To: Medical Directors and staff of Opioid Treatment Programs

From: Robert Goldstein, MD, PhD, Commissioner

Massachusetts Department of Public Health

Cc: Mike Levine

MassHealth

Date: September 2024

Re: Best Practice: Promoting Infectious Disease Testing in MA Opioid Treatment Programs (OTPs)

Purpose¹

This document is intended for medical directors and staff of all licensed clinic-based and community-based Opioid Treatment Programs (OTPs) to promote infectious disease testing for individuals enrolled in MassHealth. While this guidance focuses on OTP patients who are MassHealth members, recommendations to optimize infectious disease testing apply to OTP patients presenting with all coverage types, including those who may be uninsured.

Best Practice

Upon intake assessment at OTP, all patients should be offered testing for HIV, HCV and syphilis, in addition to any other clinically appropriate serologies. Testing should also be offered following any high-risk exposure and/or at the request of the patient.

Background

Individuals with Opioid Use Disorder (OUD) who use or have used drugs, particularly those who inject or have injected drugs, face an elevated risk for infectious disease acquisition and transmission. While OTPs are often siloed from other forms of healthcare, they are required to provide substance use care in the context of other physical and behavioral health challenges with which patients may present. Medical providers at OTPs are required to assess the medical history of patients upon admission and at

¹This document is offered as a reference and is not intended to provide legal advice. Providers and programs in need of legal advice may wish to consult their attorney.

least annually. For some patients, the OTP may be their most consistent source of health care. Thus, the OTP's role in facilitating infectious disease testing is crucial to the timely diagnoses, treatment, and proactive management of infectious conditions in individuals with OUD.

Infectious Disease and Drug Use

In MA, between 2020-2022, 15% of individuals recently diagnosed with HIV reported injection drug use (IDU) as their primary risk factor for HIV acquisition, with an additional 4% reporting both male to male sexual contact and injection drug use exposures, such that IDU exposure contributed to nearly 1 in 5 recently reported infections. Furthermore, 95% of individuals diagnosed with HCV with an exposure mode documented reported that they had ever injected drugs.

HIV and HCV Co-Infection and Syphilis

Twenty percent of individuals diagnosed with HIV are co-infected with HCV; among those with a history of IDU, the rate of co-infection is approximately 90%. Drug use, particularly stimulants, like cocaine and methamphetamine, or commonly injected drugs in general (such as opiates) is associated with sexual behaviors that increase the likelihood of exposure to HIV, syphilis, and other STDs. In MA, infectious syphilis rates have increased over the past decade from 8.8 cases per 100,000 population in 2014 to 20.3 cases per 100,000 population in 2023. Among all infants born with congenital syphilis in MA in 2023, 29% of maternal contacts reported substance use (excluding alcohol). In the same year, among all infectious syphilis cases interviewed and responded, 23.3% reported substance use (excluding alcohol).²

Offering Infectious Disease Testing in OTPs

Massachusetts Regulations

42 CFR Part 8 and 105 CMR 164.000: *Licensure of substance use disorder treatment programs* ³ governs the operation of OTPs in MA. These regulations do not directly address infectious disease testing, but several sections support the provision of infectious disease education and assessment. Section 164.043(C)(2) requires programs to designate an HIV/AIDS coordinator who is responsible for overseeing HIV risk assessment and facilitating access to HIV testing. 164.305(D)(3) indicates this expectation applies both to HIV, and "...any other relevant laboratory studies as *clinically indicated*." Any individual who has ever injected drugs, even once, regardless of the date of last use, has a higher risk for certain blood-born infections. ⁴ Testing for HCV, HIV and syphilis as clinically indicated based on

² Massachusetts Department of Public Health, Bureau of Infectious Disease and Laboratory Sciences. Data current as of April 2024 and subject to change.

https://www.mass.gov/doc/105-cmr-164-licensure-of-substance-use-disorder-treatment-programs

⁴ https://www.cdc.gov/hiv/guidelines/testing.html
https://www.uspreventiveservicestaskforce.org/uspstf/document/ClinicalSummaryFinal/human-immunodeficiency-virus-hiv-infection-screening

the data presented above and as such is a billable service under MassHealth.⁵ Laboratory testing may be ordered by a practitioner, defined as a Physician, Physician Assistant, or Advanced Practice Registered Nurse (section 164.005). Best practice and licensing regulations suggest laboratory testing be offered at intake and following any potential high-risk exposure (recommended frequency of each test is addressed in below). 164.305 (D) indicates a full in-person physical examination, including results of serology and other clinically appropriate serologies, must be completed within 14 calendar days following a patent's admission. If an individual requests infectious disease testing anytime during treatment, testing or linkage to testing should be provided.

• Federal Agency Testing Recommendations

The Substance Use and Mental Health Services Administration (SAMHSA)⁶ recommends testing for HIV and HCV in treatment settings for individuals with OUD, particularly people who inject drugs. The Centers for Disease Control and Prevention (CDC) recommends individuals at high risk for HIV infection, including persons who inject drugs, be tested yearly for HIV, ⁷ be tested routinely for HCV,⁸ and tested routinely for syphilis based on MA rates of infection.⁹

Standard of Care Policy for Infectious Disease Testing

OTPs should establish and implement policies for infectious disease testing as a general standard of care. A practitioner may request an independent clinical laboratory to perform one or more tests on a single date. Order requests may not exceed 180 days in length except for order requests for testing for substances, which may not exceed 30 days in length. Order requests are not permissible when such repeated tests are medically necessary and required as part of the member's medical or drug treatment plan. An authorized prescriber is defined as any individual who is authorized under state law to prescribe drugs pursuant to M.G.L. c. 94C and authorized to order the test under M.G.L. c. 111D. Studies have found that implementing policies for infectious disease testing into the general standard of care can increase the delivery of routine preventive care services, including testing services.

Ordering Testing

Individuals authorized to order laboratory testing in Massachusetts may order medically necessary testing for a patient while practicing in an OTP service setting.¹⁶ The recommended test for HIV is HIV-

⁵ https://www.mass.gov/doc/130-cmr-450-administrative-and-billing-regulations/download

⁶ https://store.samhsa.gov/sites/default/files/pep21-02-01-002.pdf

⁷ https://www.cdc.gov/hiv/group/hiv-idu.html

⁸https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm

⁹ https://www.cdc.gov/nchhstp/atlas/syphilis/index.html

CDC recommends offering syphilis testing to all sexually active people aged 15-44 years in counties with a rate of primary & secondary syphilis among women aged 15-44 years that is greater than 4.6 per 100,000 people. The MA rate is 11.8 per 100,000 population.

¹⁰ https://www.mass.gov/doc/130-cmr-401-independent-clinical-laboratory-services

¹¹ https://www.mass.gov/doc/130-cmr-401-independent-clinical-laboratory-services

¹² https://www.mass.gov/doc/130-cmr-401-independent-clinical-laboratory-services/download

¹³ https://www.mass.gov/regulations/130-CMR-40100-independent-clinical-laboratory-services

¹⁴ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7878627/

¹⁵ https://pubmed.ncbi.nlm.nih.gov/22956695/

¹⁶ https://www.mass.gov/doc/130-cmr-401-independent-clinical-laboratory-services

1/2 antigen/antibody combination test. The recommended test for Hepatitis C is a Hepatitis C antibody test with reflex to nucleic acid test (NAT) to detect HCV RNA. Diagnosis of syphilis requires the use of nontreponemal and treponemal tests. The tests are run in sequence and both types of tests must be used to distinguish between an untreated infection or a past infection that has been successfully treated. ¹⁷

Consent to Testing

Every patient offered infectious disease testing has the option to accept or decline testing. Physicians, healthcare providers and facilities should be aware of specific requirements concerning HIV testing. ¹⁸ To release the results of an HIV test to anyone other than the individual tested requires written consent. Ordering clinicians are responsible for delivering test results to patients and for otherwise adhering to the standard of care. DPH's Partner Services program receives all new positive syphilis and HIV lab results and can discuss results with patients and ensure connection to care for treatment. Additional services for individuals testing positive for HIV, Syphilis and HCV, as well as prevention services, are listed at the end of this document.

OTPs Licensed as Clinical Laboratories

Any OTP also licensed as a clinical laboratory, should adhere to the regulations and standards applicable to clinical lab operations for any infectious disease testing performed. This will ensure infectious disease testing is conducted within the appropriate legal and quality framework.¹⁹

MassHealth Billing Regulations

MassHealth enrolled providers must follow all applicable state and federal regulations²⁰ related to infectious disease testing for individuals covered by MassHealth, including 130 CMR 450.00: *Administrative and Billing Regulations*.

Infectious Disease Case Reporting

105 CMR 300.00 *Reportable diseases, surveillance, and isolation and quarantine requirements* ²¹ requires positive cases be reported to DPH. ²²

¹⁷ Testing performed at the State Public Health Laboratory by default covers HIV, HCV, and Syphilis on a single phlebotomy specimen and includes all necessary reflex testing. Other clinical laboratories may have different testing protocols.

https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111/Section70F

¹⁹ https://www.mass.gov/regulations/130-CMR-40100-independent-clinical-laboratory-services

²⁰ https://www.mass.gov/regulations/130-CMR-450000-administrative-and-billing-regulations

https://www.mass.gov/regulations/105-CMR-30000-reportable-diseases-surveillance-and-isolation-and-quarantine-requirements https://www.mass.gov/lists/infectious-disease-reporting-and-regulations-for-health-care-providers-and-laboratories

²² https://www.mass.gov/infectious-disease-surveillance-reporting-and-control

COMMUNITY-BASED INFECTIOUS DISEASE PREVENTION AND LINKAGE TO CARE SERVICES IN MASSACHUSETTS

Any staff member or individual interested in prevention and care services should use the list below to contact providers or facilitate linkage to services.

SERVICES FOR PEOPLE LIVING WITH HIV

HIV Drug Assistance Program (HDAP) - must be HIV+ to enroll

This drug assistance program provides financial assistance to facilitate access to prescribed medications for eligible, enrolled individuals living with HIV infection. HDAP covers health insurance premium payments, and the full-pay or co-pay costs of prescription medications. Medications are provided from designated pharmacies at no cost to the patient.

https://crihealth.org/drug-assistance/

Insurance Support - must be HIV+ to enroll

Community Resource Initiative offers hands-on guidance navigating insurance, assistance with enrollment, and help paying for health insurance premiums, ensuring that people living with HIV can get and keep comprehensive health coverage and avoid gaps in treatment and care.

https://crihealth.org/insurance-support/

MassCARE (Massachusetts Community AIDS Resource Enhancement)

A statewide program which provides access to coordinated, comprehensive, family-centered, culturally and linguistically competent medical care, social service support and peer services for women, infants, children and youth living with HIV and their affected family members.

https://www.mass.gov/masscare

PREVENTION, TREATMENT, HARM REDUCTION, AND TESTING SERVICES

Integrated Testing & Linkage Services (ITLS)

The Massachusetts Department of Public Health supports programs where individuals can obtain screening and linkage to treatment for HIV, hepatitis C, sexually transmitted infections, and tuberculosis infection. https://www.mass.gov/info-details/integrated-testing-and-linkage-services-locator

Syringe Service Programs (SSPs)

SSPs provide prevention and health promotion services to persons who inject drugs. Through these programs clients may receive sterile needles and syringes free of cost, dispose of used needles and syringes, and receive referrals to other services such SUD treatment services, testing for HCV, HIV, and other sexually transmitted infections, as well as overdose education and Narcan (naloxone).

https://www.mass.gov/syringe-service-programs

Naloxone Access

Naloxone distribution programs in Massachusetts (MA) include Overdose Education and Naloxone Distribution (OEND) programs and Community Naloxone Program (CNP) affiliate programs. These programs provide

naloxone at no cost to community members.

https://www.mass.gov/info-details/harm-reduction-program-locator

Massachusetts Substance Use Disorder Helpline

The Helpline is a statewide, public resource for finding substance use, harm reduction, treatment, recovery, and problem gambling services. Helpline services are free and confidential, and available 24/7. mahelpline.org

Partner Services Program Information for the Public

When people in Massachusetts are diagnosed with one of several sexually transmitted diseases (STDs), the Department of Public Health can provide various health services. These could include linking to care and treatment, supporting medical care engagement and re-engagement if patients have fallen out of care, supporting linkage to other health and social services, anonymously notifying partners of a potential exposure, assisting partners with getting testing and treatment/care.

https://www.mass.gov/info-details/partner-services-program-information-for-the-public

The Behavioral Health Help Line (BHHL)

The Behavioral Health Help Line (BHHL) is a 24/7 hotline that connects individuals and families to the full range of treatment services for mental health offered in Massachusetts, including outpatient, urgent, and immediate crisis care. Call or text 833-773-2445.

Non-Occupational Post-Exposure Prophylaxis (nPEP)

The Community Resource Initiative Non-Occupational Post-Exposure Prophylaxis (nPEP) program is designed to provide immediate access to treatment and cover the cost of HIV post-exposure prophylaxis for individuals who:

- Are HIV-negative
- May have been exposed to HIV through a non-work-related exposure
- Have no health insurance or are underinsured

https://crihealth.org/prevention/pep/

Pre-Exposure Prophylaxis (PrEP)

The Massachusetts Pre-Exposure Prophylaxis Drug Assistance Program (PrEPDAP) helps eligible Massachusetts residents pay for approved medications that can prevent the acquisition of HIV. https://crihealth.org/prevention/prepdap/

TB Drug Assistance Program

The purpose of the Community Resource Initiative Tuberculosis Drug Assistance Program (TDAP) is to ensure that clinicians and patients can access the Tuberculosis medications they need in a timely and cost-effective manner. TDAP utilizes designated pharmacies located at or near Tuberculosis clinic sites for patients to pick up their prescriptions.

https://crihealth.org/drug-assistance/tdap/

Care That Fits You

A campaign and website for men who have sex with men. Provides links and resources for HIV prevention and treatment, hepatitis, STIs, and more.

https://carethatfitsyou.org/

Food/Meals

For those who qualify for services, Community Servings offers home-delivery of medically tailored meal program for people living with critical or chronic illnesses and food insecurity. Eligibility is based on medical or behavioral health diagnosis and ability to maintain a healthy diet and independent lifestyle. This program serves residents of Massachusetts. Clients residing outside of the delivery area may qualify for shipping. https://www.servings.org/

EDUCATIONAL RESOURCES FOR CLIENTS/PATIENTS

Massachusetts Health Promotion Clearinghouse: Hep C, HIV, PrEP, STDs/STIs, and substance use focused Education Materials for Providers and Consumers https://massclearinghouse.ehs.state.ma.us/PROG-BID/BIDLS page.html

Hepatitis C (HCV) Information for Patients and Providers

https://www.mass.gov/hepatitis-c-hcv

Hepatitis C: What to know now about testing and treatment

https://www.mass.gov/info-details/hepatitis-c-what-to-know-now-about-testing-and-treatment

Naloxone (Narcan) Access

There are different options to access Narcan in Massachusetts.

https://www.mass.gov/info-details/where-to-get-naloxone-in-massachusetts

YouCan Reverse an Overdose

Educational series about providing information about reversing an overdose including learning the signs of an overdose, how to respond, using naloxone, and using rescue breathing in response to an overdose, even if you don't have Narcan.

Learn more: YouCan.info

EDUCATIONAL RESOURCES FOR PROVIDERS

STD & HIV information for healthcare and public health professionals

The latest STD information and resources from DPH and DPH partners.

https://www.mass.gov/info-details/std-information-for-healthcare-and-public-health-professionals

CDC STI Treatment Guidelines 2021

CDC's Sexually Transmitted Infections (STI) Treatment Guidelines, 2021 provide current evidence-based prevention, diagnostic and treatment recommendations. The recommendations are intended to be a source for clinical guidance. Healthcare providers should always assess patients based on their clinical circumstances and local burden.

https://www.cdc.gov/std/treatment-guidelines/default.htm

Sylvie Ratelle STD/HIV Prevention Training Center (PTC)

The Prevention Training Center is a project of DPH's Division of STD Prevention. The Center offers free courses for health care providers in the diagnosis, treatment, and management of STDs and prevention of HIV.

https://ratelleptc.org/

STD Clinical Consultation Service

The Clinical Consultation Service is intended for licensed healthcare professionals and STD program staff. We do not provide direct medical care, treatment planning, or medical treatment services to individuals.

https://www.stdccn.org/render/Public

The New England AIDS Education and Training Center (NEAETC)

The NEAETC provides HIV/AIDS education, consultation, technical assistance, and resource materials to health care professionals throughout New England. https://www.neaetc.org/

STD Partner Services Program information for healthcare providers

Partner Services Program assists people diagnosed with STDs, including HIV, get treated for their infection, notify their partners that they may have been exposed to an STD, and helps partners get testing and medical care. Providers can call the Partner Services Program at 617-983-6999.

https://www.mass.gov/partner-services-program-psp

HIV Pre-Exposure Prophylaxis (PrEP) information for providers

https://www.mass.gov/info-details/hiv-pre-exposure-prophylaxis-prep-information-for-providers

Hepatitis C (HCV) Information for Patients and Providers

https://www.mass.gov/hepatitis-c-hcv

Enhancing Hepatitis C Testing and Treatment Toolkit

This toolkit provides resources and best practices to help providers to identify and successfully treat hepatitis C infection. The majority of new hepatitis C infections in Massachusetts occur among people who inject drugs. This toolkit includes recommendations for reaching individuals who inject drugs. The toolkit was designed for primary care providers but includes tools and information which other health care providers may find useful. https://www.mass.gov/resource/enhancing-hepatitis-c-testing-and-treatment

Grayken Training and Technical Assistance

"Back to Basics: Infectious Diseases" This training is held at no cost, provides CEs and covers sexually transmitted infections, skin and soft tissue infections, and respiratory infections and is designed to meet some of the educational requirements for Massachusetts healthcare teams working in BSAS-licensed or approved facilities. Addictiontraining.org

Bureau of Substance Addiction Services (BSAS) Training Calendar

Trainings and Events provided by BSAS on topics relevant to working in addiction prevention, harm reduction, treatment, and recovery funded https://careersofsubstance.org/training-events

Case reporting to DPH

Confirmed cases of HIV, HCV or syphilis are reportable to the Department of Public Health, Bureau of Infectious Disease and Laboratory Sciences under state regulation 105 CMR 300.000 Reportable Diseases, Surveillance, and Isolation & Quarantine Requirements.

https://www.mass.gov/infectious-disease-surveillance-reporting-and-control