

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
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**CLINICAL ADVISORY:
ROUTINE HIV SCREENING IN MASSACHUSETTS**

TO: Massachusetts Clinical Care Providers

FROM: John Auerbach, Commissioner of Public Health
Lauren Smith, MD, MPH, Medical Director
Kevin Cranston, MDiv, Director, Bureau of Infectious Disease
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Date: July 2012

Re: Routine HIV screening and changes to Massachusetts law governing consent

This Massachusetts Department of Public Health (MDPH) Clinical Advisory is meant to communicate the Department's strong support of HIV screening as a component of routine health care of all patients in the Commonwealth and to clarify recent changes to M.G.L. c. 111, §70F.

In September 2006, the Centers for Disease Control and Prevention (CDC) issued the "*Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*" in which the CDC recommends the **routine screening of all adult and adolescent patients for HIV infection**. The revised recommendations advocate for including routine HIV screening as part of the normal standard of care provided to all patients, regardless of the patient's risk history or motivation for seeking health care or whether the patient presents with symptoms of HIV infection. Routine HIV screening in all clinical care settings can identify individuals infected with HIV who would otherwise not have been tested, increasing the number of HIV+ patients who receive the early care shown to prevent or delay progression of the infection. Knowledge of one's HIV infection is also well documented to be associated with reduced risk behavior and subsequent transmission. Because of the benefits to individuals and the general public of early diagnosis and treatment, MDPH strongly endorses this approach.

On April 27, 2012, Governor Deval Patrick signed into law the final version of SB 2158--*An Act increasing screening for HIV*—which became Chapter 84 of the Acts of 2012 (<http://www.malegislature.gov/Laws/SessionLaws/Acts/2012/Chapter84>). This change in state law removes the requirement to obtain written informed consent prior to HIV testing. **The bill now allows for verbal informed consent from the individual being tested.** The confidentiality protections for disclosing

the results of a person's HIV test and identifying a person as the subject of an HIV test remain the same, requiring written informed consent. The law takes effect on July 26, 2012.¹

Verbal Consent Sufficient for HIV Screening

The elimination of the requirement for written informed consent for HIV screening in exchange for verbal informed consent maintains the expectation that the individual being tested be provided with information about the test and the opportunity to ask/clarify any questions. Individuals being screened have the right to know they are being offered an HIV test and have the right to accept or deny testing and know what the results of the test mean. **There is no requirement to document verbal consent**, but providers may choose to document verbal consent in the patient's medical record or client file.

The MDPH has developed a document, which is available free of charge, that provides information on HIV counseling and testing including a description of the different types of tests: ***Counseling and Testing: HIV Questions and Answers***. The Department considers a process which includes review of this MDPH-issued document (or a document that includes equivalent information) and the opportunity for patients/clients to ask questions to be a sufficient level of information prior to verbal consent, and is recommended to accompany any HIV testing or screening (see www.mclearinghouse.com).

Written Informed Consent Required for Release of Testing Information

Obtaining written consent to care generally includes a release of medical information to insurers (for billing purposes) or to other treating providers and is generally obtained during the initial engagement to care. The revised c. 111, § 70F defines "written informed consent" as a written consent form for each requested release of the HIV test results or medical records containing such information. The law does not specify who may obtain the consent to release this information. Generally local practice or institutional protocols dictate who obtains consent for release of information – it may be office staff or clinical staff.

All individuals diagnosed with HIV infection should have the option to receive optimal medical care. This is achieved when all clinical providers treating an individual have appropriate legal access to medical information. Written consent for release of results should not occur until the individual has received test results, with the exception of prenatal care. MDPH strongly recommends the use of distinct and separate HIV release consent language within the general consent document when a general consent for release of test results or medical records is employed (see model informed consent language). The release must state to whom or to where the test results will be released. The recipient(s) of the information should be identified as a provider of care appropriate for that patient. In addition, if the individual medical record is an electronic medical record (EMR) that is shared outside of a licensed facility, consent to share HIV test results in that EMR should be included as well.

Primary Care

The nature of primary care supposes ongoing long-term care as a patient within a medical home. Routine screening for HIV can occur multiple times throughout the course of primary care. If an individual presents for a routine primary care visit and verbally consents to receive HIV screening, when the individual receives the test results written informed consent should be obtained to share the test results or medical record containing such information as part of a referral to an infectious disease specialist or other appropriate clinical care. The consent to release the individual's test results or medical record containing test result should specifically identify the provider(s) who will receive the information (see model informed consent language). To facilitate obtaining consent, MDPH recommends this be part of a general consent with a

¹ The law also specifically underscores that reporting HIV infection to the Department of Public Health, as required by regulations, is not a violation of law: "It shall not be a violation of this section for any physician, health care provider, health care institution or laboratory to report information to the department of public health under chapter 111 or chapter 111D and regulations promulgated there under. No physician, health care provider, health care institution or laboratory required to report shall be liable in any civil or criminal action by reason of any such report."

distinct and separate section for HIV test result release (alternatively a separate consent form may be employed). Either a separate consent or a general consent with a discrete HIV test release section is sufficient to meet the requirements of M.G.L. c. 111, § 70F. In some cases, release of HIV test results for medical care within a licensed institution or facility may not require additional consent from the patient (see Frequently Asked Questions at the end of this document to determine if written consent for release is necessary based on specific facility licensure arrangements.) In certain settings, such as jails or pre-release programs when an individual may be transferred before receiving test results, written consent to release test results by the patient (pre-result) to another facility would ensure timely referral to care.

Prenatal Care

The nature of prenatal care is short-term ongoing care leading to delivery. **MDPH, the CDC and the American Congress of Obstetricians and Gynecologists (ACOG) strongly recommend that routine HIV screening be offered to ALL pregnant women as part of their prenatal care, regardless of their risk profile.** Routine HIV screening can identify previously undiagnosed or unreported HIV infection, facilitate the provision of effective and early clinical care to mothers for their own health, and effectively reduce the risk of transmitting the infection to their newborns. 105 C.M.R. 130.616 (C) (2) requires all maternal and newborn services to have documentation of informed consent for both maternal and newborn care. If a woman is admitted for maternal care and verbally consents to HIV screening, **MDPH strongly recommends the inclusion of distinct and separate language in the consent for prenatal and maternity care for the release (and documentation) of maternal HIV test results to the newborn's medical record.** Documentation of results in the newborn record will support access to medical care for the newborn as appropriate and prevent unnecessary testing of the newborn. Because of the limited time a woman will be in care to deliver the newborn, and the medical advances in preventing perinatal transmission, MDPH recommends that consent be obtained prior to the woman getting test results. Consent may also be obtained on a separate form. Either a separate consent or a general consent with a discrete HIV test release section is sufficient to meet the requirements of M.G.L. c. 111, § 70F. In some cases, release of HIV test results for medical care within an institution or facility may not require additional consent from the patient (see Frequently Asked Questions at the end of this document to determine if written consent for release is necessary based on licensure.) (NOTE: 105 C.M.R. 130.627 (A), (B) requires that antenatal blood serology be included in the maternal record and significant maternal diseases be documented in the newborn record. MDPH considers an HIV test to be part of antenatal blood serology and a positive HIV test result in a pregnant woman to be an indicator of significant maternal disease that should be documented in a newborn's chart.)

Model Informed Consent for Release of HIV Test Results

MDPH recommended standard language to document informed written consent for release of HIV test results. **For further information please review *Frequently Asked Questions - M.G.L. c. 111, §70F* at the end of this document.**

RELEASE OF HIV TEST RESULTS/MEDICAL RECORDS CONTAINING SUCH INFORMATION

As required by M.G.L. c. 111, § 70F, I give permission to share information from my medical record about HIV antibody and antigen testing with

Print name of facility and provider

Patient Initials

Date

Routine HIV Screening Should Be Incorporated into Clinical Practice

In September 2006, the Centers for Disease Control and Prevention (CDC) issued the "*Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*" in which the CDC recommends the routine screening of all adult and adolescent patients for HIV infection ([Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings](#)).

The CDC revised recommendations advocate for including routine HIV screening as part of the standard of care provided to patients, **regardless** of the patient's risk history or motivation for seeking health care or whether the patient presents with symptoms of HIV infection. Routine HIV screening identifies unsuspected HIV infection and facilitates rapid referral and early entry into clinical care.

MDPH is committed to assisting providers to implement routine HIV testing in order to increase the early detection and effective treatment of HIV infection. Early identification of HIV infection and initiation of appropriate care can reduce morbidity, mortality and transmission to others. Routine HIV screening in primary and urgent care settings can identify individuals infected with HIV who would otherwise not have been tested, increasing the number of HIV+ patients who receive the early care shown to prevent or delay progression of the infection. Knowledge of one's HIV infection is also associated with reduced risk behavior and subsequent transmission.

All providers are encouraged to assess their clinical environments, patient population, and resources to determine the best way to incorporate routine HIV screening into their clinical practice. There are several models that may be employed effectively within a given facility/clinical environment. A health care provider should recommend HIV screening as a standard component of medical care and routinely offer patients an HIV test. The term "health care provider" may include individuals such as the patient's physician, nurse practitioner, physician's assistant, intake nurse, medical assistant, or other staff as appropriate for the setting.

Reimbursement for HIV Screening Tests

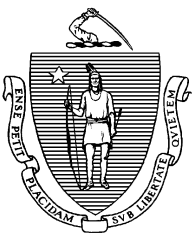
HIV screening may be offered and accessed at several different types of facilities: primary care, urgent care, walk-in clinics, community health centers, hospitals, AIDS Service Organizations (ASO), health fairs, and other settings. Reimbursement streams therefore vary as well. Sites may provide free testing, sliding fee payment scales, or bill third-party payers. The American Medical Association (AMA) and the American Academy of HIV Medicine (AAHIVM) have developed *Coding guidelines for routine HIV testing in health care settings* to help address reimbursement (see [AMA and AAHIVM Releases Coding Guidelines for Routine HIV Testing](#)).

Connecting Individuals with HIV to Care

It is imperative that patients are linked to medical care in a timely manner once confirmed to be HIV-positive. Prompt entry into medical care ensures that patients receive appropriate laboratory tests and disease staging. Appointments with a primary care or infectious disease specialist should be scheduled to occur within one week of a patient receiving the HIV diagnosis. Prompt assessment of health status at baseline is essential to maximize health care outcomes for newly diagnosed individuals.

A prompt connection to care also ensures that patients receive complete and accurate information about HIV disease progression, antiretroviral treatment options, management of co-morbid conditions, and guidance to reduce the risks of HIV transmission to sexual and drug injection partners. Connecting HIV-positive patients to medical care also serves as a point of entry for other health, assessment, and social services programs; including: case management, benefits advocacy, substance use treatment, mental health counseling, risk reduction services, and partner services, among others.

Linkage to HIV primary care also provides a bridge to connect patients with supported referrals to a range of specialty medical care services, including sexually transmitted infection (STI) treatment, viral hepatitis services, nutrition support, family planning, psychiatry, endocrinology, cardiology, and other areas that may directly impact persons living with HIV/AIDS.



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Frequently Asked Questions - M.G.L. c. 111, §70F

Routine HIV testing can be promoted and implemented while still complying with M.G.L. c. 111, §70F (70F).

- Q.** Does the law require written patient consent in order to test the patient for HIV?
A. No, the law only requires verbal consent.
- Q.** What is the definition of verbal informed consent?
A. Verbal informed consent means voluntary agreement by the patient to be screened for HIV with an understanding of what is going to happen and why. The consent may be spoken or written.
- Q.** Does the verbal consent given by the patient have to be documented?
A. No. The law does not require documentation. The provider may choose to make a note in the medical or client file.
- Q.** Does 70F require a pre-test counseling session before an HIV test is administered?
A. No. Section 70F does not establish any specific counseling requirements.
- Q.** Does the law require written consent in order to release information on test results, HIV status, or medical record containing this information?
A. Yes. The law requires written informed consent to release the results of an individual's antibody or antigen test or for the release of medical records containing such information.
- Q.** What is the definition of written informed consent?
A. Written informed consent means voluntary agreement by the patient, indicated by the patient's written signature, for the release of the results of an individual's HIV antibody or antigen test or the release of medical records containing such information to an identified party for an identified purpose.
- Q.** Does the law specify who should obtain written informed consent?
A. No. Generally this function is facility- or practice-based.
- Q.** May a written consent to release the results of an individual's antibody or antigen test or for the release of medical records containing such information be included among other consents and legal documents at intake? May the consent to release this information be part of a general consent to care or general consent for release of medical information developed by individual sites?
A. Yes. The consent may be part of a general consent to care form or general consent for the release of medical records/information as long as the consent to release of HIV information is a discrete section of the consent.

Q. Does a provider need a separate written consent from a patient to release the patient's HIV-related medical information to another provider working within the same health care facility or clinical practice?

A. If a patient consents to an HIV test, it is understood that the results of that test will be recorded in the patient's medical record. If another provider within the same facility or practice needs to see the patient's record *for purposes of treating that patient*, a separate consent for the release of the HIV-related information is not required. A provider is considered to be within the same facility or practice when their business falls under the same **licensure**. If the provider intends to release HIV test results or medical records containing such information to another provider who is external to their own medical facility (not operating under the same licensure), even if the other provider or facility shares the same EMR with the referring provider, written consent to release information is required. Written consent would also be required to document the HIV-related information in an EMR if the EMR is shared among providers not operating under the same licensure, even if no referral is made. Consent to release this information may be obtained at the initiation of care or at any point during the care process.

Q. Does the law specify how the signed consent needs to be stored?

A. No. Section 70F does not mention storage of consent release forms. Existing rules and regulations regarding confidential storage of medical records apply to releases of medical information.