STATE OF MAINE
DEPARTMENT OF PROFESSIONAL & FINANCIAL REGULATION
BOARD OF LICENSURE IN MEDICINE

Janet T. Mills
Governor

Maroulla S. Gleaton, MD
Chair

Timothy Terranova
Executive Director

Joan F. Cohen
Commissioner

TESTIMONY OF TIMOTHY TERRANOVA
EXECUTIVE DIRECTOR
BOARD OF LICENSURE IN MEDICINE
DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION
L.D. 1970

An Act to Amend the Laws Regarding Consent for HIV Testing and Disclosure of Related Medical Information for Insurance Purposes
Presented by Representative Osher
Before the Joint Standing Committee on Health Coverage, Insurance & Financial Services

May 20, 2025 at 1:00 p.m.

Senator Bailey, Representative Mathieson, and members of the Health Coverage, Insurance and Financial Services Committee, I am Tim Terranova, Executive Director of the Maine Board of Licensure in Medicine ("BOLIM"). I am here today to testify in neither for nor against LD 1970.

BOLIM licenses and regulates allopathic physicians and physician assistants in Maine. BOLIM is composed of 11 members: 6 physicians who actively practice medicine; 2 physician assistants who actively render medical services; and 3 public members. BOLIM's mission is to protect the public by ensuring its licensees are ethical, professional and competent. It fulfills this mission by licensing, regulating, and educating physician and physician assistants.

This bill seeks to change the standard of consent needed to perform an HIV test. It appears that this may be an effort to update the law to conform with recent CDC guidelines. Those guidelines are attached to this letter and state, in part:

- HIV screening should be voluntary and free from coercion. Patients should not be tested without their knowledge.
- Opt-out HIV screening (notifying the patient that an HIV test will be performed, unless the patient declines) is recommended in all health care settings. CDC also recommends that consent for HIV screening be incorporated into the general informed consent for medical care in the same manner as other screening or diagnostic tests.
- Requirement of specific signed consent for HIV testing is not recommended. General informed consent for medical care is considered sufficient to encompass informed consent for HIV testing.

Unfortunately, as written, this bill goes beyond those guidelines and may cause confusion and/or harm to providers and patients.

The guidelines state "general *informed* consent" is sufficient. However, the bill creates a new type of consent "general consent". BOLIM licensees must provide informed consent. Informed consent is a recognized and

defined standard in the practice of medicine. Informed consent includes the ability of the patient to decline a procedure or test. Creation of a second type of consent may lead to confusion among licensees and patients.

The "general consent" appears to allow the test to be performed on a patient who has provided general consent for a medical procedure or test but not consent for an HIV test. This could be interpreted as a patient giving consent for a cholesterol check or knee surgery automatically having given consent for an HIV test. Any procedure or test could fit into this example.

BOLIM already sees complaints about HIV tests performed without informed consent. If patients are no longer notified and tests are performed, complaints will increase. When a complaint comes before BOLIM, the licensee will be held to the informed consent standard.

A number of the complaints BOLIM receives, although outside the Board's enforcement jurisdiction, relate to the question of who pays for an HIV test. If a patient is uninsured or has a high deductible should they pay for a test they were not told would be performed? If they are insured, should an insurance company pay for a test that was not agreed to by the patient?

BOLIM would recommend changing section 1 to read, "Except as provided in this section and section 19203, subsections 4 and 5, an HIV test must be voluntary and undertaken only with a patient's informed consent." and deleting the rest of the paragraph. In addition, BOLIM would recommend removing section 1(A) as it is covered by informed consent.

Thank you for the opportunity to provide these comments regarding LD 1970. I would be happy to answer questions now or at the work session.

Office Location: 161 Capitol Street Augusta, ME 04330
Mailing Address: 137 State House Station, Augusta, Maine 04333
www.maine.gov/md

Phone: (207) 287-3601 TTY: Please Call Maine Relay 711 Consumer Assistance: (888) 365-9964 Fax: (207) 287-6590

Sexually Transmitted Infections Treatment Guidelines, 2021

HIV Infection: Detection, Counseling, and Referral

Infection with HIV causes an acute but brief and nonspecific influenza-like retroviral syndrome that can include fever, malaise, lymphadenopathy, pharyngitis, arthritis, or skin rash. Most persons experience at least one symptom; however, some might be asymptomatic or have no recognition of illness (*406–409*). Acute infection transitions to a multiyear, chronic illness that progressively depletes CD4+ T lymphocytes crucial for maintenance of effective immune function. Ultimately, persons with untreated HIV infection experience symptomatic, life-threatening immunodeficiency (i.e., AIDS).

Effective ART that suppresses HIV replication to undetectable levels reduces morbidity, provides a near-normal lifespan, and prevents sexual transmission of HIV to others (*95–97,410– 412*). Early diagnosis of HIV and rapid linkage to care are essential for achieving these goals. Guidelines from both the U.S. Department of Health and Human Services and the International AIDS Society–USA Panel recommend that all persons with HIV infection be offered effective ART as soon as possible, both to reduce morbidity and mortality and to prevent HIV transmission (*413*).

STD specialty or sexual health clinics are a vital partner in reducing HIV infections in the United States. These clinics provide safety net services to vulnerable populations in need of HIV prevention services who are not served by the health care system and HIV partner service organizations. Diagnosis of an STI is a biomarker for HIV acquisition, especially among persons with primary or secondary syphilis or, among MSM, rectal gonorrhea or chlamydia (*197*). STD clinics perform only approximately 20% of all federally funded HIV tests nationally but identify approximately 30% of all new infections (*414*). Among testing venues, STD clinics are high performing in terms of linkage to HIV care within 90 days of diagnosis; during 2013–2017, the percentage of persons with a new diagnosis in an STD clinic and linked to care within 90 days increased from 55% to >90% (*415,415*).

Screening Recommendations

The following recommendations apply to testing for HIV:

- HIV testing is recommended for all persons seeking STI evaluation who are not already known to have HIV infection. Testing should be routine at the time of the STI evaluation, regardless of whether the patient reports any specific behavioral risks for HIV. Testing for HIV should be performed at the time of STI diagnosis and treatment if not performed at the initial STI evaluation and screening (*82,195,416*).
- CDC and USPSTF recommend HIV screening at least once for all persons aged 15–65 years (*417*).
- Persons at higher risk for HIV acquisition, including sexually active gay, bisexual, and other MSM, should be screened for HIV at least annually. Providers can consider the benefits of offering more frequent screening (e.g., every 3–6 months) among MSM at increased risk for acquiring HIV (*418,419*).
- All pregnant women should be tested for HIV during the first prenatal visit. A second test during the third trimester, preferably at <36 weeks' gestation, should be considered and is recommended for women who are at high risk for acquiring HIV infection, women who receive health care in jurisdictions with high rates of HIV, and women examined in clinical settings in which HIV incidence is ≥1 per 1,000 women screened per year (*138,140*).
- HIV screening should be voluntary and free from coercion. Patients should not be tested without their knowledge.
- Opt-out HIV screening (notifying the patient that an HIV test will be performed, unless the patient declines) is recommended in all health care settings. CDC also recommends that consent for HIV screening be incorporated into the general informed consent for medical care in the same manner as other screening or diagnostic tests.
- Requirement of specific signed consent for HIV testing is not recommended. General informed consent for medical care is considered sufficient to encompass informed consent for HIV testing.

- Providers should use a laboratory-based antigen/antibody (Ag/Ab) combination assay as the first test for HIV, unless persons are unlikely to follow up with a provider to receive their HIV test results; in those cases screening with a rapid POC test can be useful.
- Preliminary positive screening tests for HIV should be followed by supplemental testing to establish the diagnosis.
- Providing prevention counseling as part of HIV screening programs or in conjunction with HIV diagnostic testing is not required (*6*). However, persons might be more likely to think about HIV and consider their risk-related behavior when undergoing an HIV test. HIV testing gives providers an opportunity to conduct STI and HIV prevention counseling and communicate risk-reduction messages.
- Acute HIV infection can occur among persons who report recent sexual or needle-sharing behavior or who have had an STI diagnosis.
- Providers should test for HIV RNA if initial testing according to the HIV testing algorithm recommended by CDC is negative or indeterminate when concerned about acute HIV infection (https://stacks.cdc.gov/view/cdc/50872).
- Providers should not assume that a laboratory report of a negative HIV Ag/Ab or antibody test indicates that the requisite HIV RNA testing for acute HIV infection has been conducted. They should consider explicitly requesting HIV RNA testing when concerned about early acute HIV infection.
- Providers should assess eligibility of all persons seeking STI services for HIV PrEP and PEP. For persons with substantial risk whose results are HIV negative, providers should offer or provide referral for PrEP services, unless the last potential HIV exposure occurred <72 hours, in which case PEP might be indicated.

Diagnostic Considerations

HIV infection can be diagnosed by HIV 1/2 Ag/Ab combination immunoassays. All FDA-cleared HIV tests are highly sensitive and specific. Available serologic tests can detect all known subtypes of HIV-1. The majority also detect HIV-2 and uncommon variants of HIV-1 (e.g., group O and group N).

According to an algorithm for HIV diagnosis, CDC recommends that HIV testing begin with a laboratory-based HIV-1/HIV-2 Ag/Ab combination assay, which, if repeatedly reactive, is followed by a laboratory-based assay with a supplemental HIV-1/HIV-2 antibody differentiation assay (https://stacks.cdc.gov/view/cdc/50872). This algorithm confers an additional advantage because it can detect HIV-2 antibodies after the initial immunoassay. Although HIV-2 is uncommon in the United States, accurate identification is vital because monitoring and therapy for HIV-2 differs from that for HIV-1 (*420*). RNA testing should be performed on all specimens with reactive immunoassay but negative supplemental antibody test results to determine whether the discordance represents acute HIV infection.

Rapid POC HIV tests can enable clinicians to make a preliminary diagnosis of HIV infection in <20 minutes. The majority of rapid antibody assays become reactive later in the course of HIV infection than conventional laboratory-based assays and thus can produce negative results among persons recently infected (e.g., acutely infected persons). Furthermore, HIV home-test kits only detect HIV antibodies and therefore will not detect acute HIV infection. If early or acute infection is suspected and a rapid HIV antibody assay is negative, confirmatory testing with combined laboratory-based assays or RNA testing should be performed. CDC recommends that all persons with reactive rapid tests be assessed with a laboratory-based Ag/Ab assay. Additional details about interpretation of results by using the HIV testing algorithm recommended by CDC are available at https://stacks.cdc.gov/view/cdc/48472.

Acute HIV Infection

Providers serving persons at risk for STIs are in a position to diagnose HIV infection during its acute phase. Diagnosing HIV infection during the acute phase is particularly important because persons with acute HIV have highly infectious disease due to the concentration of virus in plasma and genital secretions, which is extremely elevated during that stage of infection (*421,422*) (https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/acute-and-recent-early-hiv-infection?view=full ↗). ART during acute HIV infection is recommended because it substantially reduces infection transmission to others, improves laboratory markers of disease, might decrease severity of acute disease, lowers viral setpoint, reduces the size of the viral reservoir, decreases the rate of viral mutation by suppressing replication, and preserves immune function (https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/acute-and-recent-early-hiv-infection?view=full ↗).

Persons who receive an acute HIV diagnosis should be referred immediately to an HIV clinical care provider, provided prevention counseling (e.g., advised to reduce the number of partners and to use condoms correctly and consistently), and screened for STIs. Information should be provided regarding availability of PEP for sexual and injecting drug use partners not known to have HIV infection if the most recent contact was <72 hours preceding HIV diagnosis.

When providers test by using the CDC algorithm, specimens collected during acute infection might give indeterminate or negative results because insufficient anti-HIV antibodies and potentially insufficient antigen are present to be reactive on Ag/Ab combination assays and supplemental HIV-1/HIV-2 antibody differentiation assays. Whenever acute HIV infection is suspected (e.g., initial testing according to the CDC algorithm is negative or indeterminate after a possible sexual exposure to HIV within the previous few days to weeks, especially if the person has symptoms or has primary or secondary syphilis, gonorrhea, or chlamydia), additional testing for HIV RNA is recommended. If this additional testing for HIV RNA is also negative, repeat testing in a few weeks is recommended to rule out very early acute infection when HIV RNA might not be detectable. A more detailed discussion of testing in the context of acute HIV infection is available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/initiation-antiretroviral-therapy?view=full.

Treatment

ART should be initiated as soon as possible for all persons with HIV infection regardless of CD4+ T-cell count, both for individual health and to prevent HIV transmission (https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines).

Persons with HIV infection who achieve and maintain a viral load suppressed to <200 copies/mL with ART have effectively no risk for sexually transmitting HIV (*95–97,421*). Early HIV diagnosis and treatment is thus not only vital for individual health but also as a public health intervention to prevent new infections. Knowledge of the prevention benefit of treatment can help reduce stigma and increase the person's commitment to start and remain adherent to ART (*423*). The importance of adherence should be stressed as well as the fact that ART does not protect against other STIs that can be prevented by using condoms. Interventions to assist persons to remain adherent to their prescribed HIV treatment, to otherwise reduce the possibility of transmission to others, and to protect themselves against STIs, have been developed for diverse populations at risk (*424*) (https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines).

Comprehensive HIV treatment and care services might not be available in facilities focused primarily on STI treatment. Providers in such settings should be knowledgeable about HIV treatment and care options available in their communities and promptly link persons who have newly diagnosed HIV infection and any persons with HIV infection who are not engaged in ongoing effective care to a health care provider or facility experienced in caring for persons living with HIV (https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines).

Other HIV Management Considerations

Behavioral and psychosocial services are integral to caring for persons with HIV infection. Providers should expect persons to be distressed when first informed that they have HIV. They face multiple adaptive challenges, including coping with the reactions of others to a stigmatizing illness, developing and adopting strategies to maintain physical and emotional health, initiating changes in behavior to prevent HIV transmission to others, and reducing the risk for acquiring additional STIs. Many persons will require assistance gaining access to health care and other support services and coping with changes in personal relationships.

Persons with HIV infection might have additional needs (e.g., referral for substance use or mental health disorders). Others require assistance to secure and maintain employment and housing. Persons capable of reproduction might require family planning counseling, information about reproductive health choices, and referral for reproductive health care.

The following recommendations apply to managing persons with diagnosed HIV infection:

- Link persons with HIV infection to care and start them on ART as soon as possible.
- Report cases (in accordance with local requirements) to public health and initiate partner services.

- Provide prevention counseling to persons with diagnosed HIV infection.
- Ensure all persons with HIV infection are informed that if they achieve and maintain a suppressed viral load, they have effectively no risk for transmitting HIV. Stress that a suppressed viral load is not a substitute for condoms and behavioral modifications because ART does not protect persons with HIV against other STIs.
- Provide additional counseling, either on-site or through referral, about the psychosocial and medical implications of having HIV infection.
- Assess the need for immediate medical care and psychosocial support.
- Link persons with diagnosed HIV infection to services provided by health care personnel experienced in managing HIV infection. Additional services that might be needed include substance misuse counseling and treatment, treatment for mental health disorders or emotional distress, reproductive counseling, risk-reduction counseling, and case management. Providers should follow up to ensure that patients have received services for any identified needs.
- Persons with HIV infection should be educated about the importance of ongoing medical care and what to expect from these services.

STI Screening of Persons with HIV Infection in HIV Care Settings

At the initial HIV care visit, providers should screen all sexually active persons for syphilis, gonorrhea, and chlamydia, and perform screening for these infections at least annually during the course of HIV care (*425*). Specific testing includes syphilis serology and NAAT for *N. gonorrhoeae* and *C. trachomatis* at the anatomic site of exposure. Women should also be screened for trichomoniasis at the initial visit and annually thereafter. Women should be screened for cervical cancer precursor lesions per existing guidelines (*98*).

More frequent screening for syphilis, gonorrhea, and chlamydia (e.g., every 3 or 6 months) should be tailored to individual risk and the local prevalence of specific STIs. Certain STIs can be asymptomatic; their diagnosis might prompt referral for partner services, might identify sexual and needle-sharing partners who can benefit from early diagnosis and treatment of HIV, and might prompt reengagement in care or HIV prevention services (e.g., PEP or PrEP) (*8*). More detailed information on screening, testing, and treatment is provided in pathogen-specific sections of this report.

Partner Services and Reporting

Partner notification is a key component in the evaluation of persons with HIV infection. Early diagnosis and treatment of HIV among all potentially exposed sexual and injecting drug sharing partners can improve their health and reduce new infections. For those partners without HIV infection, partner services also provide an opportunity for offering HIV prevention services, including PrEP or PEP (if exposure was <72 hours previous) and STI testing and treatment.

Health care providers should inform persons with diagnosed HIV infection about any legal obligations of providers to report cases of HIV to public health; the local confidential processes for managing partner services, including that a public health department still might be in contact to follow up in their care and partner services; and the benefits and risks of partner notification and services. Health care providers should also encourage persons with a new HIV diagnosis to notify their partners and provide them with referral information for their partners about HIV testing. Partner notification for exposure to HIV should be confidential. Health care providers can assist in the partner notification process, either directly or by referral to health department partner notification programs. Health department staff are trained to use public health investigation strategies for confidentially locating persons who can benefit from HIV treatment, care, or prevention services. Guidance regarding spousal notification varies by jurisdiction. Detailed recommendations for notification, evaluation, and treatment of exposed partners are available in *Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydial Infections* (*111*).

Special Considerations

Pregnancy

All pregnant women should be tested for HIV during the first prenatal visit. A second test during the third trimester, preferably at <36 weeks' gestation, should be considered and is recommended for women who are at high risk for acquiring HIV, women who receive health care in jurisdictions with high rates of HIV infection, and women served in clinical settings in which prenatal screening identifies ≥1 pregnant woman with HIV per 1,000 women screened (*138*). Diagnostic algorithms for HIV for pregnant women do not differ from those for nonpregnant women (see STI Detection Among Special Populations). Pregnant women should be informed that HIV testing will be performed as part of the routine panel of prenatal tests (*138*); for women who decline HIV testing, providers should address concerns that pose obstacles, discuss the benefits of testing (e.g., early HIV detection, treatment, and care for improving health of the mother and reducing perinatal transmission of HIV), and encourage testing at subsequent prenatal visits. Women who decline testing because they have had a previous negative HIV test result should be informed about the importance of retesting during each pregnancy. Women with no prenatal care should be tested for HIV at the time of delivery.

Testing pregnant women is crucial because knowledge of infection status can help maintain the woman's health, and it enables receipt of interventions (i.e., ART or specialized obstetrical care) that can substantially reduce the risk for perinatal transmission of HIV. Pregnant women with diagnosed HIV infection should be educated about the benefits of ART for their own health and for reducing the risk for HIV transmission to their infant. In the absence of ART, a mother's risk for transmitting HIV to her neonate is approximately 30%; however, risk can be reduced to <2% through ART, obstetrical interventions (i.e., elective cesarean delivery at 38 weeks' pregnancy), and breastfeeding avoidance (https://clinicalinfo.hiv.gov/en/guidelines/perinatal/whats-new-guidelines). Pregnant women with HIV infection should be linked to an HIV care provider experienced in managing HIV in pregnancy and provided antenatal and postpartum treatment and advice. Detailed and regularly updated recommendations for managing pregnant patients with HIV infection are available at https://clinicalinfo.hiv.gov/en/guidelines/perinatal/whats-new-guidelines .

HIV Infection Among Neonates, Infants, and Children

Diagnosis of HIV infection in a pregnant woman indicates the need for evaluating and managing the HIV-exposed neonate and considering whether the woman's other children, if any, might be infected. Detailed recommendations regarding diagnosis and management of HIV infection among neonates and children of mothers with HIV are beyond the scope of these guidelines but are available at https://clinicalinfo.hiv.gov/en/guidelines . Exposed neonates and children with HIV infection should be referred to physicians with expertise in neonatal and pediatric HIV management.

Last Reviewed: July 22, 2021