision; or

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

Public Health Law (PHL) § 2786 gives the Commissioner the authority to promulgate regulations concerning the implementation of PHL Article 27-F, which includes PHL § 2781 (HIV related testing), as amended by: section 2 of Part A of Chapter 60 of the Laws of 2014; Section 1 of Part I of Chapter 57 of the Laws of 2015; and Section 1 of Chapter 502 of the Laws of 2016; and which also includes PHL § 2781-a (Required offering of HIV related testing), as amended by Section 2 of Chapter 502 of the Laws of 2016; and which also includes PHL § 2782 (Confidentiality and disclosure), as amended by Chapter 461 of the Laws of 2016. PHL § 2139 gives the Commissioner the authority to promulgate regulations to effectuate the purposes of PHL Article 21, Title 3, which includes PHL § 2135 (Confidentiality), as amended by section 3 of Part A of Chapter 60 of the Laws of 2014.

### **Legislative Objectives:**

Amendments to the existing law increased HIV testing in the State and promote patient linkage and retention in care. Implementing this legislation is critical to identifying HIV-positive New Yorkers and linking them to care. Chapter 502 of the Laws of 2016 allows health care providers to perform HIV tests as part of routine medical care without informed consent from the patient, provided that the patient is advised that an HIV-test will be performed and does not object. Chapter 502 also expands the requirement to offer HIV testing to individuals over the age of 64.

Chapter 461 of the Laws of 2016 allows disclosure of confidential HIV-related

information to qualified researchers for medical research purposes upon the approval of a research protocol under applicable State or federal law.

**Needs and Benefits:**

Effective April 1, 2014 and April 1, 2015, amendments contained in the 2014-15 and 2015-2016 enacted New York State budgets, respectively, and effective November 28, 2016, Chapter 502 of the Laws of 2016 authorized additional changes to HIV offering and testing in New York State. These amendments made HIV testing part of routine medical care and improved linkage and retention to care. The amendments also brought the laws concerning HIV testing into alignment with the Centers for Disease Control and Prevention (CDC) recommendations for routine HIV screening in healthcare settings. Chapter 461 of the Laws of 2016 allows confidential HIV related information to be used and disclosed for research under the requirements of State and federal law that apply to the use and disclosure of other types of protected health information for research purposes.

These regulation amendments implement amendments to the Public Health Law by:

- Removing the requirement for informed consent prior to ordering an HIV-related test, including elimination of written consent for HIV testing in New York State correctional facilities, and removing references to consent forms.
- Adding a provision stating that performing an HIV test as part of routine medical care requires at a minimum advising that an HIV-related test is being performed prior to ordering an HIV-related test.
- Removing the reference to expiration of an individual's informed consent.

- Allowing local and state health departments to share HIV surveillance information with health care providers, including entities engaged in care coordination, for purposes of patient linkage and retention in care.
- Deleting the reference to post-test counseling; rather, reference is made to seven key points of information in Public Health Law Section 2781(3).
- Clarifying language pertaining to reporting by blood and tissue banks.
- Inserting updates to the list of reportable HIV-related test results that need to be reported. These updates are consistent with the CDC and Association of Public Health Laboratories guidance related to the diagnosis of HIV infection. Additionally, reporting of results for NYS residents and NYS-located clinicians is explicitly required. This change was designed to address known gaps in reporting.
- Including language specifically stating that reports must include the requesting provider and facility. The requirement is expected to improve the quality of provider data and lead to more complete data. This should improve accuracy of the Department's surveillance data and consequently, National HIV/AIDS Strategy retention and care measures.
- Removing the requirement that the information on HIV provider reporting forms associated with newly diagnosed cases of HIV infection be reported within 60 days.
- Adding individuals who were previously diagnosed as HIV positive, and who are at elevated risk of transmitting HIV to others, to the contact notification prioritization process.

- Removing the requirement that data on the partners of HIV cases be destroyed after three years, and stating that the Department will establish a policy for “record retention and schedule for disposition.”
- Eliminating the upper age limit of 64 for the offering of HIV testing.
- Allowing the disclosure of HIV related information to qualified researchers in compliance with State and federal law.

**Costs:**

The HIV offering and testing amendments were intended to streamline the process of HIV testing, and may result in an incremental increase in testing acceptance. Associated costs to providers responsible to make the mandatory HIV testing offer may result from the increased acceptance of HIV testing. However, HIV testing costs are fully reimbursable by Medicaid, Medicare, private insurance and third party providers. It is also an allocated expense within the Department of Corrections and Community Supervision. HIV screening for persons aged 15-65 and for all pregnant women is recommended by the U.S. Preventive Services Task Force. Such screening is covered as a preventive service, without cost-sharing by the patient.

**Local Government Mandates:**

The amendment authorizes but does not mandate local and state health departments to share HIV surveillance information with the current health care providers of the patient for purposes of patient linkage and retention in care. There is no additional impact on

local governmental providers of primary care. Procedures are in place for the voluntary process of providers requesting surveillance information of use to them.

**Paperwork:**

No change in reporting paperwork is required for the purpose of sharing surveillance data with current health care providers. Procedures are in place for the voluntary process of providers requesting surveillance information of use to them. As technology advances, updated protocols will be established for the secure receipt of provider inquiries and for appropriate responses to providers.

**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. Regional meetings were held in person and via conference call in Albany, Syracuse, Buffalo and New York City, and were attended by over 550 participants. Input was also solicited from the Healthcare Association of New York State, Greater New York Hospital Association, Medical Society of the State of New York, Community Health Care Association of New York State, New York State Association of County Health Officials, the New York Civil Liberties Union, NYS AIDS Advisory Council, New York City Department of Health and Mental Hygiene and local health departments.

**Federal Standards:**

The rules do not exceed or conflict with any minimum standards of the Federal

government for the same or similar subject.

**Compliance Schedule:**

Upon publication of Notice of Adoption in the State Register.

**Contact Person:**

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**STATEMENT IN LIEU OF  
REGULATORY FLEXIBILITY ANALYSIS  
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS**

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

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

No rural area flexibility analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse impact on facilities in rural areas, and it does not impose reporting, record keeping or other compliance requirements on facilities in rural areas.

**STATEMENT IN LIEU OF  
JOB IMPACT STATEMENT**

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

## ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (NYSDOH) received a total of 36 comments, which all expressed support of the proposed amendments to Part 63 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York.

Comments were received from health care providers, community-based organizations and government stakeholders.

### **Comment:**

Commenters requested that NYSDOH remove all references to “informed consent” for HIV-testing.

### **Response:**

The final regulation removes a reference to informed consent in section 63.3(d) to clarify that during routine medical care, a provider may perform an HIV test by simply advising the individual, or, when the individual lacks capacity to consent, a person authorized to consent to health care for such individual, that an HIV test will be performed, unless the individual objects.

### **Comment:**

Commenters requested that NYSDOH clarify that when a patient lacks capacity to consent, the advisement that an HIV test will be performed should be to the individual authorized to consent to health care for the patient.

**Response:**

NYSDOH agrees that if the patient lacks capacity to consent, the health care provider must advise the person authorized to consent to health care for the patient. The final regulation includes that clarification in section 63.3(a).

**Comment:**

Commenters suggested that the regulation uses the terms “protected individual” or “individual” to refer to the patient, consistent with the definition in Public Health Law section 2780(6) and 10 NYCRR section 63.1(g).

**Response:**

NYSDOH agrees, and the final regulation adopts this convention in most instances. The regulation does, however, still use the word “patient” in a few instances where the word is more appropriate in context.

**Comment:**

The existing regulation requires that a person who orders an HIV test provide the laboratory with information specified by NYSDOH. NYSDOH requires that such information include the protected individual’s addresses and date of birth. One commenter suggested that NYSDOH incorporate this requirement explicitly in the regulation.

**Response:**

NYSDOH accepts this recommendation. In the final regulation, in section 63.3(a), the word “address” has been replaced with “addresses and date of birth.”

**Comment:**

One commenter requested that the regulation not restrict how providers explain the seven key points under Public Health Law section 2781(2) when ordering an HIV test.

**Response:**

NYSDOH accepts this recommendation. In the proposed regulation, the phrase “through electronic, written or oral means” was intended to allow the explanation of the seven key points through any means. The final regulation deletes this phrase to clarify that providers are not limited in how they may explain the seven key points, so long as the provider does in fact provide the explanation.

**Comment:**

As reflected in the proposed regulation, during routine care, a health care provider may not perform an HIV test over the patient’s objection. The Public Health Law, however, provides for court-ordered HIV testing in certain cases. One commenter suggested language to clarify that the regulation allows an HIV test over the objection of the individual being tested pursuant to law and regulation.

**Response:**

NYSDOH agrees with this comment. The final regulation adds the words “except as authorized or required by law” to section 63.3(a) and 63.3(b)(7).

**Comment:**

One commenter suggested minor changes to the wording of the requirements for post-test counseling of persons who test HIV-positive. The commenter asked that the regulation specify that the term “social services” includes public benefits, in relation to discrimination. The commenter also suggested a minor change in the wording of the requirement to inform individuals that providers may contact them for purposes of linkage and retention in care.

**Response:**

NYSDOH accepts these suggestions. The final regulation makes minor changes to the wording of section 63.3(e)(2) and section 63.3(e)(13).

**Comment:**

In section 63.8(j), the proposed regulation states that NYSDOH shall establish a records retention and disposition schedule for the destruction of information identifying a contact collected in the course of contact notification activities, rather than the current requirement of destruction within three years. A local health department (LHD) suggested that the regulation should allow LHDs to establish their own records retention and disposition schedules.

**Response:**

The intent of the proposed regulation was to allow the government agency that maintains the records to establish its own records retention and disposition schedule. Accordingly, the final regulation clarifies that where an LHD maintains the records instead of NYSDOH, the LHD may establish its own records retention and disposition schedule.

**Comment:**

One commenter suggested amending 63.4(a)(2) to add reporting for “all results of a diagnostic algorithm interpreted as positive for HIV antibody and/or HIV nucleic acid” and amending 63.4(a)(4) to add “reporting of the nucleotide sequence.”

**Response:**

The “diagnostic algorithm” referenced in the commenter’s suggested language is recommended by the Centers for Disease Control and Prevention (CDC), the Association of Public Health Laboratories, and the U.S. Food and Drug Administration (FDA) for initial patient screening and diagnosis. It is not recommended for screening blood or organ donors for HIV infection, which is the basis for the reporting requirement in Section 63.4(a)(2). The suggested language for section 63.4(a)(4) is also unnecessary, because the Commissioner can designate a different reporting format if HIV molecular testing technology changes. Accordingly, NYSDOH did not make any changes in response to this comment.

**Comment:**

Commenters suggested that the proposed amendment to Part 63 authorizes sharing of incarcerated patient data with outside organizations without limiting language ensuring privacy. Additionally, the commenter expressed concern over eliminating the “informed consent” requirement for HIV testing for incarcerated individuals, related to confidentiality.

**Response:**

The regulation involves minimal risk to confidentiality. Incarcerated individuals are treated the same as non-incarcerated individuals. No changes were made to the regulations in response to these comments.

**Comment:**

One commenter expressed concerns about the elimination of verbal notification that an HIV test will be performed.

**Response:**

At a minimum, patients must be orally advised that HIV testing will be conducted, and patients always have the right to decline the test. If the health care provider wishes, the provider may obtain consent to an HIV test in writing, in which case verbal notification is not required.