

Integrating Hepatitis C Virus (HCV) Services into Narcotic Treatment Programs (NTPs) in California: Frequently Asked Questions

BACKGROUND

Effective July 1, 2020, the California Department of Health Care Services (DHCS) finalized new NTP regulations. NTPs now must test for hepatitis C and offer an optional HIV test before admitting applicants for detoxification or maintenance treatment, with some exceptions.¹ In this document, the California Department of Public Health (CDPH) and DHCS provide answers to questions that frequently arise on integrating HCV services into NTPs. Use the hyperlinked questions below to jump to the answer to each question.

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¹ California Code of Regulations (CCR), Title 9, Chapter 4, Section 10270.

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TESTING

What is the recommended HCV testing sequence?

HCV testing should be initiated with a U.S. Food and Drug Administration (FDA)-approved HCV antibody test, which can be conducted using the HCV OraQuick fingerstick rapid test or a traditional blood draw. HCV antibody testing shows if someone has ever had hepatitis C, but it does not diagnose current infection. Individuals with a reactive HCV antibody test result should have same-day reflex or follow-up testing with an FDA-approved test for HCV ribonucleic acid (RNA), which is needed to diagnose current hepatitis C infection. For more information, see the [Recommended Testing Sequence for Identifying Current HCV Infection](#).

Which is preferable, HCV rapid fingerstick testing or a traditional blood draw?

There are pros and cons to both testing modalities in an NTP setting.

A benefit of **HCV rapid fingerstick testing** is that results are available in less than 30 minutes, and it does not require finding a vein, which may be difficult for people who have been injecting for many years. If performing a rapid test, programs will need to do an HCV-related blood draw for people with a positive rapid HCV antibody test result (also known as a reactive HCV antibody test result), although positivity rates will vary and may be high in many NTPs.

Potential downsides of the rapid fingerstick test include the cost (around \$15-20), which may be more than a lab-based antibody test, the interruptions to clinic flow from waiting for 20 minutes for HCV antibody rapid test results, and the limited utility of stand-alone HCV antibody results without HCV RNA testing in high hepatitis C prevalence settings such as NTPs. For information on rapid HIV and HCV testing, visit the [CDPH HIV and HCV Testing](#) webpage.

The benefits of **performing a blood draw** are that it can be integrated into existing procedures for syphilis testing, which has been required in NTPs for many years, and that a laboratory can use the same tube of blood to test for syphilis and for HCV. Another benefit of a traditional blood draw is that it facilitates HCV antibody testing with a “reflex” to HCV RNA, where the HCV RNA test is conducted automatically if the HCV antibody test is reactive. Commercial laboratories offering reflex testing only charge for the HCV RNA test if the HCV antibody result was reactive. The downside of a traditional blood draw is that it requires phlebotomy capacity and/or a contract with a laboratory, and requires finding a vein, highlighting the importance of having highly experienced phlebotomists on staff. Reflex testing may require collecting two tubes of blood for the initial blood draw—one for HCV antibody test and one for the HCV RNA test—laboratories will provide specific testing protocols. NTPs could consider offering both HCV rapid fingerstick testing and blood draw with reflex testing to accommodate client preference.

Is written patient consent required to provide HCV testing?

Prior to admission, patients must provide written consent to participate in an NTP.² If a person consents to participation in an NTP, HCV testing is an admission requirement except as otherwise noted below (see “What if a patient declines HCV testing?”). However, there is no separate (special) written consent required for HCV testing beyond the consent to participate in the NTP, and the HCV test does not need to be listed in the general consent form. Verbal consent to HCV testing is acceptable and must be documented in the patient’s record.

CDPH recommends using opt-out testing language and offering patient education to promote the benefits of testing. Sample opt-out testing language could include, for example, “As part of routine care, we will take your blood pressure, and test for syphilis, hepatitis C, and tuberculosis. We also offer HIV testing. Please let me know if you do not want to be tested.” Posters, videos, flyers, and counseling sessions can educate patients on hepatitis C. See the Additional Resources section on pages 7-8 for links to sample patient education materials.

What if a patient declines HCV testing?

According to DHCS, the NTP is required to offer testing and document in the medical record a reason for patient refusal. According to DHCS, the following may be considered by the Medical Director when determining if a patient may opt out of HCV testing:

- If the patient was recently treated for hepatitis C infection and cured, and is absent of ongoing risk factors (i.e., are using pills and not injecting)
- If the patient is in crisis and is not prepared to receive an HCV diagnosis; in this case, the patient should be offered HCV testing after they are stable
- If the patient’s veins are severely damaged to the extent that a blood specimen cannot be obtained.^{3, 4}

² California Code of Regulations Title 9 Section 10290

³ [Narcotic Treatment Programs Regulations FAQs](#). Revised July 2021.

⁴ CCR, Title 9, Chapter 4, Section 10270(a)(2).

In the patient's veins are damaged, rapid HCV antibody testing could also be offered if available and fingerstick dried blood spot testing offered for confirmatory HCV RNA.

What if a patient accepts HIV testing?

If an individual opts into an HIV test, California Health and Safety Code 120990 specifies that the individual should be provided information about the test, including the following:

- Numerous treatment options are available for a patient who tests positive for HIV
- Individuals who test HIV negative should be advised of the importance of routine testing.

Most HIV test results are expected to be negative, however individuals who receive a positive test result should be linked to care as soon as possible. NTPs should establish a protocol for linkage at the health department and HIV clinic. Patients who test negative for HIV should also be offered HIV pre-exposure prophylaxis (PrEP). For more information on PrEP, please see pages 26 and 27 of the [U.S. Public Health Services PrEP for the Prevention of HIV Infection in the United States – 2021 Update, A Clinical Practice Guideline](#).

What documentation is required if conducting testing through our primary care clinic?

Any documentation from the primary care provider is sufficient if it confirms whether the patient was tested. Types of documentation may include, but are not limited to, electronic medical record, physical chart, or paper chart.

My program will send blood samples to a lab for HCV testing. If we have a Clinical Laboratory Improvement Amendments (CLIA) waiver or license, would we need to update it?

No, if RNA test samples will go to a separate lab for processing, the NTP would not need to update the CLIA waiver or license since the offsite lab will be performing the test. A CLIA *certificate of waiver* is only necessary for HCV testing if program staff will perform rapid testing and if more complex tests will not be performed. Sites conducting higher complexity tests for other conditions can contact the accrediting organization (regarding Certificates of Accreditation) or contact CLIA at LFSCCLIA@cdph.ca.gov to add the rapid test to the testing menu.

NAVIGATION/LINKAGES

What are the requirements if a patient tests positive for hepatitis C?

According to DHCS, linkages to hepatitis C care and treatment should be included in the patient's record for those NTP patients who test positive for hepatitis C, this includes even patients that NTPs only test for HCV antibodies but not for HCV RNA.¹

What if my program does not have dedicated staff to help link patients with hepatitis to care? How can I pay for the cost of hepatitis C linkages to care and patient navigation?

There may be existing resources that NTPs can leverage to support patient navigation. For example, some NTPs in counties that have opted into the Drug Medi-Cal Organized Delivery System (DMC-ODS) have leveraged case management (care coordination) as a covered service to educate and link people to HCV care. CDPH has also funded 22 local health jurisdictions (LHJs) for hepatitis C-related activities, including HCV testing, patient navigation and/or care coordination. The following LHJs are using state funds through June 30, 2024, for HCV services:

Local Health Jurisdiction
Alameda County (excluding Berkeley)
Humboldt
Kern
Long Beach
Los Angeles County (excluding Pasadena, Long Beach)
Marin
Monterey
Orange
Riverside
Sacramento
San Bernardino
San Diego
San Francisco
San Joaquin
San Luis Obispo
San Mateo
Santa Barbara
Santa Clara
Santa Cruz
Shasta
Sonoma
Ventura

There are also several organizations that have expressed interest in collaborating with NTPs to offer HCV testing, patient navigation, care coordination, and/or treatment through telehealth, mobile testing services, and/or partnerships with other local treating providers. See Organizations Available for Potential Partnerships under Resources on page 7 of this document.

HEPATITIS C TREATMENT

How do I find a specialist in my area to accept linkages for hepatitis C care and treatment?

Access to hepatitis C specialty care varies greatly across and within various geographic regions of California. Treating clinicians may include members of the specialty associations focused on liver disease, gastroenterology, or infectious disease medicine. However, primary care providers can treat most patients with HCV, except those with complex or advanced liver disease, with the training and support of specialty care providers. A [federally qualified health center](#) (FQHC) near you may treat HCV or have primary care providers interested in treating HCV in collaboration with your program. Some FQHCs may even be able to treat at NTPs. Project ECHO (see Training section), which trains primary care providers in underserved areas to treat hepatitis C, may also be aware of local, experienced, non-specialty care providers who treat HCV in your area.

Can NTPs treat hepatitis C on-site?

CDPH recommends NTPs consider offering on-site hepatitis C treatment, which has been shown to increase treatment completion among patients receiving medications for opioid use disorder. Programs licensed to provide primary care may be able to bill Medi-Cal for treating hepatitis C infection. Additional treatment strategies may include copay and medication patient assistance programs for people who are uninsured and, if the treating entity is eligible and enrolled, the 340B drug pricing program. For more information about the 340B program, visit the Health Resources and Services Administration, [Office of Pharmacy Administration](#) website.

For clinics not licensed to offer primary care, options for consideration may include collaborating with a nearby FQHC or other primary care clinic serving your NTP patient population. The FQHC can clinically manage and prescribe hepatitis C treatment, such as through a mobile health van parked outside the NTP or by prescribing hepatitis C medications that the NTP dispenses alongside medications for opioid use disorder (e.g., directly observed therapy). Another option—if the patient approves—is for the HCV medications to be delivered to the NTP for the patient to store (i.e., in secure lockers) on-site and self administer. This may be especially helpful for patients experiencing homelessness who may have difficulty holding onto their hepatitis C medications without a safe and secure place to store them.

Telehealth allows many patients to receive care from an outside clinician while physically remaining in the NTP, reducing patient barriers to care, and facilitating HCV treatment completion. There are also programs that may be available to provide testing on-site. See **Organizations Available for Potential Partnerships** on page 8 for more information.

Is a referral to a specialist necessary for HCV treatment?

There is no statewide requirement for a referral to a specialist for hepatitis C treatment. Specialty referral requirements may vary by health insurer. Clinicians managing patients with hepatitis C should consult the Association for the [Advanced Study of Liver Diseases/Infectious](#)

[Diseases Society of America \(AASLD/IDSA\) hepatitis C treatment guidelines](#) for recommendations on when to refer patients to a specialist, such as for serious or advanced liver disease or complex comorbidities. Medi-Cal Rx, effective January 1, 2022, does not require referral to a specialist for hepatitis C treatment authorization for Medi-Cal beneficiaries.

How will Medi-Cal Rx impact hepatitis C treatment?

Medi-Cal Rx has standardized Medi-Cal pharmacy benefits statewide, under one delivery system. Prior authorizations are no longer required for medications on the [DHCS Contract Drug List](#), which includes the two most commonly prescribed hepatitis C treatment medications. Prior authorizations are still required to provide clinical justification for use of a non-contract drug list product. Treating clinicians are no longer required to submit genotype or HCV viral load results for prior authorization, but should include the International Classification of Diseases, Tenth Revision (ICD-10) code for chronic hepatitis C (B18.2) when requesting approval for hepatitis C treatment medications. For more information, visit the [Medi-Cal Rx](#) website.

TRAINING

What training is necessary for staff to test for HCV?

If non-clinical staff and certified phlebotomists will be providing rapid testing, training from the CDPH Office of AIDS or its agents or using an approved curriculum is required to conduct the HCV rapid test. Business and Professions Code (BPC) section [1206.5](#) allows medical doctors (MDs), doctors of osteopathic medicine (DOs), nurse practitioners (NPs), physician assistants (PAs), pharmacists,⁵ registered nurses (RNs), licensed vocational nurses (LVNs),⁶ and medical assistants (MAs),⁷ among others, to perform CLIA-waived testing within their respective scopes of practice. See the [HCV Rapid Testing Frequently Asked Questions](#) for information on training for non-clinicians and resources for clinicians new to hepatitis C.

Physicians can draw blood within their scope of practice, and registered nurses and licensed vocational nurses can draw blood if authorized by a licensed physician and surgeon.⁸

What other hepatitis C training is available for NTP providers?

Project ECHO holds video-conference-based community clinics with didactic lectures and de-identified participant case presentations to increase primary care provider capacity and confidence treating hepatitis C infection. Email HCVECHO@ucsf.edu to register for the University of California, San Francisco ECHO (clinics every other Wednesday from 11:30am-1:00pm) or visit the [University of Southern California \(USC\) ECHO](#) website to register for the

⁵ Title 16 California Code of Regulations section [1793.1](#) allows a licensed intern pharmacist to perform the duties of a licensed pharmacist while acting under the supervision of a pharmacist.

⁶ Specific requirements for LVNs are outlined in BPC section [1242.6](#).

⁷ Specific requirements for MAs are outlined in BPC section [2069](#).

⁸ Business and Professions Code [1242.6](#)

USC Project ECHO (clinics on the second and fourth Thursday of the month from 12:00pm-1:00pm).

University of Washington has an excellent, free, comprehensive, up to date website, [Hepatitis C Online](#), which features a self-guided course on hepatitis C screening, diagnosis, and treatment.

The AASLD/IDSA [HCV Guidelines: Recommendations for Testing, Managing, and Treating Hepatitis C](#) include a [simplified treatment algorithm](#) for managing hepatitis C among HCV treatment-naïve patients without cirrhosis.

Visit the [Pacific Southwest Addiction Technology Transfer Center](#) site for details on technical assistance and online training for professionals in the addiction treatment field. Complete an [online form](#) to request technical assistance or training on a new topic.

Additional resources and recorded webinars are available online:

- [California Society of Addiction Medicine Guidelines for Physicians Working in California Opioid Treatment Programs](#): Pages 73-78 include information on HCV.
- [Addiction Technology Training Centers Network: Your Guide to Integrating HCV Services into Opiate Treatment Programs](#): Tips on planning for HCV services integration from a systems change perspective.
- [Integrating HIV and HCV Testing and Linkages to Care into NTPs](#) (password: HCV4NTPs): Webinar for California NTPs.
- [Hepatitis C 101 Webinar](#) (password HepatitisC2021!): This training covers the basics of HCV transmission, epidemiology, and natural history.
- [Hepatitis C Outreach, Testing, and Navigation Webinar](#) (password:TreatHCV1!): Highlights the importance of same-day services and supporting patients initiating HCV care.
- [Hepatitis C Care Coordination Webinar](#) (password: HepCare123.): Panelists discuss best practices for developing a care coordination program and overcoming obstacles.

ADDITIONAL RESOURCES

Testing

- CDPH [Hepatitis B and Hepatitis C Screening Toolkit for Primary Care Providers](#) (*update pending*)
- [National Viral Hepatitis Roundtable – Hepatitis C Resources Page](#): Includes resources to help support integrating routine HCV screening into electronic health records, etc.

Hepatitis C Treatment

- [DHCS Hepatitis C Treatment Policy for the Management of Chronic Hepatitis C](#): Provides information on the most recent guidelines for treating hepatitis C among people with Medi-Cal.

- [Issue Brief: Hepatitis C Treatment Among People Who Inject Drugs \(PDF\)](#): Reviews the evidence on HCV cure rates and medication adherence among people who use drugs.
- [Medi-Cal Rx Contract Drug List](#)

Hepatitis C Education for Patients and Staff

- [Centers for Disease Control and Prevention](#): Provides patient fact sheets, posters, etc. for patient education.
- [National Alliance of State and Territorial AIDS Directors: HCV Community Navigation Toolkit](#): Includes a health promotion guide on page 46 with answers to common questions and a navigation training [webinar](#).

Organizations Available for Potential Partnerships⁹

- The [Chronic Liver Disease Foundation](#) may be able to provide free hepatitis C testing and linkages in drug treatment programs once every 12 weeks. Contact info@chronicliverdisease.org or call 888-565-5321 for more details.
- [Integrated Care Systems](#) is a pharmacy that currently provides free hepatitis C care coordination in partnership with NTPs in California. Call 888-864-0936 for more details on the HCV Compliance Program.
- The University of California San Francisco (UCSF) DeLIVER clinic provides mobile hepatitis C medical services outside of NTPs in the San Francisco area and is exploring providing telehealth HCV treatment in collaboration with other organizations across California. Contact hcvecho@ucsf.edu for more details.

Technical Assistance

For assistance identifying and leveraging potential partnerships in your geographic area, and for other forms of information and technical assistance, please contact the CDPH, Sexually Transmitted Diseases Control Branch, HCV subject matter experts at CDPH.HEP@cdph.ca.gov. For more information on the new HCV policy, please contact DHCSNTP@dhcs.ca.gov.

⁹ The organizations are examples, and not intended to serve as an exhaustive list or endorsement of any company or its products.