

NYS Hepatitis C Testing Law Frequently Asked Questions

OVERVIEW

1. When did the testing law go into effect?

The testing law is effective January 1, 2014.

2. What are the Department's expectations around compliance?

The Department has worked collaboratively since the law went into effect to assist providers in complying with its terms. DOH expects all facilities and providers covered by the law to implement the routine offer of testing and other provisions of the law by the law's effective date, or that facilities and providers have made their specific technical assistance needs known to the Department and are making substantial progress toward full compliance. Several evaluation projects will be undertaken to determine the extent to which the law has been implemented in a variety of settings.

3. What are the key provisions of the law?

- A hepatitis C screening test must be offered to every individual born between 1945 and 1965 receiving health services as an inpatient of a hospital or receiving primary care services in the outpatient department of a hospital or in a freestanding diagnostic and treatment center or from a physician, physician assistant, or nurse practitioner providing primary care.
- If an individual accepts the offer of the hepatitis C screening test and the screening test is reactive, the health care provider must offer the individual follow-up health care or refer the individual to a health care provider who can provide follow-up health care. The follow-up health care must include a hepatitis C diagnostic test.
- The offer of testing must be culturally and linguistically appropriate.

4. What is the benefit of testing someone for hepatitis C?

There are several reasons why someone should be tested for hepatitis C. Knowing one's hepatitis C status will help prevent hepatitis C transmission to others. Early clinical evaluation and ongoing disease monitoring can also improve health outcomes. Additional measures can be taken to protect the liver from further harm such as getting vaccinated for hepatitis A and B, decreasing or eliminating alcohol consumption and understanding the interactions among herbal supplements, over the counter medications, and prescription medications. Finally, hepatitis C is a curable disease for most. Better and more effective treatments are now available. The earlier in the disease process someone receives treatment, the greater chance they have to be cured.

5. Why is it important to test persons born between 1945 and 1965?

- According to the Centers for Disease Control and Prevention (CDC), more than 75% of adults infected with hepatitis C are people born from 1945 through 1965 (baby boomers).
- The reason that baby boomers have high rates of hepatitis C is not completely understood. However, it is believed that most baby boomers became infected in the 1970s and 1980s when rates of hepatitis C and drug use were highest. Since people with hepatitis C can live for decades without symptoms, many baby boomers are unknowingly living with an infection they got many years ago that can lead to liver disease, liver failure and cancer.
- Hepatitis C is primarily spread through contact with blood from an infected person. Many baby boomers could have gotten infected from contaminated blood and blood products before widespread screening of the blood supply began in 1992 and universal precautions were adopted. Others may have become infected from injecting drugs, even if only once in the past. Still, many baby boomers do not know or remember how or when they were infected.

6. Does everyone who becomes infected with hepatitis C virus become chronically infected?

No. For a small percentage of people, the hepatitis C virus infection will resolve on its own, but the majority of people who become infected will progress to chronic infection (75-80%). People whose hepatitis C infection resolves will have antibodies to hepatitis C virus, but will not be actively infected with the virus. People who are chronically infected will have antibodies to hepatitis C virus and will have the virus present in their body.

7. What is the difference between a hepatitis C screening test and hepatitis C diagnostic test?

- The initial hepatitis C screening test is a test that detects the presence of hepatitis C antibodies in the blood. A reactive result on a hepatitis C screening test is interpreted as a presumptive positive for hepatitis C antibodies in the blood. This means a person may have been infected with the hepatitis C virus at some point in time. It does not mean they are currently infected. There are laboratory based (i.e., EIA) and point of care (i.e., rapid test) hepatitis C antibody screening tests.
- The hepatitis C diagnostic test (also known as an HCV RNA test) is a laboratory test that detects the presence of the hepatitis C virus in the blood. The presence of hepatitis C virus in the blood indicates current hepatitis C infection.

8. Does a reactive hepatitis C screening test mean someone is currently infected with hepatitis C?

No, not necessarily. A reactive hepatitis C (antibody) screening test can occur under three different circumstances. One possibility is that there is current hepatitis C infection; a second possibility is that there was hepatitis C infection in the past that has resolved meaning the person is no longer infected; and a third possibility is that the result is a false positive, meaning that the person was never infected with hepatitis C. In order to confirm current/active hepatitis C infection, the patient must have a hepatitis C diagnostic (HCV RNA) test. The patient should presume they are infected until they have the hepatitis C diagnostic test done.

9. Is hepatitis C reflex testing available through commercial labs?

Yes, reflexing to a hepatitis C diagnostic test (HCV RNA test) following a reactive hepatitis C screening test is recommended and clinicians can now order a hepatitis C reflex test from several

commercial laboratories. The laboratory will do the hepatitis C antibody test, and if the result is positive, the laboratory will immediately perform an HCV RNA test on the same specimen. Only one tube of serum is needed. This reflex test provides the information needed to determine hepatitis C infection status in one step, without having the patient return for a second blood draw.

- For Quest search test # 91438X - <http://www.questdiagnostics.com>
- For LabCorp, search test # 144028 - <https://www.labcorp.com>
- For BioReference, search test # B125-6 - <http://www.bioreference.com>

10. Is there a hepatitis C rapid antibody test?

Yes. There is currently one FDA approved hepatitis C rapid antibody test. Blood specimens collected for hepatitis C rapid antibody testing can be collected via fingerstick or venipuncture. Test results are available in 20 minutes.

REQUIRED OFFER OF HEPATITIS C TESTING

11. Does the requirement that hepatitis C testing be offered to all persons born between 1945 and 1965 apply in all medical settings?

The requirement for the offering of testing applies to:

- Persons receiving inpatient services at hospitals;
- Persons receiving primary care services through hospital outpatient clinics and diagnostic and treatment centers; and
- Persons receiving primary care services from physicians, physician assistants, and nurse practitioners regardless of setting.

Emergency Departments are not required by the law to offer hepatitis C screening testing, but are encouraged to do so.

12. Which clinicians must offer hepatitis C testing under this law?

Providers who must offer hepatitis C testing include physicians, physician assistants, and nurse practitioners providing primary care regardless of setting and without regard to board certification.

13. Does the offer of hepatitis C screening testing apply to emergency departments?

No. Emergency Departments are not required by the law to offer hepatitis C screening testing, but are encouraged to do so.

14. What are the exceptions to the mandatory offer of hepatitis C testing in the hospital, diagnostic and treatment center, and primary care settings noted in the law?

The law does not require an offer of testing to be made:

- When the individual is being treated for a life-threatening emergency.
- When the individual has previously been offered or has been the subject of a hepatitis C related test (unless otherwise indicated due to on-going risk factors).

- When the individual lacks the capacity to consent* (though in these cases, the offer may also be made to an appropriate person who is available to provide consent on behalf of the patient).

* The exception as stated in the law refers to the individual lacking the capacity to accept the offer. The reference to 'capacity to consent' does not imply written, informed consent for the hepatitis C test, but rather capacity to understand the test offer.

15. Instead of making the offer, can we just let patients know that testing is available if they want it?

No. Letting a patient know that testing is available is not an offer of testing. An example of an offer would be, “We are routinely offering hepatitis C testing to all persons born between 1945 and 1965. Would you like to be tested for hepatitis C?”

16. Must an individual have risk factors for hepatitis C to be offered a hepatitis C test?

No. The offer is required for all persons born between 1945 and 1965 except as noted in Question 14. Persons with risk factors should be offered the test as part of standard medical care.

17. As a patient born between 1945 and 1965, what do I do if when I’m seeking care, I am not offered a hepatitis C test?

If you meet the criteria set out by the law and are not offered a hepatitis C test by a health care provider, 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 that your health care provider is not complying with the law, send us your name and contact information, the name of the provider, and whatever details you think would be helpful to hepatabc@health.state.ny.us and the situation will be reviewed.

18. Is the hepatitis C screening test mandatory?

The law mandates the offer of hepatitis C screening testing only, not testing itself. However, if a person accepts the offer, the facility must be able to provide the testing in the same manner as other types of similar screening testing.

19. Does the law require insurance companies to pay for the hepatitis C test? What if the patient doesn’t have insurance?

No, the law does not require insurance companies to pay for the test. However, the U.S. Preventive Services Task Force (USPSTF) issued a B grade on screening for hepatitis C among persons born between 1945 and 1965. The USPSTF recommendation signifies that hepatitis C screening among this population will be covered by most public and private insurance. This is because the Affordable Care Act (ACA) requires that private insurance plans cover USPSTF A or B recommended services without cost sharing. Medicaid Managed Care plans must also cover these services. Hepatitis C testing is also now covered by Medicare.

If a patient accepts the offer of a test but lacks insurance or has insurance that may not pay for the test, clinicians should follow their normal protocol for any other test that might be ordered and may not be covered.

In addition, there are a number of free hepatitis C rapid testing sites throughout the state. For a complete list of those sites, go to:

- the DOH web site at: <http://www.health.ny.gov/diseases/communicable/hepatitis/> or
- <http://nychepbc.org/> (NYC hepatitis C testing sites only)

20. As a facility or clinician covered by the law, can we refer out for testing if someone accepts or ask the person to come back at another time?

In general, it is expected that covered facilities and clinicians have the capacity to provide the hepatitis C screening test. Hepatitis C screening testing should be handled the same way any other routine test is provided in the same facility or office. If it is the facility's policy to give a patient a lab slip to have routine lab tests, including the hepatitis C screening test, conducted at an off-site draw station, this is acceptable.

If an individual accepts the offer of the hepatitis C screening test and the screening test is reactive, as stated in the law, the health care provider may refer the individual to a health care provider who can provide follow-up health care which includes a hepatitis C diagnostic test.

21. Does the required offer of a hepatitis C screening test apply to nursing homes, retail clinics, urgent care centers, STD clinics, employee health services and family planning sites that provide primary care?

Even though these facilities are not specifically mentioned in the law, if primary care is being provided by a physician, physician assistant, or nurse practitioner, they are required to make the offer.

22. If a patient is only under observation (i.e., 23 hour stay) and not admitted to the hospital, do they need to be offered the hepatitis C screening test?

No. Patients under observation and not admitted as inpatients are not required to be offered the test.

23. Under the new law, do all patients at-risk for hepatitis C need to be screened and offered hepatitis C testing or only patients in the birth cohort?

Under the new law, only those patients born between 1945 and 1965 are required to be offered a hepatitis C screening test. Although the new law requires the offer of a test only for those born between 1945 and 1965, CDC recommends hepatitis C testing be offered to all persons at risk for hepatitis C, such as injection drug users, those that received a blood transfusion or organ donation before 1992, persons living with HIV, anyone with abnormal liver tests, health and safety workers who have been exposed to blood on the job and persons on long term dialysis.

24. Are local health department STD clinics mandated to offer hepatitis C screening under the new law if the patient does not have a primary care provider, but is receiving gynecological services only?

Primary care is defined in the law as the medical fields of family medicine, general pediatrics, primary care, internal medicine, primary care obstetrics, or primary care gynecology, without regard to board certification. If primary care is being provided at the STD clinics, the hepatitis C screening test must be offered.

25. How can I be sure if the state will consider my clinic to be a primary care provider mandated to make the offer of hepatitis C testing?

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.

26. Do Ambulatory Surgery Centers have to offer the hepatitis C screening test?

No. Ambulatory surgery centers would not be covered by the mandated testing offer provision since they do not offer primary care

27. How often does the offer of hepatitis C testing need to be repeated?

All persons born between 1945 and 1965 need to be offered a hepatitis C test once, unless they have ongoing risk factors for hepatitis C infection

28. Can RNs perform the test with a non-patient specific standing order?

Yes, the NYS Education Law (Subdivision 4 of section 6909) allows RNs to perform an HCV test with a non-patient specific order, also known as a standing order.

29. For record keeping purposes, is the offer of a hepatitis C test considered confidential information that needs to be protected?

Any information kept in a patient's medical record is protected by HIPAA – the Health Insurance Portability and Accountability Act.

30. If I provide a poster or brochure which contains the required information on testing and that asks patients to let a staff person know if they would like a hepatitis C test, does that satisfy the offer requirement?

No. The test offer must be more than a provision of information, the advertisement of a recommendation, or an invitation for a patient to ask for testing. Patients should be asked directly in writing or orally if they would like a hepatitis C test.

31. Is a separate consent required for hepatitis C testing?

No. There is no separate (special) consent required for hepatitis C testing. Whatever method your facility uses to obtain consent for other types of medical services (e.g., testing, screenings, procedures, etc.), consent for HCV screening would be included. For example, for facilities using a general medical consent for medical services, this would cover HCV testing.

The exception as stated in the law refers to the individual lacking the capacity to accept the offer. The reference to 'capacity to consent' does not imply written, informed consent for the hepatitis C test.

32. If using the general medical consent, does the hepatitis C screening test have to be specifically listed in the consent language?

No. The hepatitis C screening test does not specifically need to be identified in the consent language. However, we do recommend that the patient receives some type of education on hepatitis C, including the rationale for the screening test. The educational information can be provided in many different formats, including a fact sheet, brochure or a poster.

Patient materials related to the NYS hepatitis C testing law are available free of charge at: http://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis_c/providers/testing_law.htm

33. Does the law require documentation that the offer was made?

No, there is no requirement in the law requiring formal documentation that the offer of a hepatitis C screening test was made. However, for internal tracking and quality assurance purposes, providers may want to document that the offer was made.

34. How do patients decline testing and what documentation is required?

Patients always have the option to decline testing. They may do so orally or in writing. There is no requirement for formal documentation of the declination. However, a notation in the patient's medical record of the offering of the test and the patient's declination may help keep track of those patients that have already been offered the test.

PROVISION OF TEST RESULTS

35. What happens if the patient's hepatitis C screening test is reactive?

As stated in the law, any individual with a reactive screening test result must either be offered follow-up health care or referred to a health care provider that can provide follow-up health care. The follow-up health care must include hepatitis C diagnostic testing. If the screening test is performed by a laboratory, the laboratory may reflex the specimen to the hepatitis C diagnostic. See question 9.

36. What type of information should I provide a patient with a reactive hepatitis C screening test?

- Explain the meaning of the reactive antibody test and counsel on the need for diagnostic testing (Hepatitis C RNA test) to confirm a diagnosis of chronic hepatitis C.
- Explain that the patient is most likely chronically infected and provide basic hepatitis C disease and treatment information.
- Discuss the importance of minimizing risk behaviors to avoid transmitting hepatitis C infection to others, and encourage notification and screening of needle sharing and sexual partners.
- Discuss healthy liver practices, including stopping or reducing alcohol intake and getting vaccinated against hepatitis A and B, if appropriate.

- Encourage the patient to make these healthy choices, and describe the importance of regular medical care.

37. What type of information should I provide a patient with a non-reactive hepatitis C screening test?

- Explain the meaning of the non-reactive antibody test, ensuring that the patient understands a negative antibody test does not protect him/her from future infection in the event of risk-taking behaviors.
- Discuss that if the patient was recently exposed (in the last 6 months), he/she may be in a window period and recommend repeat screening in 6 months, and provide information on hepatitis C prevention, risk and harm reduction.
- Encourage the patient to make healthy choices and to get vaccinated against hepatitis A and B, if appropriate.

38. Can I test people for hepatitis C and have their results sent to another facility to be provided back to the patients?

No. The facility conducting the test is responsible for provision of results and follow-up health care or a referral for follow-up health, including a hepatitis C diagnostic test.

39. Are Partner Services and Partner Notification Services available for persons testing positive for hepatitis C?

No. Unlike HIV, there is no requirement to offer partner services for those testing positive for hepatitis C. Providers should counsel the individual and recommend that their sexual and needle sharing partners also get tested.

FOLLOW-UP HEALTH CARE FOR PERSONS WHO SCREEN REACTIVE FOR HEPATITIS C

40. What does the law mean by follow-up health care for those that have a reactive test?

At a minimum, follow-up health care must include a hepatitis C diagnostic test (i.e., HCV RNA test). CDC also recommends a brief alcohol screening and intervention as appropriate, hepatitis A and B vaccination as appropriate, medical monitoring of disease and an evaluation of treatment eligibility.

41. The law requires that persons ordering hepatitis C testing provide or refer for follow-up health care for those who test reactive. If I am making a referral, do I have to make an actual appointment?

Referrals should be made using your agency's current process and systems for doing so.

42. Does the referral for follow-up care need to be with a hepatitis C specialist such as a Gastroenterologist, Hepatologist or Infectious Disease provider? What are the documentation requirements?

The law does not specify the clinician specialty but does specify that the referral must be for follow-up hepatitis C care. The patient's medical record should reflect the name of the

provider/facility to whom the referral appointment was made. The Department's website includes contact information for providers of hepatitis C care and treatment.

http://www.health.ny.gov/diseases/communicable/hepatitis/docs/directory_nysdoh-ai_providers.pdf

43. Do I need to document that the hepatitis C reactive patient kept the referral for follow-up health care?

No, the law does not require that you confirm that the referral was kept.

44. How soon after a hepatitis C reactive result is provided should the referral appointment for follow-up medical care take place.

The follow-up referral appointment should take place as soon as possible. The earlier someone receives the follow-up hepatitis C diagnostic test to confirm the presence of infection, the earlier they can be evaluated for treatment, take steps to prevent transmission, and take measures to protect their liver from further harm.

BILLING AND REIMBURSEMENT

45. What do we do if a patient does not have health insurance and accepts the offer of the hepatitis C screening test?

There are a number of free hepatitis C test sites throughout the state. For a complete list of those sites, go to:

- <http://www.health.ny.gov/hepatitis/> or
- <http://nycheabc.org/> (NYC hepatitis C testing sites only)

Free hepatitis C rapid test kits are also available for providers through the NYSDOH Hepatitis C Rapid Testing Program. Providers wishing to provide hepatitis C rapid testing may be eligible to enroll in this program. These tests kits are available for use with persons that do not have health insurance coverage. For more information on the NYS Hepatitis C Rapid Testing Program, go to: <http://www.health.ny.gov/diseases/communicable/hepatitis/> or call 518-486-6806.

46. Is the hepatitis C screening test covered by Medicaid, Medicare or other insurances?

Medicaid currently covers hepatitis C screening. All billing and payments are subject to and paid in accordance with Medicaid regulation. This website is regularly updated with important, useful and relevant information. We strongly encourage you to review the site:

http://www.nyhealth.gov/health_care/medicaid

Persons with private insurance should refer to their policy or contact their carrier.

Medicare also covers hepatitis C screening and hepatitis C treatment.

47. What are the proper CPT codes for the hepatitis C screening test and hepatitis C diagnostic tests?

Test Type	CPT Code
Hepatitis C antibody test	86803
HCV RNA Qualitative	87521
HCV RNA Quantitative	87522

48. Must hepatitis C testing offered under the law be provided for free?

No. The hepatitis C test when offered according to the law does not need to be provided for free.

49. If a person does not want any out of pocket expenses or to have his insurance company know he was tested for hepatitis C, can I refer him to a state, local or community provider that conducts free hepatitis C testing?

Yes. If a patient would otherwise refuse a hepatitis C test, it is appropriate to make this kind of referral. Patients who would like information about free testing sites may call 1-800-522-5006. For a complete list of free hepatitis C testing sites, go to:

- <http://www.health.ny.gov/diseases/communicable/hepatitis/>
- <http://nychepbc.org/> (NYC hepatitis C testing sites only)

50. Where can I find more information on the Patient Assistance Programs (PAP) for individuals who are not eligible for health insurance and/or need financial assistance for accessing hepatitis C medications or other hepatitis C related services?

There are a number of resources for individuals who need help accessing free hepatitis C medications or other hepatitis C related services, including assistance with high co-pays. For a complete list go to:

<http://nychepbc.org/resources/health-care/medications/>

OTHER QUESTIONS

51. What is the penalty if a provider does not offer the hepatitis C screening test?

For health care facilities that the NYSDOH regulates, non-compliance with the law could result in a statement of deficiencies. Also, for any person or entity to which the law applies, the NYSDOH could impose a fine of up to \$2,000 per violation under Public Health Law section 12.

52. Will formal regulations be developed for the law? If so, when will they be available?

No. The DOH will not be issuing formal regulations pursuant to this law. Instead, DOH will provide guidance such as FAQs.

53. Will NYSDOH require any data to 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. However, reporting of acute and chronic hepatitis C cases is mandated under the New York State Sanitary Code (10 NYCRR

2.1, 2.10). Cases are required to be reported to the local health department in the county where the patient resides.

For questions on cases residing outside of NYC, call NYSDOH at 518-473-4439 or go to:
http://www.health.ny.gov/forms/instructions/doh-389_instructions.pdf

For residents of NYC, cases are reported to the New York City Department of Health and Mental Hygiene. For additional information on reporting cases to the NYCDOHMH go to:
<http://www.nyc.gov/html/doh/html/hcp/hcp-urf1.shtml>.

54. Where can I find information on the HIV testing law?

Information on the HIV testing law can be found on the NYSDOH web site at:
<http://www.health.ny.gov/diseases/aids/regulations/>

55. Will the NYSDOH be updating their 2005 hepatitis C clinical guidelines?

Yes, the NYSDOH is updating the hepatitis C clinical guidelines. The audience for the guidelines will be primary care providers. The guidelines will include the newly approved hepatitis C therapies.