OVERVIEW

1. When will 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. We expect that all facilities and providers have implemented the routine offer of testing and other provisions of the law or have made their specific technical assistance needs known to the Department and are making substantial progress toward full compliance. Several evaluation projects are underway to determine the extent that 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 to testing someone for HCV?

There are several reasons why someone should be tested for HCV. Knowing your HCV status will help prevent HCV 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 between herbal supplements, over the counter and prescriptions medications. Finally, HCV 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 person 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 have become 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 and 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 HCV infection, a second possibility is that there was HCV 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 HCV. 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.

Last update: December 9, 2013
9. Is HCV reflex testing available by commercial labs?

Yes, reflexing to an HCV Diagnostic Test (HCV RNA test) following a reactive HCV 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 HCV infection status in one step, without having the patient return for a second blood draw.

- For Quest search test # 91438X - [http://www.questdiagnostics.com](http://www.questdiagnostics.com)
- For LabCorp, search test # 144028 - [https://www.labcorp.com](https://www.labcorp.com)
- For BioReference, search test # B125-6 - [http://www.bioreference.com](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, 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 providers 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).

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@.state.ny.us and the situation will be reviewed.

18. Is 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.

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. Hepatitis C testing is covered by Medicaid and most private insurance plans. Currently, hepatitis C testing is not covered by Medicare. The law does not necessarily require insurance to pay for a hepatitis C test any time a patient accepts an offer to get one. 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.

In addition, there are a number of free HCV test sites throughout the state. For a complete listing of those sites go to the DOH web site at: http://www.health.ny.gov/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 offer the hepatitis C screening test. Hepatitis C screening testing should be handled the same way any other routine test is offered 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 offer of 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?

Yes. Even though these facilities are not specifically mentioned in the law, if primary care is being provided by a physician, physician assistant, 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 HCV screening test?

No. Patients under observation and not admitted as inpatients do not need 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 testing 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 use, those that received a blood transfusion before 1992, etc.

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?

Yes. 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.

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. 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 at least once, unless they have ongoing risk factors for hepatitis C infection.

27. Can RNs perform the test without a patient specific standing order?

RNs can make the “offer”, but according to NYS Education, RNs are required to have patient specific orders in order to perform the test itself.

28. 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 - Health Insurance Portability and Accountability Act.

29. 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 an 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.

30. Is a separate consent required for HCV testing?

No. There is no separate consent for HCV testing. The general medical consent is all that is needed.

31. 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.

32. 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. In instances where patients decline testing, a notation in the patient’s medical record of the offering of the test and the patients declination should be made.

33. 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.

Last update: December 9, 2013
34. 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.

35. 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 (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.

36. 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.

37. 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 HEALTHCARE FOR PERSONS WHO SCREEN REACTIVE FOR HEPATITIS C**

38. 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 HCV 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 and medical monitoring of disease.
39. The law requires that persons ordering hepatitis C testing provide or refer for follow-up health care for those who test. 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.

40. 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 with whom the appointment was made. The Department’s website includes contact information for additional providers providing hepatitis C care and treatment. http://www.health.ny.gov/diseases/communicable/hepatitis/docs/directory_nysdoh-ai_providers.pdf

41. 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.

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

The follow-up appointment should take place as soon as possible. The earlier someone receives that follow-up HCV 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

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

There are a number of free HCV test sites throughout the state. For a complete listing of those sites go to: http://www.health.ny.gov/hepatitis/ or http://nychepbc.org/ (NYC hepatitis C testing sites only)

Free HCV rapid test kits are also available for providers through the NYSDOH Hepatitis C Rapid Testing Program. Providers wishing to provide HCV 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/hepatitis/ or call 518-486-6806.

44. 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:

Last update: December 9, 2013
Persons with \textit{private insurance} should refer to their policy or contact their carrier.

\textbf{Medicare} does not cover hepatitis C screening. However, Medicare coverage for hepatitis C screening may be available in the near future. Medicare does cover HCV treatment.

\textbf{45. What are the proper CPT codes for the HCV screening test and HCV diagnostic tests?}

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<th>Test Type</th>
<th>CPT Code</th>
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</thead>
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<td>HCV antibody test</td>
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<tr>
<td>HCV RNA Qualitative</td>
<td>87521</td>
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<tr>
<td>HCV RNA Quantitative</td>
<td>87522</td>
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\textbf{46. 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.

\textbf{47. 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:
- \url{http://www.health.ny.gov/hepatitis/}
- \url{http://nychepbc.org/} (NYC hepatitis C testing sites only)

\textbf{OTHER QUESTIONS}

\textbf{48. Will formal regulations be developed for the law? If so, when will they be available?}

No. The DOH will not be developing/issuing formal regulations for this law. Instead, DOH will provide guidance such as FAQs.

\textbf{49. Will NYSDOH require any data 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 (10NYCRR 2.10,2.14). Cases are required to be reported to the local health department in the county where the patients resides.

For questions on cases residing outside of NYC, call NYSDOH at 518-474-4439 or go to:
\url{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:

Last update: December 9, 2013
50. 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/

51. Will the NYSDOH be updating their 2005 HCV clinical guidelines?

Yes, the NYSDOH will begin the process of updating the HCV clinical guidelines beginning in January 2014. The audience for the guidelines will be primary care providers. The guidelines will include the newly approved HCV therapies.