HIV Testing, Reporting and Confidentiality in New York State 2023 Update: Fact Sheet and Frequently Asked Questions New York State Department of Health AIDS Institute

New York State Public Health Law (PHL) related to HIV testing has evolved over the years to keep pace with changes in the epidemic and clinical practice. Key provisions were enacted in 2010, 2014, 2015 and 2016 and comprehensive updated *HIV/AIDS Testing, Reporting and Confidentiality of HIV-Related Information* regulations were finalized and published in the New York State Register on May 17, 2017.

The following changes were adopted and posted in the New York State Register on March 22, 2023:

- 1. Reducing the timeframe for reporting of new HIV diagnoses from 14 days to 7 days;
- 2. Requiring the reporting of every case of acute HIV within 24 hours of diagnosis;
- 3. Requiring the reporting of the results of HIV testing done for purposes of insurance underwriting decisions by the clinician under whose medical license the HIV-testing was ordered.

This document includes all developments since 2010 and represents the current regulatory landscape. Note: 2023 updates are highlighted by being placed in boxes in this document.

How to use this document:

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1. The Requirement to Offer HIV Testing as a Routine Part of Health Care

HIV testing must be offered at least once as a routine part of health care to all patients age 13 or older receiving primary care services at an outpatient clinic or primary care services from a physician, physician assistant, nurse practitioner or midwife.

In order to identify cases of HIV infection among people who are not engaged in regular primary care services, the law also requires that hospitals offer HIV testing to all inpatients and persons seeking services in emergency departments with the following exceptions:

- When the individual is being treated for a life threatening emergency;
- When the individual has previously been offered or has previously been tested for HIV (unless otherwise indicated due to risk factors);
- When the individual is comatose or determined by the attending provider to lack mental capacity to consent.

IMPORTANT POINTS:

- NYS Public Health Law mandates the <u>offer</u> of HIV testing to all patients age 13 or older.
- The 2016 amendments to the NYS Public Health Law removed the previous upper age limit of 64.
- The offer of HIV testing is most effective when it is presented as a clinical recommendation of the health care provider.
- The offer of HIV testing must be documented in the patient medical record.

HIV Testing Toolkit: Resources to Support Routine HIV Testing for Adults and Teens

The New York State Department of Health (NYSDOH) developed a toolkit for primary care providers that contains all of the resources needed to meet New York State clinical guidelines and legal requirements for offering voluntary, routine HIV testing as a part of health care to all patients aged 13 and older. Please click to access the <u>HIV Testing Clinician's Toolkit</u>.

Updated HIV Diagnostic Testing Algorithm

The HIV Diagnostic Testing Algorithm is a multi-test algorithm, incorporating tests that detect HIV antigens, antibodies and RNA. The final interpretation is based on a combination of test results. All preliminary positive HIV rapid test results <u>must</u> be confirmed through additional testing performed at a clinical laboratory. More information can be found at: <u>https://www.hivguidelines.org/hiv-testing-acute-infection/hiv-testing/#tab_3</u>

FAQ 1: How often does the offer of HIV testing need to be repeated?

In addition to offering HIV testing once in the course of routine care, testing should be offered annually to patients whose behavior indicates elevated risk. In order to promote early identification, HIV testing may be offered as frequently as every three months to patients with identified risk behaviors. Since many people choose not to disclose their risk behaviors, providers should consider adopting a low threshold for recommending HIV testing.

FAQ 2: Which health care facilities and health care providers are impacted by the requirement to offer HIV testing?

HIV testing must be offered in the following health care settings:

- Primary care services in diagnostic and treatment centers (including school-based clinics and family planning sites)
- Primary care services in outpatient departments of hospitals
- Inpatient departments of hospitals
- Emergency departments

HIV testing must be offered by physicians, physician assistants, nurse practitioners or midwives who provide primary care, or their representatives, regardless of setting. Primary Care means the medical fields of:

- Family medicine
- General pediatrics
- Primary care
- Internal medicine
- Primary care obstetrics/gynecology

FAQ 3: Does the offer of HIV testing apply to nursing homes, college health services, retail clinics, urgent care centers, employee health services or STD clinics that provide primary care? Yes. Even though these facilities are not specifically mentioned in the law, if primary care is being provided by a physician, physician assistant, nurse practitioner, or midwife, they are required to make the offer regardless of board certification of the practitioner or setting where primary care is provided.

FAQ 4: If I am unsure, how can I determine if my facility is covered by the law?

The important thing is to consider what your facility does rather than what your facility is called. For instance, an urgent care center that offers many or all of the services available at a family physician's office would be considered a primary care provider. However, there are diagnostic and treatment centers that are restricted to ambulatory surgery, and these would not be covered by the mandated testing offer provision since they do not offer primary care.

FAQ 5: How do the latest changes in regulations pertaining to HIV testing impact HIV testing practices in prenatal and maternity settings?

New York's regulatory framework for preventing perinatal transmission of HIV has proven highly effective and remains unchanged. The 2016 updates to HIV testing do remove the requirement to obtain consent for HIV testing in writing or orally (see <u>Section 2</u>). All pregnant people must be offered HIV testing as a clinical recommendation as early as possible during pregnancy. Third trimester testing is recommended for all pregnant people in NYS who tested negative for HIV earlier in their pregnancy. When being offered HIV testing, the individual should be provided the key points of information and informed of their right to decline the test (see Section 3). Pregnant people who are diagnosed as living with HIV should be linked to treatment as soon as possible to protect their health and prevent transmission of HIV to the newborn. Pregnant people who present to the labor/delivery setting with no history of HIV testing during their current pregnancy should be counseled with the recommendation for HIV testing. If the birthing parent declines testing in labor/delivery, they should be informed that the newborn will be tested immediately at birth without their consent. All newborns, including those tested at birth, are routinely tested for HIV through the New York State Newborn Screening Program. Documentation of the individual's prenatal HIV testing should be forwarded to the delivering hospital and a copy of the HIV test history results should be placed in the newborn's medical record to ensure administration of medications during labor/delivery and initiation of medication to the infant for the first four-six weeks of life or until the infant is definitively excluded from HIV infection. To access the latest regulations visit: https://regs.health.ny.gov/content/section-40521-perinatal-services

FAQ 6: As a patient, what do I do if I am not offered an HIV test?

If you are not offered an HIV test by a health care provider covered by the law or their representative, you should bring it to the attention of that provider and ask for a test or an explanation for why the offer was not made. If you believe your health care provider is not complying with the law, email your name and contact information, the name of the provider, and whatever details you think would be helpful to <u>hivtestlaw@health.ny.gov</u> and the situation will be reviewed. Or, you can complete the patient complaint form found at <u>http://www.health.ny.gov/forms/doh-4299.pdf</u> and submit it to the address indicated on the form.

2. Removal of Requirement for Written or Oral Patient Informed Consent to HIV Testing

Effective November 28, 2016, amendments to the New York State Public Health Law removed the requirement for written or oral 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. The objective of the update is to eliminate barriers to HIV testing and make HIV testing comparable to the manner in which other important laboratory tests are conducted. HIV testing remains voluntary and patients have the right to refuse an HIV test, but obtaining written or oral consent for testing is no longer required in any setting. At a minimum, patients must be advised orally that an HIV test is going to be performed. If the patient objects to the HIV test, this must be noted in the patient's medical record. HIV test requisition forms submitted to laboratories do not require provider certification of informed consent.

IMPORTANT POINTS:

- As part of the HIV testing process, patients must be provided information about HIV as defined by Public Health Law. See <u>Section 3</u> for details. Information may be provided orally, in writing, through office signage or in any other patient-friendly audio-visual format.
- If the patient declines the offer of an HIV test, this must be noted in the patient's medical record.
- For patients diagnosed as living with HIV, the health care provider administering testing must arrange, with the consent of the patient, an appointment for HIV medical care. Simply providing the name of a care provider is not sufficient. A specific appointment with a provider who offers HIV care must be provided (see <u>Section 4</u> for details).

2023 Update: Obtaining Written Informed Consent for HIV Testing Performed for Insurance Underwriting Purposes and Reporting of Such Results

The 2023 update to HIV testing regulations mandates that tests performed for insurance underwriting purposes be reported when they indicate a diagnosis of HIV or AIDS.

- 1. It is important to note that regulations regarding the conduct of HIV testing for insurance purposes are outlined in New York Insurance Law Sec. 2611, not Public Health Law.
- 2. The 2023 update does not change the informed consent procedure for these tests.
- 3. The 2016 updates to public health law that removed the requirement for written informed consent apply to HIV testing as part of routine health care, but do not apply to HIV testing for purposes of insurance underwriting decisions.
- 4. Health care providers conducting HIV testing for insurance purposes <u>must obtain patient written</u> <u>informed consent</u> before conducting an HIV test.

FAQ 7: The goal of the NYSDOH is to streamline the process of HIV testing and make it similar to how other important laboratory tests are conducted. What are some approaches that health care facilities may implement to simplify the process of HIV testing and increase the number of people aware of their HIV status?

While consent no longer has to be obtained orally or in writing, it is standard practice that health care facilities provide services in accordance with patient consent. At a minimum, patients must be orally informed that HIV testing is going to be conducted and have the right to decline an HIV test. Below are two different ways that health care facilities can operationalize HIV testing in a manner that meets or exceeds the minimum requirement of the law:

 A member of the care team orally informs the patient that HIV testing will be conducted. Key points of information, including informing the patient that they may decline an HIV test, may be provided orally, in writing, electronically, through office signage or in any other patient-friendly audio-visual method. If the patient objects, the HIV test would not be conducted and the patient objection must be noted in the patient's medical record. 2. The health care facility may include an explanation that HIV testing is routinely conducted in the general medical consent statement that is signed to authorize treatment during the visit. If the patient signs a general medical consent that includes informing the patient about HIV testing, they have effectively been informed of the test and provided consent. This would exceed the minimum requirement of the law (i.e. that a patient be advised orally than an HIV test is going to be performed) but may serve as an efficient manner to operationalize HIV testing in some health care facilities. Key points of information, including informing the patient that they may decline an HIV test, may be provided orally, in writing, electronically, through office signage or any other patient-friendly audio-visual method. If the patient objects, the HIV test would not be conducted and the patient objection must be noted in the patient's medical record.

In cases where the patient declines HIV testing, it would be good practice for the health care provider to inquire about the reason and take the opportunity to address these concerns and explain the clinical benefits of every person knowing their HIV status. Health care facilities should have policies and procedures in place to ensure that if a patient objects to the test, that HIV testing is not conducted.

FAQ 8: Do the consent procedures in the law apply to tests used for monitoring HIV disease progression or treatment such as viral load, CD4 count, or HIV resistance tests? No. The law applies specifically to testing that is being performed for the initial diagnosis of HIV infection. The law does not apply to tests used for monitoring HIV disease progression or to assess treatment effectiveness.

FAQ 9: New York State Public Health Law has, since early in the epidemic, allowed minors to consent to their own HIV test, without parental involvement. How does the removal of the requirement of written or oral consent for HIV testing impact HIV testing of minors? The intent of recent amendments to the Public Health Law is to facilitate routine HIV testing for all persons age 13 and older. Minors have the ability to consent to the HIV test without parental/guardian involvement and must be provided the required information about HIV and afforded the right to object to an HIV test. Amendments to the NYSDOH regulations in 2017 allow minors to consent to HIV treatment as well as preventive services. For more information, see <u>Section 5</u>.

3. Information to Be Provided to the Patient Prior to an HIV Test

Prior to conducting diagnostic HIV testing, information about HIV must be provided orally, in writing, through signage or in any other patient-friendly audio-visual format. Placing the NYSDOH <u>HIV testing clinic poster</u> in a visible location or providing patients with the NYSDOH <u>patient brochure on HIV testing</u> are simple ways of conveying this information to patients. The key points of information that must be provided are:

- HIV testing is voluntary and all HIV test results are confidential (private);
- HIV can be transmitted through unprotected sex, sharing needles, childbirth or breastfeeding;
- Treatment for HIV is very effective, has few or no side effects and may involve taking just one pill once a day;
- Partners can keep each other safe by knowing their HIV status and getting HIV treatment or taking HIV pre-exposure prophylaxis (PrEP). Not sharing needles and practicing safer sex will help protect against HIV, hepatitis C and other STDs.
- It is illegal to discriminate against a person because of their HIV status and services are available to help address discrimination;
- Anonymous HIV testing (without giving your name) is available at certain public testing sites;
- HIV testing is a routine part of health care but you have the right to decline an HIV test. Testing will not be performed if you object. If you wish to decline HIV testing, inform the health care provider.

FAQ 10: How are the key points of information provided to patients who may be unconscious or comatose?

In cases where the patient is unconscious or comatose, the <u>Family Health Care Decisions Act</u> (FHCDA) has provisions which allow a surrogate to make treatment decisions. Clinicians should follow their facility's policies and procedures regarding the FHCDA. The surrogate would have authority to make decisions about HIV testing and should be provided points of information about HIV, including that testing will not be performed over the surrogate's objection.

4. Post-Test Counseling and Requirements to Link Newly Diagnosed Patients to HIV Care

<u>When testing indicates a diagnosis of HIV infection</u>, the person ordering HIV testing or their representative must provide the patient the final interpretation of diagnostic testing, and, with the patient's consent, schedule an appointment for follow-up HIV medical care.

IMPORTANT NOTE: A person with laboratory evidence of acute or early HIV infection (i.e. detectable HIV antigen and virus, but no evidence of HIV antibodies) has a high likelihood of passing the virus to sexual or needle sharing partners and should be counseled about how to avoid passing the virus to others. The **Medical Provider HIV/AIDS and Partner/Contact Report Form (PRF) (DOH-4189)**, must be submitted within 24 hours of diagnosis of acute HIV. See <u>section 7</u> for more information.

Patient education should be provided that addresses:

- That the diagnosis means the person is living with HIV, a lifelong health condition;
- That people can live a healthy life with HIV. HIV treatment is effective, has few or no side effects and may involve taking just one pill once a day;

- That financial assistance is available, if needed, for HIV medical care and HIV medications;
- That the patient can pass HIV to sexual or needle sharing partners and strategies for avoiding transmission; including information about mother to child transmission;
- The importance of notifying sexual or needle sharing partners to prevent further transmission and to promote access of exposed persons to HIV testing, health care and prevention services;
- The range of partner notification options and available partner services programs;
- That names and other information about the patient is not shared during the partner notification process;
- That all cases of HIV infection are reported to the NYSDOH;
- That known contacts, including a known spouse, are reported to the NYSDOH;
- The risk of domestic violence and performance of domestic violence screening using the NYSDOH-approved <u>domestic violence screening protocol</u>;
- That HIV-related information is confidential; information may be shared with medical providers to provide needed care but may not be shared with others without patient authorization to release confidential HIV-related information;
- That a minor who has been diagnosed with HIV may consent to their own HIV treatment (if applicable);
- That patient <u>authorization to release confidential HIV-related information</u> may be revoked at any time;
- That discrimination against persons with HIV in the areas of employment, housing, public accommodations, health care and social services is prohibited by law;
- That if a person with HIV appears to be out of care, they may be contacted by the medical provider or health department staff to address barriers to entry into care and promote engagement in care.

IMPORTANT INFORMATION: Undetectable equals Untransmittable (U=U): There are many important reasons to start HIV treatment as soon as possible. In addition to getting treatment to support their own health, a person living with HIV who is on HIV treatment and virally suppressed for 6 months or longer has effectively no risk of passing HIV to a partner through sex.

<u>A person who tests negative for HIV infection must be informed of the result and provided</u> information concerning the risk of acquiring HIV through sexual and needle sharing activities. Pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) should be discussed as prevention options. This information may be in the form of written materials such as the NYSDOH document titled *Information for Patients with a Negative HIV Test Result* available in <u>English</u> or <u>Spanish</u>. The negative test result and required information do not need to be provided in person. Other mechanisms such as email, mail, and phone may be used as long as there is an established protocol. Alternative methods of delivering results must be discussed with the patient. It is not appropriate to tell patients that if they are not contacted, they may assume their test was negative.

Patients with potential recent exposure to HIV present diagnostic challenges due to the "window period," or the length of time after infection that it takes for antibodies or the virus to be detected by HIV diagnostic tests. More information about the window period for various types of tests can be found at https://www.hivguidelines.org/hiv-testing-acute-infection/hiv-testing-acute-infection/hiv-testing/#tab_2. Clinicians should be familiar with the testing process used by the laboratory conducting testing for their patients because recommendations for retesting patients with recent exposure will vary depending on the test used.

<u>A person with inconclusive or incomplete HIV diagnostic testing results</u> (i.e. when the HIV Diagnostic Testing Algorithm did not produce an overall valid or conclusive result) must be informed that the test result was inconclusive or incomplete and have an additional specimen collected as soon as possible. In these cases, the entire algorithm should be repeated. More information is available at <u>https://www.hivguidelines.org/hiv-testing-acute-infection/hivtesting/#tab_3</u>

The NYSDOH may be able to assist if you have difficulty locating a patient in need of additional testing to resolve inconclusive HIV diagnostic testing. See <u>Section 9</u> of this document for more information, including how to contact partner services programs throughout NYS. For additional information visit: <u>www.health.ny.gov/diseases/communicable/std/partner_services</u>

FAQ 11: To meet the requirement to arrange follow-up care for a patient newly diagnosed with HIV, is it sufficient to simply provide the name of a local HIV care provider?

No, the law specifies that the health care provider who ordered testing is responsible for providing or arranging for an appointment for follow-up HIV care. This means that an actual appointment date and time scheduled as soon as possible should be provided. It is considered the gold standard for a newly diagnosed person to begin HIV treatment on the same day. While that may not always be possible, it is ideal for people to begin treatment within three days and in no case should it take longer than thirty days to begin treatment. A best practice is for HIV testing providers to have formal or informal agreements with HIV clinical providers to promote a "warm handoff" of patients to HIV clinical care in a timely fashion. Every reasonable effort should be made to link persons who are newly diagnosed with HIV to health care, prevention, supportive services and partner services. If you are having difficulty making an appointment for a patient, contact Charles Gonzalez, MD at <u>Charles.Gonzalez@health.ny.gov</u>.

Q 12: Does the appointment need to be with an Infectious Disease Provider or HIV Specialist?

The law does not specify the clinician specialty. The NYSDOH website includes contact information for Designated AIDS Centers and other resources to help identify providers and health care facilities offering HIV care. Visit the AIDS Institute's <u>Provider Directory</u>.

FAQ 13: Is the health care provider who conducted the test responsible for confirming that the patient attended the appointment for follow-up HIV care?

The law requires that the patient's medical record must document the name of the provider/facility with whom the appointment was made but does not require that the HIV testing provider document that the appointment was kept. However, best practice, in support of ending the epidemic, would be to establish a protocol that includes confirmation of the individual's attendance at the initial appointment.

5. Expansion of Minor Consent for HIV Treatment and Preventive Services

2017 amendments to the NYSDOH's regulations allow minors to consent to their own HIV treatment and HIV preventive services such as pre-exposure prophylaxis (PEP) and post-exposure prophylaxis (PEP) without parental/guardian involvement (10 NYCRR Part 23). Part 23 has long established the legal capacity of minors to consent to treatment and preventive services for sexually transmitted diseases (STDs). Provisions in Part 23 require that the Commissioner of Health promulgate a list of STDs. The 2017 amendments to 10 NYCRR Part 23 added HIV to the list of STDs, thereby bringing minor capacity to consent to HIV treatment and preventive services on par with other STDs. In addition, under Part 23, medical or billing records may not be released or made available to the parent or guardian without the minor patient's permission.

After being diagnosed, young people currently face barriers that can prevent or delay access to care, including denial and fear of their HIV status, misinformation, HIV-related stigma, low self-esteem, lack of insurance, homelessness, substance use, mental health issues, and lack of adequate support systems. Because of these factors, many young people need the ability to consent to their HIV treatment. Updates to the regulation help ensure that more young people have optimal health outcomes and prevent transmission of HIV to others. In addition, minors will now have the ability to consent to HIV-related preventive services, including PrEP and PEP just as they can consent for other reproductive or sexual health-related services.

FAQ 14: Does the change in the NYSDOH Regulations mean that clinical providers must not seek to engage the parents or guardians of a minor in the minor's HIV health care or HIV prevention decisions?

The change in regulations means that minors have the ability to consent to their own HIV treatment and prevention services, without the involvement of a parent or guardian. Clinical providers may, over time, discuss with their minor patients opportunities for parental or guardian involvement in these decisions, including exploring with the young person the potential benefits of parental or guardian involvement. However, decisions about the involvement of a young person's parent or guardian must be left to the young person. Clinical providers should maintain a high level of sensitivity to the concerns of the young person regarding potential negative consequences of involvement of a parent or guardian. Discussions

about whether to involve a parent or guardian should never result in a delay in starting HIV treatment or prevention services.

FAQ 15: If a young person does not want their parent(s) or guardian(s) to be informed that they are taking PrEP or PEP, what can be done to stop the explanation of benefits form (EOB) from being sent to the parent's address?

Minors may contact the health care plan and request that an alternative address be used when issuing an EOB for services provided to the adolescent patient. The minor, with assistance from a health or support services provider when possible, should contact the health plan to determine what procedures or forms are required to request an address change. Furthermore, minors should make this request before seeking billable health care services in order to allow enough time for the health plan to make the necessary changes to their information system. In some situations, the minor may list the health care provider's address as the alternative address for EOB notifications. Minors should be advised that Insurance Law §3234(c) allows the primary policyholder to demand an EOB even if one is not required. Adult children who are covered by their parents' insurance plan as well as other adults who are concerned about, or at risk of, retaliation from their partner or spouse may also wish to redirect EOBs. Insurance Law §2612(h)(2)(A) and 11 NYCRR 244.3 provide protections for the redirection of communications from health plans for victims of domestic violence.

FAQ 16: What can providers communicate to minors who consent to PrEP or PEP about their ability to access financial assistance to pay for PrEP and PEP?

Regardless of age, many people benefit from assistance with navigating payment for PrEP or PEP. This is especially true for minors. Health and support services providers working with a minor interested in PrEP should seek to connect the patient to a PrEP specialist in the community whenever possible. Providers working with minors around PrEP may direct these young people to a local sexual health Clinic or STD Clinic that offers PrEP. Minor patients of these clinics have the right to request that their insurance plans not be billed for services and may have access to services on a sliding fee scale. Medicaid will cover the cost of PrEP but prior approval may be required. Minors who are covered by private insurance may need assistance determining how their plan covers the various expenses of PrEP.

Minors who follow the directions outlined in FAQ 15 (see above) can take steps to avoid having EOBs sent to their parents. Minors have access to assistance from the New York State PrEP Assistance Program (PrEP-AP) which covers the cost of health care appointments and lab work when these services are accessed through a provider registered with PrEP-AP. The Gilead Co-Pay Coupon and Medication Assistance Program are not available to minors but other patient assistance programs may be available to minors. For a complete review of resources related to paying for PrEP, please review the NYSDOH <u>Payment Options for PrEP</u>. To be effective, PEP must be initiated as soon as possible. Initiation of PEP should not be delayed in order to make arrangements for payment. Minors who are victims of sexual assault should be directed to the

emergency room and are eligible for assistance from the NYS Office of Victim Services. For a complete description of payment options, please review the NYSDOH <u>Payment Options for PEP</u> <u>Following Non-Occupational Exposures Including Sexual Assault</u>.

6. Documentation Requirements

According to the Public Health Law, the following elements pertaining to HIV testing must be documented in the patient medical record:

- The patient was advised that HIV testing is being done;
- If the patient declines the HIV test;
- For patients with confirmed HIV infection, the name of the provider/facility with whom the follow-up appointment was made.

FAQ 17: Is it acceptable to use drop-down boxes or checklists in electronic health records to meet the documentation requirements for advising the patient that HIV testing is being done?

Yes. Drop down boxes or checklists are acceptable. HIV testing documentation requirements are not intended to create undue burden on health care providers or facilities. Similarly, brief statements such as "Patient advised that HIV testing will be conducted" or "Patient declined HIV testing" are sufficient to meet documentation requirements.

FAQ 18: Does the inclusion of the HIV test result in the medical record meet the requirement of advising the patient that HIV testing is being done?

No. Having the test result in the record does not indicate that the patient was advised of the HIV test. Including the test result in the medical record is considered standard practice, separate from the requirement of documenting that the patient was advised of the test.

7. Health Care Provider HIV Reporting Requirements

2023 Update to HIV Reporting Requirements

The **Medical Provider HIV/AIDS and Partner/Contact Report Form (PRF) (DOH-4189)**, must be submitted:

- <u>within 24 hours of diagnosis of acute HIV</u>, including primary HIV infection, acute retroviral syndrome, and early HIV infection.
- within 7 days of all other initial diagnosis of HIV, HIV illness, or AIDS diagnoses.
- HIV-testing conducted in the context of insurance institution underwriting decisions is required to be reported to NYSDOH by clinicians under whose medical license the HIV-testing is ordered.

Details are provided below.

New York State Public Health Law Article 21 requires the reporting of persons with HIV and AIDS to the NYSDOH. The law also requires that reports contain the names of sexual or needlesharing partners known to the medical provider or whom the patient wishes to have notified. Under the federal HIPAA Privacy Rule, public health authorities have the right to collect or receive information "for the purpose of preventing or controlling disease" and in the "conduct of public health surveillance..." without further authorization. This provision of HIPAA regulations authorizes medical providers to report HIV/AIDS cases to the NYSDOH or the New York City Department of Health and Mental Hygiene (NYCDOHMH) without obtaining patient permission.

The **Medical Provider HIV/AIDS and Partner/Contact Report Form (PRF) (DOH-4189)**, must be submitted <u>within 7 days</u> of diagnosis for persons with the following diagnoses or with known sex or needle-sharing partners:

- Initial/New HIV diagnosis First report of testing documenting HIV diagnosis; acute cases of HIV must be reported within 24 hours.
- **Previously diagnosed HIV (non-AIDS)** Applies to a medical provider who is seeing the patient for the first time.
- Initial/New diagnosis of AIDS Including <200 CD4 cells/mm³ or an opportunistic infection (AIDS-defining illness).
- **Previously diagnosed AIDS** Applies to a medical provider who is seeing the patient for the first time.
- Known sex or needle-sharing partners of persons with diagnosed HIV infection.

Clinicians seeing for the first time a patient previously diagnosed with HIV or AIDS should report to the NYSDOH using the PRF. The rationale is that this is often the only indication the NYSDOH receives of a patient new to New York, but not newly diagnosed, and perhaps not in need of extensive Health Department Partner Services. Additionally, particularly for the well suppressed patient who moves into NYS, the report by the clinician can be the only indication that the person is in fact HIV positive.

Information regarding electronic reporting via the HIV/AIDS Provider Portal (see below) or paper forms is available from the NYSDOH at **518-474-4284;** clinicians located in NYC, call **212-442-3388.** In order to protect patient confidentiality, faxing of reports is not permitted.

HIV/AIDS Provider Portal

The HIV/AIDS Provider Portal is an electronic system which enables clinicians to:

- 1. meet their reporting requirements electronically;
- 2. provide a mechanism for clinicians statewide to notify the NYSDOH that a patient needs linkage to Health Department Partner Services; and,
- 3. submit inquiries for patients with diagnosed HIV infection who are thought to be in need of assistance with linkage to or retention in HIV medical care.

A NYSDOH Health Commerce System (HCS) Medical Professionals account is required. After logging into the HCS at https://commerce.health.ny.gov/, select "Refresh My Applications List" on the left side and then under "My Applications" select *HIV/AIDS Provider Portal*. Follow the prompts to set up an account. For detailed directions on how to set up an account on the HIV/AIDS Provider Portal, click <u>here.</u>

FAQ 19: The 2023 update specifies that cases of acute HIV infection be reported within 24 hours. What is the rationale for this change?

It is a public health priority that persons with diagnosed acute or early HIV infection are offered timely partner services to ensure the individual is linked to HIV treatment, and their sexual or needle-sharing contacts are tested/treated for HIV to prevent transmissions and outbreaks. Initiation of antiretroviral therapy (ART) during the early stage of HIV infection can benefit individuals and reduce HIV transmission. Treatment of acute and early HIV infection with combination ART improves laboratory markers of disease progression. Data also suggest that treatment of acute HIV infection might decrease the severity of acute disease, lower the viral set point, slow disease progression rates in the event therapy is stopped, reduce the size of the viral reservoir, and decrease the rate of viral mutation by suppressing viral replication and preserving immune function. Because very high levels of virus in blood and genital secretions increase infectiousness during and immediately after acute HIV infection, initiating treatment during acute infection can also reduce the risk of HIV transmission substantially.

Acute HIV infection is the earliest stage of HIV disease, and it precedes the development of detectable antibodies to HIV resulting from the viral infection. A report of acute HIV infection must include the basis for the determination or diagnosis, which is: (i) laboratory testing results demonstrating the presence of p24 antigen and HIV virus (RNA or DNA), in the absence of HIV antibodies; and/or (ii) clinical evidence of documented negative testing history which includes previous negative or indeterminate test results within 180 days before the first confirmed positive HIV test result of any type.

For information about laboratory diagnosis and clinical management of cases of acute HIV, please visit <u>https://www.hivguidelines.org/hiv-testing-acute-infection/acute-hiv/#tab_0</u>.

FAQ 20: What guidance is available for notifying partners of people newly diagnosed as living with HIV?

New York State Public Health Law requires that medical providers talk with HIV-diagnosed individuals about their options for informing their sexual and needle-sharing partners that they may have been exposed to HIV. The *HIV Testing Toolkit: Resources to Support Routine HIV Testing for Adults and Teens* contains guidance and resources about talking to your patients about HIV testing. Additionally, the NYSDOH Partner Services program or NYC Health Department Contact Notification Assistance Program provides assistance to people living with HIV and medical providers who would like help notifying partners. See <u>Section 9</u> of this document for more information, including how to contact partner services programs throughout NYS.

FAQ 21: How has the 2016 update impacted reporting by blood and tissue banks?

As in the past, blood and tissue banks are required to report confirmed positive HIV antibody test results. The 2016 update includes the requirement to report reactive nucleic acid tests.

8. Laboratory Reporting Requirements

Laboratory reporting of suspected or confirmed positive findings or markers of HIV infection is mandated under New York State Public Health Law. Guidance has been prepared in an effort to assist permitted clinical laboratories and blood banks in meeting their obligations to report HIV-related laboratory test results, as well as other communicable disease markers. The guidance is available on the Wadsworth Laboratory <u>website</u>.

HIV laboratory reporting is an essential source of information for New York's HIV surveillance efforts and maintaining high quality, complete data is critical to tracking progress toward National HIV/AIDS Strategy retention and care measures and NY's effort to end the epidemic. To keep pace with advances in HIV care, testing technologies and disease monitoring, there have been some important changes to HIV laboratory reporting requirements. Laboratories and blood/tissue banks performing tests for screening, diagnosis or monitoring of HIV infection for NYS residents and/or NYS health care providers (regardless of patient residence) must report the following laboratory tests or series of tests used in the diagnosis of HIV infection:

- All reactive/repeatedly reactive initial HIV immunoassay results AND all positive, negative or indeterminate results from all supplemental HIV immunoassays performed under the second or third step in the diagnostic testing algorithm, including HIV-1/2 antibody differentiation assay, HIV-1 Western blot, HIV-2 Western blot or HIV-1 Immunofluorescent assay;
- All HIV nucleic acid (RNA or DNA) detection tests (qualitative and quantitative), including tests on individual specimens for confirmation of nucleic acid-based testing (NAT) screening results;
- All CD4 lymphocyte counts and percentages, unless known to be ordered for a condition other than HIV;
- HIV genotypic resistance testing via the electronic submission of the protease, reverse transcriptase and integrase nucleotide sequence;
- Positive HIV detection tests (culture, P24 antigen).

All HIV-related laboratory reporting, including by NYC providers and for NYC residents, must be made directly to the NYSDOH, submitted electronically via the NYSDOH Electronic Clinical Laboratory Reporting System (ECLRS).

To improve the quality of data, and in keeping with changes that allow for enhanced use of surveillance data to improve linkage and retention in care, laboratories are required to report

results using patient identifying, demographic and locating information, as well as the requesting provider and facility ordering the lab test. The 2016 update requires that when labs report HIV-related test results, the following information must be included:

- Patient name, date of birth, and other identifying information;
- Patient demographic information (e.g., sex at birth, race/ethnicity, etc.);
- Patient address and telephone number;
- Provider ordering the test and facility name;
- Complete provider and facility address and telephone number;
- Provider and facility National Provider Identification.

For a complete list of this information and instructions on how to report required data elements, please call 518-474-4284 or contact <u>BHAELab@health.ny.gov</u>.

FAQ 22: NYS has required specific statements regarding disclosure of HIV-related information on the laboratory report. Are these statements still required?

A statement regarding re-disclosure of HIV-related information under 10 NYCRR Section 63.5 is no longer required on reports of test results because the lab report is necessary to provide appropriate care or treatment.

FAQ 23: Do the updates to law change any of the existing requirements for reporting preliminary positive HIV testing results?

Yes. As stated above, clinical laboratories or blood/tissue bank are required to report results from tests approved for use within the diagnostic testing algorithm, including reactive/repeatedly reactive initial HIV immunoassay results AND all positive, negative or indeterminate results from all supplemental HIV immunoassays (HIV-1/2 antibody differentiation assay, HIV-1 Western blot, HIV-2 Western blot or HIV-1 Immunofluorescent assay). For additional information, please visit the following website https://www.wadsworth.org/sites/default/files/WebDoc/CDRG%20NYState%202020_101920%202.pdf or contact https://www.wadsworth.org/sites/default/files/WebDoc/CDRG%20NYState%202020_101920%202.pdf or contact https://www.babeworth.org/sites/default/files/WebDoc/CDRG%20NYState%202020_101920%202.pdf or contact https://www.babeworth.org/sites/default/files/WebDoc/CDRG%20NYState%202020_101920%202.pdf or contact https://www.babeworth.org/sites/default/files/WebDoc/CDRG%20NYState%202020_101920%202.pdf

FAQ 24: Can HIV lab results be posted on an electronic medical record?

Yes. Facilities may post such information but are responsible for the protection of confidential information.

9. Partner Services and the Role of Partner Services Programs

Medical providers or their designee must explain to all newly diagnosed patients the importance of notifying any sexual or needle-sharing partners that they may have been exposed to HIV. Partner services is a cornerstone of HIV prevention efforts that provides an opportunity for sexual or needle sharing contacts of a person living with HIV to be offered testing in a timely manner, and if diagnosed with HIV infection, be linked into care. Every

physician or other person authorized to order diagnostic testing is required to report HIV and AIDS diagnoses to the health department. This report must include identifying information about any contacts known to the clinical provider or provided to the clinical provider by the patient. The HIV/AIDS <u>Provider Portal</u> described in <u>Section 7</u>, may be used to report cases, including partners and to request assistance from the health department with partner notification. As part of post-test counseling, the following must be provided to the patient:

- 1. An explanation of the importance of notifying sexual or needle sharing partners to prevent further transmission, and to promote early access of exposed persons to HIV testing, health care, and prevention services;
- 2. A description of notification options and assistance available to the protected individual;
- A discussion about the risk of domestic violence and screening for domestic violence prior to partner notification in accordance with the <u>NYSDOH domestic violence</u> <u>screening protocol</u>;
- 4. The fact that known contacts, including a known spouse, will be reported to the health department. That protected persons will also be requested to cooperate in contact notification efforts of known contacts and that protected persons may name additional contacts they wish to have notified with the assistance of the provider or authorized public health officials; and
- 5. An explanation that the name and other information about the person living with HIV will be protected during the contact notification process.

The NYSDOH Partner Services Program and the NYC Health Department Contact Notification Assistance Program (CNAP) provide a wide range of services, including: performing notifications; assisting patients with decision making; and consulting with health care providers. In some situations, Partner Services Specialists can meet with the patient at the same time that the laboratory results are given to assist with post-test counseling and development of a partner notification plan. Additional NYSDOH/NYCDOHMH services may be available such as assistance in locating persons who test positive but who do not return for their results. For more information about partner services and how to contact partner services programs throughout NYS, visit: https://health.ny.gov/diseases/communicable/std/partner_services/index.htm.

IMPORTANT POINT:

In recognition of the need for ongoing partner services beyond the time of initial diagnosis of HIV, the 2016 updates to the NYSDOH Regulations formally prioritized partner services for people who were previously diagnosed with HIV who are at elevated risk of transmitting the virus to others. Several factors are considered as evidence of elevated risk of transmitting the virus to others. These factors include that the individual: 1) is not engaged in health care services, 2) is not virally suppressed; 3) has had a recent STD; or 4) has recently moved back to NYS from another jurisdiction.

FAQ 25: Will the NYSDOH provide outreach to previously diagnosed patients to assist with partner notification and/or link them to care or is this only done for newly diagnosed cases?

Yes. The 2016 updates to the NYSDOH regulations specifically add patients to the contact notification prioritization process who were previously diagnosed with HIV and are at elevated risk of transmitting HIV to others. Partner services staff may also be available to help link and re-engage these persons, if they are out-of-care. Updated law and regulations allow for sharing of patient-level information to promote linkage and retention in care. For more information see <u>Section 10</u>.

10. Confidentiality of HIV-Related Information in Medical and Social Services Records

New York has a long history of affording a high level of protection for HIV-related patientspecific information. HIV-related information is any information that shows a person:

- Had an HIV-related test (such as an HIV antibody test, CD4 test, viral load test, PCR [polymerase chain reaction]) test, or other test;
- Has HIV-infection, HIV-related illness, or AIDS;
- Has been exposed to HIV;
- Has any of these conditions and has information on any of their sexual contacts or needle-sharing contacts.

Note: The offer of an HIV test is not considered confidential information.

Generally, HIV-related information can only be disclosed if the person signs an approved HIV release form. The NYSDOH Form 2557 <u>Authorization for Release of Medical Information and</u> <u>Confidential HIV Related Information</u>, is used for this purpose. This form allows for the release of both HIV-related information and non-HIV-related information. The NYSDOH Form 5032 titled <u>Authorization for Release of Health Information (Including Alcohol/Drug Treatment and Mental Health Information) and Confidential HIV/AIDS Related Information is available for use when information to be released includes information about alcohol or substance use that is afforded additional protection under federal regulation 42 C.F.R. Part 2.</u>

However, HIV-related information may be shared without an HIV-specific consent form by medical providers and other clinical entities when needed to provide appropriate medical care or treatment. For example:

- When making a referral for HIV-related care, such as when arranging HIV care for a newly diagnosed person;
- Medical professionals working on the treatment team with the person's existing provider may discuss a patient's HIV-related information with each other or with their supervisors, but only to give necessary care;
- Medical personnel and certain other supervisory staff may have access to HIV-related information to provide or monitor services if the person is in jail or prison or is on parole.

FAQ 26: When releasing HIV-specific information to another health care provider, is it necessary to include a statement that the information may not be re-disclosed without the protected individual's consent?

Updates to the law add two additional items to the current list of exceptions to the requirement that disclosures of HIV-related information be accompanied by a re-disclosure statement. The additional exceptions are disclosure to:

- A health care provider or health facility when knowledge of the HIV-related information is necessary to provide appropriate care;
- Third party reimbursors or their agents to the extent necessary to reimburse health care providers for health services; provided that, where necessary, an otherwise appropriate authorization for such disclosure has been secured by the provider.

FAQ 27: May a medical provider share confidential HIV information from a person's medical record with a case manager or other staff person from a community based organization without a signed release?

No. In order to disclose HIV-related information from a medical record to a non-medical provider for any purpose, including linkage to care, a specific signed release is required.

11. Sharing of Patient-Specific Information to Promote Linkage/ Retention in HIV Care

Information reported to the NYS and NYC HIV/AIDS Surveillance Systems is afforded the highest level of protection, beyond the levels of protection afforded to HIV-related information contained in medical records. It is essential that people living with HIV trust that state and local health departments will safeguard the privacy of information included in surveillance systems. Amendments to the New York State Public Health Law §2135 that went into effect on September 1, 2010 allow state and local health departments to share information from the HIV/AIDS surveillance system with health care providers for the purpose of linkage and retention in HIV care. Since that time, post-test information provided to people with newly diagnosed HIV included making these individuals aware that if a person with HIV appears to be out of care, that person may be contacted by the medical provider or health department staff to address barriers to entry into care and promote engagement in care. The 2010 amendments were further clarified under the 2016 regulations to also include sharing of information with care coordination entities (see FAQ §32-33).

Information That Can be Shared with Health Care Providers and Care Coordination Entities The NYSDOH and the NYCDOHMH are able to share surveillance information for the purpose of promoting linkage and retention in HIV care. Information most likely to be helpful for these purposes will include:

- General information about care status;
- Patient relocation out of state or out of region;
- Report of death and date.

IMPORTANT POINT: Amendments to New York State Public Health Law allow for the sharing of information for the purpose of linkage and retention in HIV care. Therefore, information shared is limited to the points listed above.

Who May Request Information from the NYS or NYC HIV Surveillance System

Information may be requested by:

- A licensed medical practitioner with a documented or verifiable diagnostic, clinical or public health interest in the patient* (see Note)
 - The licensed medical provider may be a physician, midwife, nurse practitioner or physician assistant;
 - The health care provider may designate an individual within their practice or at an affiliated organization to submit a request and receive the information. Examples of affiliated organizations may include: health home entities; care coordination entities; Regional Health Information Organizations; and/or CBOs involved in patient linkage and retention;
- Medical Director of a managed care organization or their designee, including persons the Medical Director may designate from an affiliated health home or care coordination agency.
- Care coordinators may request information from the NYS or NYC HIV Surveillance System with a written documented affiliation with the licensed medical practitioner of the patient.

***Note:** If the NYSDOH does not have a record of the association between the patient and an affiliated health care provider, CBO laboratory testing program or care coordination entity, the NYSDOH will request information from the provider to document the association.

Requirements for Requesting Information

Eligible providers requesting information should be prepared to provide the following patient information to the NYSDOH:

- Patient first and last name;
- Patient date of birth;
- Patient sex assigned at birth;
- Patient last known address and telephone number;
- Patient's date of last contact with the requesting health provider (including laboratory test type and date);
- If known and applicable, the following should also be provided:
 - o Medicaid Member Client Identification Number (CIN);
 - New York State Department of Corrections and Community Supervision or Criminal Justice System identifier (NYSID, DIN)

When seeking information about patient linkage to care status, information provided regarding patient relocation and reports of death may help health care facilities update their active patients list and accurately report on their facility cascade of care.

Directions for Requesting Information

The HIV/AIDS <u>Provider Portal</u> is an electronic system which enables clinicians to meet their Public Health reporting requirements electronically and provides a mechanism to submit to the NYSDOH inquiries for patients residing anywhere in the state with diagnosed HIV infection who are thought to be in need of assistance with linkage to, or retention in, HIV care. See <u>Section 7</u> for more information about the HIV/AIDS Provider Portal.

NYC HIV Care Status Report System

Eligible NYC providers with patients who are out-of-care can use the NYC Health Department's <u>HIV Care Status Reports System</u> (CSR) to obtain NYC current care and vital status. Eligible NYC providers may also call the NYC Health Department HIV Epidemiology and Field Services Program's Provider Call Line (NYC PCL) at 212-442-3388 for care status queries about ≤10 patients at one time.

For Urgent Requests:

In the event of an urgent request, such as an out-of-care pregnant or breastfeeding woman living with HIV or individuals with suspected acute HIV infection, the NYSDOH or the NYCDOHMH can be contacted for more immediate assistance.

For Providers Located in NYS outside of New York City: Urgent requests should be called into the Bureau of HIV/AIDS Epidemiology at 518-474-4284 from 8:00am to 4:45pm Monday-Friday.

<u>NYC Health Department Provider Call Line</u>: For providers located within NYC, urgent requests should be called into the NYC Health Department's NYC PCL at 212-442-3388 from 8:00am and 4:45pm Monday-Friday.

Timeline for Receiving Information

Urgent requests will be responded to within 1 business day. For routine requests to the NYS Provider Portal, the turn-around time will be within 1-3 business days. Depending on the volume of requests at any given time, the turnaround time for routine requests may be up to 2 weeks. Queries submitted to the NYC CSR system are returned within 1 day.

FAQ 28: When should an eligible provider consider submitting a request for information about an individual to the NYS HIV/AIDS Provider Portal (NYS Portal) or the NYC Provider Call Line (NYC PCL) or NYC HIV Care Status Reports System (NYC CSR)?

Requests for information should be placed for persons who are not engaged in care for an extended period of time and in-house efforts to reach an individual have been exhausted. The

following are examples of vulnerable patients, situations and timeframes where submitting a request for information to the various systems would be warranted:

- Pregnant or breastfeeding people living with HIV who are not on ART or are not known to be engaged in care (NYS Portal, NYC PCL);
- Persons diagnosed with acute HIV infection who have not attended an appointment for 30 days and in-house efforts to reach the person were unsuccessful (NYS Portal, NYC PCL);
- Persons with a detectable viral load who have not attended an appointment for more than 120 days and in-house efforts to reach the person were unsuccessful (NYS Portal);
- Any person living with HIV with no evidence of HIV care, CD4 monitoring or viral load testing for more than 6 months (NYS Portal, NYC PCL, NYC CSR).

Requests should not be placed for individuals who have consistently accessed care, are virally suppressed and/or have an isolated instance of a missed appointment.

Additional information about the NYC CSR and NYC PCL for urgent requests can be found at <u>https://www1.nyc.gov/site/doh/health/health-topics/aids-hiv-care-status-reports-system.page</u>. Additional information about the NYS HIV/AIDS Provider Portal can be found in <u>Section 7</u>.

FAQ 29: How can a medical provider grant access to the HIV/AIDS Provider Portal or NYC Care Status Reports System to others, and what tasks can those persons perform in the system?

A licensed medical provider can delegate HIV/AIDS Provider Portal access to a limited number of users to carry out clearly defined tasks in the system. All users are able to submit electronic reports of the <u>Confidential Medical Provider HIV/AIDS and Partner/Contact Report Form</u> (DOH-4189). Only the licensed medical provider or a user with the appropriate role within the portal may submit inquiries for patients who are thought to be in need of assistance with linkage to, or retention in, HIV medical care. A licensed medical provider can name a designee to access the NYC CSR for care status queries.

FAQ 30: When a medical provider grants access to the HIV/AIDS Provider Portal what protections are in place to ensure confidential information remains protected?

Medical providers who designate access to the HIV/AIDS Provider Portal should convey to their delegates the importance of protecting information related to HIV case reporting and out of care follow-up as highly confidential and should ensure that designees have appropriate training in HIPAA and <u>New York State Public Health Law Article 27-F</u>. The clinician and their agents must not disclose information obtained from the HIV/AIDS Provider Portal to any other person unless that person is legally authorized and has official reasons to obtain the information.

FAQ 31: Can a health care provider who obtains information from the NYSDOH or the NYCDOHMH share that information with other medical providers and/or with community-based organizations?

Yes. Information provided by the NYSDOH or the NYCDOHMH to a health care provider or their designee should be treated as other HIV-related information already contained within the

patient record and so can be shared according to existing rules governing the sharing of HIV medical information with other providers. Information must be handled and stored confidentially and shared in accordance with HIPAA, <u>New York State Public Health Law Article</u> <u>27-F</u>, and other applicable laws for sharing of HIV-related information.

FAQ 32: What is the process by which a health home or care coordination agency would be able to request data from the surveillance system to assist with linkage and retention in care? Licensed medical providers, including those who are part of Health Home networks, may request data from the surveillance system for their current or past patients. The health care provider may also designate an individual at an affiliated organization, such as a health home entity or care coordination entity. Managed Care Plans may appoint organizations within a Health Home network (Health Home lead agencies, care coordination agencies) to submit requests to the surveillance system. Care coordinators may request information from the NYS or NYC HIV Surveillance System with a written documented affiliation with the licensed medical practitioner of the patient.

FAQ 33: How should care coordination entities and licensed medical providers manage the process of designating multiple care coordinators from different entities?

Care coordination entities may request information from the NYS or NYC HIV Surveillance System with written documented affiliation with the licensed medical practitioner of the patient. It is strongly recommended that a single point of contact within a care coordination entity is designated by a licensed medical provider to operate on their behalf. This single point of contact should be a senior level staff member who accepts responsibility for protecting privileged, confidential and/or protected health information (PHI) according to HIPAA, NYS Public Health Law Article 27-F, and other federal and state privacy laws related to sharing and storing HIV-related information.

FAQ 34: If a health care provider has a patient who did not keep their last appointment and is

unable to contact the individual, can the NYSDOH or the NYCDOHMH be of assistance? Yes, they may be able to help in two ways: 1) The NYSDOH may be able to share information with a health care provider on the current status of care or notification that the patient has relocated out of state or region; 2) The NYSDOH staff may be able to assist with locating the individual when an urgent need to return the individual to care can be established.

<u>Information That Can be Shared with Health Care Providers and Care Coordination Entities</u> The NYSDOH and the NYCDOHMH are able to share surveillance information for the purpose of promoting linkage and retention in HIV care. Information most likely to be helpful for these purposes will include:

- General information about care status;
- Patient relocation out of state or out of region;
- Report of death and date.

FAQ 35: If a health care provider is having trouble getting prior medical records on a new

patient, can the NYSDOH provide that patient's past CD4 and viral load values?

No. The law authorizes sharing of surveillance data with a licensed medical practitioner with a documented or verifiable diagnostic, clinical or public health interest in the patient for purposes of linkage and retention in HIV care.

FAQ 36: Can information be requested for medical-legal documentation to confirm HIV status in my medical records?

No. A clinician needing to establish medical-legal documentation of HIV status should order the appropriate screening and confirmatory HIV testing. The intent of sharing data from the HIV surveillance system is to promote linkage to HIV care, not to share HIV-related information with a health care provider who is not aware of a patient's HIV status. Information regarding HIV diagnostic testing, including confirmation of an existing diagnosis, can be found at: https://www.hivguidelines.org/hiv-testing-acute-infection/

FAQ 37: Given the growing importance of Regional Health Information Organizations (RHIOs), what role can RHIOs play in promoting linkage/retention in care and to what extent is information shared between the surveillance systems and the RHIOs?

In their role facilitating electronic sharing of health-related information between health care providers, community-based organizations, and other types of entities, RHIOs can play an important role providing access to patient-specific care status information, to the extent that the patient has consented to such data sharing and the patient is receiving care from a health care facility participating in the RHIO. For the purpose of expanded data sharing in supporting patient linkage and retention in care, a RHIO is considered a care coordination entity.

Providers who are eligible to request information from the surveillance system may also be affiliated with a RHIO. Such providers can request information directly from the surveillance system rather than through their RHIO. In many cases, the RHIO may contain more complete and readily accessible information such as exact viral load lab values, other diagnoses (such as hepatitis C), and lists of recent providers. These data may be useful to care coordination. The NYSDOH is conducting special projects to explore how to best align RHIOs and other public health systems, such as conducting data matches between one RHIO and the surveillance registry, under project-specific legal agreements. It should be noted that the amendments to NYS Public Health Law §2135 that went into effect on April 1, 2014 do not currently allow for data transfer from the surveillance system to a RHIO specifically. Any such data transfer would have to be established under a project-specific legal agreement. The NYS and NYC Health Department will continue dialogue with RHIOs and will explore promising practices while recognizing the individuality of each RHIO. Additional information regarding RHIOs is available at https://www.nyehealth.org/shin-ny/what-is-the-shin-ny/.

12. Health Department Assistance with Patient No-Show Follow-Up

In instances where a patient with newly diagnosed HIV has not returned for post-test counseling, the NYS HIV Partner Services (PS) and NYC Contact Notification Assistance Program (CNAP) can assist the medical provider in locating the person to advise the individual to return to the medical provider for post-test counseling. When the HIV diagnosis is verbally confirmed by the testing provider and the provider requests such assistance, the HIV PS/CNAP Specialist can perform post-test counseling on behalf of the provider.

If, in these cases, there are partners known to the medical provider, including spouses, and if after repeated follow-up efforts the patient cannot be located or chooses not to return for post-test counseling and/or domestic violence screening, the authorized public health official, in consultation with the reporting medical provider, will determine whether notification of known partners should proceed. This decision will primarily be based on the likelihood of the index patient returning for post-test counseling, potential for risk of domestic violence, and the risk to the potentially exposed spouse and/or other sexual and needle sharing partners known to the medical provider. For partner services assistance in New York City, call 212-693-1419. In other parts of the state, call 800-541-2437.

FAQ 38: In cases where a patient with a confirmed HIV diagnosis does not return for post-test counseling and the health department has been called to assist with follow-up, will the health department take responsibility for arranging for follow-up HIV care or does this remain with the testing provider, even if the patient never returns for an appointment?

In such a case, the PS/CNAP Specialist will work with the testing provider to determine the best course of action. PS/CNAP Specialists collaborate with testing and health care providers to ensure patients understand their test results, discuss the importance of partner notification and get linked to HIV care. Depending on the specific situation and the patient's expressed preference once located, the PS/CNAP Specialist may arrange for follow-up care or the testing site may be responsible for this. Either way, the testing provider is responsible for reporting the newly diagnosed case to the health department by completing the Medical Provider Report Form. If the PS/CNAP Specialist arranges the appointment for follow-up care, the name of the provider/ facility and date of appointment will be provided to the testing site to enable the site to document this in the patient record, in accordance with their documentation requirements.

13. Reimbursement for HIV Testing

Reimbursement for HIV testing services is subject to a number of factors including the patient's health coverage, the setting offering the HIV test and other clinical considerations.

<u>Health Coverage</u>: The Affordable Care Act established ten essential health benefits which must be covered by health plans. One of the essential health benefits is preventive screenings and wellness services that have been proven cost effective by the U.S. Preventive Services Task Force (USPSTF). Routine HIV testing is considered a preventive service. Routine HIV testing is highly cost effective and was awarded the highest "A" rating by the USPSTF for the following groups: patients aged 15 to 65; younger or older patients at increased risk for HIV; and pregnant women. Medicaid, Medicare and most insurance companies will cover the cost of HIV testing in the primary care setting, especially for the groups noted above. Most individuals on Medicaid are enrolled in a Medicaid Managed Care Plan and reimbursement for HIV testing is governed by the negotiated fees between the Plan and the Provider, except in the cases of a federally qualified health center (FQHC) (see additional information below). In most cases, in the primary care setting, HIV testing will be covered by public and private health plans without a required co-pay or patient cost sharing.

<u>Setting</u>: The Affordable Care Act does not necessarily require health plans to cover an HIV test in every health care setting or whenever a patient accepts or is offered an HIV test. For example, a health plan may cover HIV testing as part of a primary care visit but not during an emergency room visit or not on an ongoing basis, absent documentation of a specific clinical indication. Persons with private health coverage should check with their policy or insurance company to determine in which settings HIV testing is covered and what co-pay may apply.

The HIV Primary Care Medicaid Program's HIV Testing visits were subsumed into the Department's Ambulatory Patient Groups (APGs) Methodology effective July 1, 2011. Since that time, only those FQHCs that are enrolled in the HIV Primary Care Medicaid Program (HPCMP) who have opted out of APG's are able to access the HPCMP's HIV Testing codes.

Other Clinical Considerations: Reimbursement for HIV counseling or testing may be covered by public and private health plans in a variety of settings when there is a specific clinical indication for HIV testing, for example, when symptoms of acute infection or advanced HIV disease are present or there is documentation of a specific risk behavior. In addition, under Medicaid, HIV counseling that occurs in conjunction with a medical visit is a billable service when a physician or other gualified health care professional spends time with the patient to discuss at some length topics including, but not limited to: HIV disease; the importance of testing; and risk factor reduction. Billing for such counseling services is through one of the Current Procedural Terminology (CPT) codes for "Preventive Medicine, Individual Counseling" (CPT codes 99401-99404) appropriate for the time spent with the patient and for which adequate documentation is made in the patient's chart. HIV counseling services are distinct from evaluation and management (E&M) services that may be reported and billed separately when performed. In addition, the HIV test itself can be billed, as can the blood draw if a non-rapid test is performed, in a manner appropriate to the provider setting (e.g., hospital outpatient clinic or diagnostic and treatment center). All billing and payments are subject to, and paid in accordance with, Medicaid regulation.

FAQ 39: Does the law require that HIV testing be provided free of charge if Medicaid, Medicare or private insurance is not in place?

No. The HIV testing law has not changed the way HIV testing is paid for. Reimbursement rules for Medicaid and private insurers are subject to change. Patients who would like information about free or anonymous testing sites may call 1-800-541-AIDS (2437).

14. Occupational Exposure

For information about HIV testing in instances of occupational exposure, please see the document titled *Occupational Exposure and HIV Testing: Fact Sheet and Frequently Asked Questions* available at

https://www.health.ny.gov/diseases/aids/providers/testing/docs/occupational_exposure.pdf

15. NYSDOH Expectations for Compliance and Enforcement Activities

The NYSDOH has worked collaboratively to assist providers in complying with HIV testing laws since the 2010 amendments went into effect. With the adoption of the 2016 amendments and now these 2023 updates, the department expects that all facilities and providers have implemented the routine offer of testing and other provisions of the law, and that health care facility policies and protocols are in full alignment with public health law governing HIV testing. If technical assistance or training is needed, please email <u>hivet@health.ny.gov</u>. Online patient complaints can be filed at: <u>https://www.health.ny.gov/diseases/aids/providers/forms/informedconsent.htm</u>. All complaints are reviewed by the NYSDOH. Action will be taken with the provider or facility as appropriate.

FAQ 40: Will the NYSDOH require any data be reported from health care facilities or private practitioners with regard to activities mandated under this law?

No. There are no new reporting requirements included in the Law. Medical providers must continue to complete and submit the NYS Medical Provider HIV/AIDS and Partner/Contact Report Form (PRF) within 14 days to report new diagnoses of HIV or AIDS, previously diagnosed persons who are new to clinic, and/or persons needing partner services. As has been the case, New York City physicians are required to send their reports to the NYC Health Department. See <u>Section 7</u> for more information or call the NYSDOH at 518-474-4284 or NYC Health Department at 212-442-3388.

16. Access to HIV Information for Medical Researchers

Effective March 28, 2017, Public Health Law §2782(1)(r) allows disclosure of confidential HIVrelated information to qualified researchers for medical research purposes upon approval of a research protocol under applicable State or federal law. This update to the Public Health Law is intended to improve the ability of qualified researchers to conduct high quality, Institutional Review Board (IRB)-approved research related to improving the medical care and treatment of persons living with HIV. Researchers at academic medical centers, with approval from the institution and the institution's IRB, may access confidential HIV-related information from medical records of patients of the academic medical center for the purposes of improving the medical care and treatment of persons living with HIV.

FAQ 41: What are the definitions of "Qualified Researcher" and "Medical Research"?

A "Qualified Researcher" is any Principal Investigator of an IRB-approved medical research study. "Medical Research" includes basic research, applied research or translational research conducted to advance knowledge in the field of HIV.

IMPORTANT POINT:

Researchers at academic medical centers who access confidential HIV-related information from medical records of patients with approval from the institution and the institution's IRB must, in all cases, ensure that this information is maintained and kept confidential in accordance with HIPAA regulations.

FAQ 42: Will qualified researchers be allowed to access information from the HIV surveillance system?

No. Researchers may not access patient-specific HIV-related information from the HIV surveillance system. Researchers at academic medical centers, with approval from the institution and the institution's IRB, may access confidential HIV-related information from medical records of patients of the academic medical center for the purposes of improving the medical care and treatment of persons living with HIV.