NEW YORK STATE HEPATITIS C TESTING LAW MAY 2024 FREQUENTLY ASKED QUESTIONS

OVERVIEW OF THE LAW

1. What are the key provisions for universal hepatitis C screening in New York State Public Health Law § 2171 and § 2500-I?

The New York State hepatitis C screening requirements include the following:

- Every individual age eighteen and older be offered a hepatitis C screening test.
- Every individual younger than eighteen, if there is evidence or indication of risk activity, be offered a hepatitis C screening test.
- Every physician or practitioner caring for a pregnant person shall order a hepatitis C screening test and record the hepatitis C test results prominently in the pregnant person's medical record at or before the time of hospital admission for delivery.
- If the hepatitis C screening test is reactive, a hepatitis C ribonucleic acid (RNA) test must be performed on the same specimen, or a second specimen collected at the same time as the initial hepatitis C screening test specimen, to confirm diagnosis of current infection.
- Individuals with a detectable hepatitis C RNA test are offered follow-up hepatitis C
 health care and treatment or are referred to a health care provider who can provide
 follow-up hepatitis C health care and treatment.

2. When did New York State's universal hepatitis C screening requirements go into effect?

New York State legislation requiring universal hepatitis C screening went into effect May 3, 2024.

3. What are the benefits of testing someone for hepatitis C?

There are several reasons why someone should be tested for hepatitis C.

- Early diagnosis allows for access to medical care that can improve one's health outcomes. Hepatitis C can be cured with 8-12 weeks of direct acting antiviral medication.
- Additional measures can be taken to protect the liver from further harm such as getting vaccinated for hepatitis A and B, limiting alcohol consumption and avoiding certain herbal supplements, vitamins and over the counter medications.
- By knowing one's hepatitis C status, one can take steps to minimize the risk of passing the virus to others.

4. Does a reactive hepatitis C screening test mean the person has hepatitis C infection?

A hepatitis C antibody test alone is not sufficient to diagnose current hepatitis C infection. To ensure complete diagnosis, legislation stipulates that if the hepatitis C screening test is reactive, a hepatitis C RNA test must be performed on the same specimen, or a second specimen collected at the same time as the initial hepatitis C screening test specimen, to confirm diagnosis of current infection.

A hepatitis C antibody positive test with <u>undetectable hepatitis C RNA</u> indicates that the person was exposed to hepatitis C previously but does not have an active hepatitis C infection. The person either cleared the hepatitis C infection spontaneously or was treated for hepatitis C previously. If spontaneous clearance of hepatitis C is suspected, best practice is to repeat the hepatitis C RNA in 3 months to ensure that the spontaneous clearance is durable. There are no further implications for future exposure to hepatitis C and education should be provided to avoid future exposure to hepatitis C.

A hepatitis C antibody positive test with <u>detectable hepatitis C RNA</u> indicates that the person has active hepatitis C infection and must be offered follow-up hepatitis C health care and treatment or are referred to a health care provider who can provide follow-up hepatitis C health care and treatment.

5. What is opt-out testing, and can we implement this as part of the law?

Opt-out testing for hepatitis C is an evidenced based approach in which people are informed that a hepatitis C screening test will be done unless they explicitly decline testing. Providing opt-out hepatitis C testing normalizes screening as part of routine comprehensive healthcare. Opt-out testing is associated with higher rates of acceptance of hepatitis C screening as compared to an opt-in approach. Therefore, it is an acceptable way to provide the hepatitis C screening test.

An example of an opt-out offer would be, "we routinely offer hepatitis C testing to everyone age 18 and older, regardless of risk. You will be tested for hepatitis C unless you decline."

6. Is there an officially sanctioned hepatitis C screening tool or template that our facility should be using?

No. There is no specific tool or template for hepatitis C screening. The requirement for hepatitis C screening is for all adults 18 years and older and all pregnant persons during each pregnancy <u>regardless</u> of risk.

For persons under the age of 18 years, the offer of hepatitis C screening is required if there is recognized risk for hepatitis C exposure. Additional information on hepatitis C screening guidelines can be found in here: https://www.hivguidelines.org/guideline/hcv-testing/

7. Can registered nurses (RNs) perform the test with a non-patient specific standing order?

Yes, the New York State Education Law (Subdivision 5 of section 6909) allows registered nurses (RNs) to perform a hepatitis C test with a non-patient specific order, also known as a standing order.

HEPATITIS C SCREENING OF ADULTS AND PERSONS UNDER 18 WITH RISK INDICATION

8. Why is it important to test all adults?

Hepatitis C testing is the first step to providing patients with curative treatment and eliminating hepatitis C in New York State.

- New cases of hepatitis C have increased disproportionately among reproductive age adults. Most new infections occur among adults 20-39 years of age, primarily among people with opioid dependance and associated injection drug use. Previous screening recommendations did not effectively identify younger individuals unless they disclose their injection drug use.
- Hepatitis C is curable. Direct acting antiviral therapies are safe and highly effective with more than 90 percent of people with hepatitis C achieving sustained virologic response (SVR) or cure with 8-12 weeks of oral therapy.
- Treatment of hepatitis C improves health outcomes. Left untreated, hepatitis C can lead to serious liver disease. Treatment of hepatitis C and the achievement of sustained virologic response (SVR) is associated with significant decreases in liver cancer, liver related mortality and all-cause mortality.
- The cost of hepatitis C treatment has substantially decreased, while long-term medical costs associated with untreated hepatitis C remain high. Studies have demonstrated the cost-effectiveness of hepatitis C screening and treatment.
- People who are treated and cured of their hepatitis C infection will not transmit the virus to others. Multiple mathematical modeling studies have concluded that treatment as prevention would have a major role in controlling and eliminating hepatitis C.

9. Which clinicians are required to provide universal hepatitis C testing?

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

10. Is the hepatitis C screening test mandatory? The requirements state "offer screening". Does this mean individuals may decline hepatitis C screening?

The <u>offer</u> of a hepatitis C screening test is mandated for all adults ages 18 and older, and for persons under 18 with indication of hepatitis C risk. A person may accept or decline the offer.

11. What are the <u>exceptions</u> to the mandatory offer of a hepatitis C screening test noted in the law?

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

- The person is being treated for a life-threatening emergency.
- The person has previously been offered or has been the subject of a hepatitis C related test (unless otherwise indicated due to on-going risk factors); or
- The person lacks the capacity to consent* to a hepatitis C screening test.

12. Instead of making the offer, can we just let patients know that hepatitis C testing is available if they ask for it?

No. Letting a patient know that testing is available is not an offer of testing. Patients must be offered hepatitis C testing verbally or in writing.

13. Would signage and inclusion in any printed materials be sufficient to cover informing the patient?

Patients must be informed either verbally or in writing that they will be tested for hepatitis C and that they may decline the test by telling the health care provider they do not wish to be tested. A sign or poster stating this would be acceptable.

An example of signage would be: Our institution screens all persons 18 years and older for hepatitis C. If you do not want to be tested, please let your health care provider know.

14. Is it acceptable to add the hepatitis C test as part of other lab work the patient may be having?

It is acceptable as long as the patient has been informed verbally or in writing that the test is being done.

15. How often does the hepatitis C screening test need to be offered?

The requirement is for the one-time offer of a hepatitis C screening test for people 18 years and older regardless of risk. If there is documentation of the offer (acceptance or refusal), a hepatitis C screening test does not need to be offered again. If there is not documentation, hepatitis C testing should be offered again.

However, the requirement for the one-time offer of a hepatitis C screening test does not replace risk-based screening recommendations. If a person, regardless of age, has ongoing risk (e.g., injection drug use) and either declined or accepted the offer and screened negative, it is recommended hepatitis C testing be offered again.

Guidance for the frequency of repeat hepatitis C screening can be found in here: https://www.hivguidelines.org/guideline/hcv-testing/

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

^{*} 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.

As part of the new law, the offer of a hepatitis C screening test is required for all persons 18 years and older and all pregnant persons regardless of risk.

Individuals under the age of 18 must be offered a hepatitis C screening test if there is an indication of risk for hepatitis C infection, such as:

- Ever sharing needles, syringes or other equipment for preparing and injecting drugs;
- Receiving a tattoo or body piercing from an unlicensed artist (e.g., on the street, while in jail, etc.);
- Snorting drugs;
- Have HIV;
- Perinatal hepatitis C exposure; or
- Health care worker exposure to blood through a needlestick or injury with a sharp object.

For additional hepatitis C screening guidelines visit: https://www.hivguidelines.org/guideline/hcv-testing/

17. For individuals under 18, do providers have to offer the test every time they see each patient if risk factors are ongoing?

Health care providers should use their clinical judgement and follow screening guidelines. If the person comes in and says they were exposed to hepatitis C, they should be re-tested. For hepatitis C screening guidelines visit: https://www.hivguidelines.org/guideline/hcv-testing/

18. Does the requirement that hepatitis C testing be offered to all persons apply in all medical settings?

The medical settings where providers are required to offer a hepatitis C screening test are:

- Article 28 licensed hospital inpatient health services.
- Emergency departments of Article 28 licensed hospital.
- Article 28 licensed hospital outpatient clinics providing primary care services.
- Diagnostic and treatment center licensed under Article 28 providing primary care services.
- Other health care settings where primary care services are being offered.

19. 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?

The legislation for hepatitis C screening among adults and persons with risk requires the offer of a hepatitis C screening test. The offer must be made at the time of the visit unless the person meets the exceptions to the law (see question 11). Performing a hepatitis C lab test 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 requisition to order lab tests, including the hepatitis C, conducted at an off-site lab draw station, this is acceptable.

20. 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?

Consider what your facility does rather than what your facility is called. For instance, an urgent care center that offers many or all 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.

21. Are primary care practices that are not Article 28 but are affiliated with a hospital included in this mandate?

Yes, Article 28 and non-Article 28 facilities and practices are required to make the offer. As stated in question 18, the required offer of hepatitis C screening extends to individuals who receive primary care services from a physician, physician assistant, nurse practitioner, or midwife providing primary care.

22. Does the required offer of a hepatitis C screening test apply to nursing homes, retail clinics, urgent care centers, sexually transmitted disease 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, or nurse practitioner, they are required to make the offer.

23. Are nursing homes required to offer hepatitis C testing to only new admissions or to existing residents as well?

The requirement to offer hepatitis C screening applies to all nursing home patients not just new admissions. For established patients, the offer could be made at the next annual physical/assessment. Patients can decline or accept the offer.

24. 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.

25. If an adult patient (or young patient with risk factors) is getting an x-ray in an Article 28 diagnostic and treatment center, would that person have to be offered hepatitis C testing?

No, if the patient is coming in only for an x-ray, they would not need to be offered hepatitis C testing.

As described in question 18, the offer of hepatitis C screening would be required in Diagnostic and Treatment Center licensed under Article 28 only for patients receiving primary care services.

26. Do the new hepatitis C screening recommendations include prisons and jails?

Yes, all jails and prisons should be screening all adults and persons at risk for hepatitis C.

27. Does the offer of a hepatitis C screening test apply to emergency departments?

Yes, emergency departments are required to offer a hepatitis C screening test except in certain situations, as noted in question 11.

28. For patients who come into the emergency department, how often should we offer them hepatitis C testing?

It depends. For most patients, offering and conducting a hepatitis C screening test once will be sufficient. However, if the patient has ongoing risk and the initial screening test was negative/non-reactive, rescreening may be appropriate. It is recommended that all offers of the hepatitis C screening test, along with the test results, be documented in the patient's medical record for tracking purposes. Guidance for the frequency of repeat testing can be found in here: https://www.hivguidelines.org/guideline/hcv-testing/

29. For patients seen in the emergency department, the confirmatory test may take hours. This will delay discharge. Do the patients need to remain in the emergency department until the results are obtained?

No, patients do not need to wait for results. Emergency departments should follow their organization's policy for communicating to the patient hepatitis C test results not available at the time of discharge. Patients should be told how they will receive any results not available at the time of discharge.

30. Are emergency departments required to order a hepatitis C screening test for all pregnant people?

Not necessarily. According to the new hepatitis C testing law for pregnant people, the pregnant persons attending physician should order the hepatitis C screening test with all other prenatal lab testing. However, if the patient presents to the emergency department and does not engage in regular prenatal care, the emergency department should order the test.

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

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

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

No, the law does not stipulate a requirement for formal documentation that the offer of a hepatitis C screening test was made for adults or persons under 18 with risk. However, for internal tracking and quality assurance purposes, providers may want to document that the offer was made.

For pregnant people, the legislation requires clear documentation of the test result in the medical record at the time of delivery. If the test result is not documented, the birth facility must conduct the test.

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

Patients always have the option to decline hepatitis C testing. They may do so verbally 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.

34. If I can see that a patient without a test at my facility was tested elsewhere, can we consider this person tested or do we need to offer again?

Yes. As long as there is documentation of that the person had a prior hepatitis C screening test, there is no need to rescreen, unless the initial test was negative and there is ongoing risk. An example would be if a provider found documentation of prior hepatitis C screening by searching for the patient's records within their regional health information organization (RHIO) and the patient had no ongoing risk.

35. The requirement includes "Outpatient departments of an Article 28-licensed hospital providing primary care services." How does this translate for specialty hospitals (cancer, orthopedics, etc.) that have outpatient extension clinics and have 'Medical Services- Primary Care' on their operating certificate, but are not a patient's primary care provider?

If the patient is not receiving primary care services from the provider, the test would not need to be offered. As outlined in question 18, the law specifically states the offer is to every individual age eighteen and older or younger than eighteen, if there is evidence or indication of risk activity, who <u>receives primary care services</u> in an outpatient setting or <u>health services</u> as an inpatient or in the emergency department of an Article 28 licensed hospital.

36. If a patient was screened PRIOR to the new requirement going into effect, and has no high-risk factors, do they need to be offered screening again? If no, what is the look-back period? Would this be based on documentation of a prior hepatitis C test in absence of other risks?

The law does not define a look back period. Whether an additional offer should be made should be based on clinical judgement.

FOLLOW-UP HEALTH CARE FOR ADULTS AND PEOPLE UNDER 18 WHO SCREEN POSITIVE/REACTIVE FOR HEPATITIS C

37. What happens if the patient's hepatitis C screening test is reactive? What follow-up health care is required?

As stated in the law, if a patient's hepatitis C screening test is reactive, a hepatitis C ribonucleic acid test (RNA) must be performed, on the same specimen or a second specimen collected at the same time as the initial hepatitis C screening test specimen, to confirm diagnosis of current infection. This is referred to as reflex testing.

For all persons with a detectable hepatitis C RNA test result, health care providers must either offer follow-up hepatitis C health care and treatment or refer the individual to a health care provider who can provide follow-up hepatitis C health care and treatment.

38. The law requires that persons ordering hepatitis C testing provide or refer for followup health care for all persons with detectable hepatitis C RNA. 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.

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

The law does not specify the clinician specialty but does specify that the referral must be for follow-up hepatitis C care. Many primary care providers are treating hepatitis C. It is recommended that the patient's medical record reflect the name of the provider/facility to whom the referral appointment was made.

40. Do all laboratories perform hepatitis C reflex testing?

Commercial laboratories perform reflex testing. Most large hospital laboratories perform hepatitis C reflex testing within their lab. Those that do not send specimens to reference laboratories. Providers should consult with their labs on protocols for specimen collection and handling. Providers must order the following test to ensure reflex testing is done: anti-HCV with reflex to HCV RNA (quantitative).

41. If ordering a hepatitis panel that includes hepatitis A, B and C testing, should hepatitis C testing with reflex be added as the hepatitis C testing option.

Yes. For clinical purposes and decision making the HCV RNA test via reflex (anti-HCV with reflex to HCV RNA) should be included.

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

No, the law does not require that you confirm the referral was kept. However, providers are encouraged to track and document referral outcomes.

43. The new law states "All persons identified with hepatitis C should receive follow-up medical care and hepatitis C treatment." Does that include a referral for treatment?

Yes, this includes hepatitis C treatment. For all persons with detectable hepatitis C RNA test result, testing providers are responsible for either offering the person follow-up hepatitis C health care and treatment or referring the person to a health care provider who can provide follow-up hepatitis C health care.

For a list of providers treating hepatitis C, go to: <a href="https://www.health.ny.gov/diseases/communicable/hepatitis/hepati

44. Do the changes to hepatitis C testing outlined in the law include rapid hepatitis C testing? If we are in the field doing rapid hepatitis C testing, would we need to follow up for a reactive with a lab draw?

The law is specific to the settings/services as outlined below. Testing services provided in the field outside of primary care would not be included.

- health services in an inpatient or in the emergency department of an Article 28 licensed hospital;
- primary care services in an outpatient department of Article 28 licensed hospital;
- primary care services in a diagnostic and treatment center licensed under Article 28; or
- primary care services from a physician, physician assistant or, nurse practitioner or midwife providing primary care.

However, if rapid testing is being performed in any of the above settings and the test is reactive, a hepatitis C RNA test must be performed on the same specimen, or a second specimen collected at the same time. Specimens may be collected via phlebotomy or dried blood spot collection.

HEPATITIS C SCREENING OF PREGNANT PERSONS

45. Why is it important to test all pregnant people?

Hepatitis C among the United State obstetric population rose nearly 10-fold over the last decade.

- Pregnant persons with hepatitis C have a 6% chance of transmitting the virus to their baby. That chance doubles in babies born to individuals who are coinfected with HIV and hepatitis C or who have high hepatitis C viral loads. Infection with hepatitis C can result in adverse fetal outcomes.
- Most people with hepatitis C have no symptoms and may not be aware of their infection. Widely screening all pregnant people regardless of risk as part of routine prenatal care removes the stigma of testing.
- Prenatal testing alerts delivery room staff to take measures to reduce risk of exposure during delivery.
- Adding hepatitis C testing at the same time as HIV and hepatitis B screening can
 facilitate access to curative treatment for the birthing parent post-partum. The
 expansion of Medicaid coverage for pregnant persons during the post-partum period

- from 60 days to 12 months, makes screening during pregnancy an important opportunity to identify future care needs for both the pregnant person and their infant.
- Testing during pregnancy also allows for identification of exposed infants who should receive testing at a pediatric visit. Testing of exposed infants consists of hepatitis C ribonucleic acid testing at age 2-6 months of age. Although direct-acting antiviral treatment is not approved for children aged <3 years, infected children aged <3 years should be monitored.

46. Who is required to order hepatitis C screening for pregnant patients?

Every physician or other authorized practitioner attending to the pregnant person is required to order a hepatitis C screening test. The pregnant person should receive education regarding the benefits of hepatitis C screening and be informed a hepatitis C test will be ordered. An opt-out approach is recommended.

47. Is a hepatitis C screening test during pregnancy mandatory?

The <u>order</u> of a hepatitis C screening test is mandated for all pregnant people during each pregnancy. Persons may refuse testing.

48. When during pregnancy is hepatitis C screening required?

Timing of hepatitis C testing is not specified in New York State's Public Health Law. It is advisable that testing take place at the first prenatal visit along with other recommended routine tests as part of standard of care, with results prominently recorded in the pregnant person's medical record before hospital admission for delivery.

49. Should hepatitis C screening be ordered even if the pregnant person was screened during a previous pregnancy or at health care encounter prior to the current pregnancy?

Yes. The order of a hepatitis C screening is required for each pregnancy regardless of risk or prior hepatitis C screening.

50. Should a person be screened for hepatitis C more than once during each pregnancy?

The order of hepatitis C screening is required during each pregnancy regardless of risk. However, if a pregnant person's test result is negative and there is ongoing risk for exposure (e.g., injection drug use) during pregnancy, rescreening during pregnancy or in the postpartum period is appropriate. Guidance for the frequency of repeat hepatitis C screening can be found in here: www.hivguidelines.org/guideline/hcv-testing

51. Does the law require documentation of hepatitis C screening for pregnant persons?

Yes. for pregnant people, the legislation requires clear documentation of the test result in the medical record at the time of delivery. If the test result is not documented, the birth facility must conduct the test.

52. If a pregnant person presents at the emergency department, does the law require a hepatitis C screening test be ordered?

Not necessarily. According to the new hepatitis C testing law for pregnant people, the pregnant persons attending should order the hepatitis C screening test with all other prenatal lab testing. However, if the patient presents to the emergency department and is not engaged in regular prenatal care, the emergency department should order the test.

53. What if a pregnant person arrives at a birthing facility for delivery and there is no evidence that a hepatitis C screening test was performed during current pregnancy?

If the pregnant person's hepatitis C test history for the current pregnancy is unknown or if there is no documentation of hepatitis C screening in the medical record at admission for delivery, the birth attendant should order the required screening and provide information regarding the benefits of testing.

FOLLOW-UP FOR PREGNANT PERSONS DIAGNOSED WITH HEPATITIS C

54. If a pregnant person is diagnosed with hepatitis C infection, when should treatment be administered?

Health care providers attending a pregnant person diagnosed with hepatitis C must provide or refer to a health care provider who can provide, follow-up hepatitis C care, and treatment. While curative direct-acting antivirals are highly effective, they have not yet been approved by the Food and Drug Administration (FDA) for use during pregnancy. Studies are ongoing to assess their safety and efficacy in pregnant people. However, treatment can be considered during pregnancy on an individual basis after a patient-physician discussion about the potential risks and benefits.

Regardless of the intention to treat, the referral of a pregnant person with hepatitis C infection during the prenatal period supports future engagement in care by developing a relationship and rapport with the hepatitis C treatment provider. This may facilitate a more seamless transition and continuity of care after delivery.

55. Where can providers refer pregnant and postpartum people for hepatitis C care and treatment?

The New York State Department of Health AIDS Institute's online directory provides information regarding hepatitis C providers across New York State. To find a hepatitis C provider that participates in the directory, go to: https://providerdirectory.aidsinstituteny.org.

FOLLOW-UP CARE FOR PERINATALLY EXPOSED INFANTS

56. Is breastfeeding recommended when the birthing parent has hepatitis C infection?

Hepatitis C is not found in breast milk. Birthing parents with hepatitis C infection can safely nurse their infant. However, hepatitis C is transmitted through contact with blood. Therefore, if a nipple becomes cracked or bleeds, the birthing parent should temporarily stop nursing with that nipple until it has healed. A referral to a Lactation Specialist is recommended so the parent may implement strategies to maintain milk supply (i.e., pump and discard).

Providers should discuss lactation plans with pregnant persons when considering timing of hepatitis C treatment. Limited data is available on the safety of breastfeeding while taking hepatitis C medications. It is recommended that hepatitis C treatment be postponed until the infant is weaned. Information on medications and their safety during pregnancy and lactation can be found at https://www.ncbi.nlm.nih.gov/books/NBK501922/

57. When should infants with perinatal hepatitis C exposure be tested?

The Centers for Disease Control and Prevention recommends all infants with perinatal hepatitis C exposure receive diagnostic testing with a hepatitis C RNA test between the ages of 2 to 6 months.

If not previously tested for hepatitis C, perinatally exposed children between the ages of 7 to 17 months should receive diagnostic testing with a hepatitis C RNA test.

If not previously tested for hepatitis C, perinatally exposed children aged 18 months and older should be screened with a hepatitis C antibody test with reflex to a hepatitis C RNA test (anti-HCV with reflex to HCV RNA).

If the hepatitis C RNA test is negative or undetectable at any of these ages, the child does not have hepatitis C infection and no further testing is indicated.

For more information regarding these CDC recommendations, visit: https://www.cdc.gov/mmwr/volumes/72/rr/rr7204a1.htm?s cid=rr7204a1 w

58. Are there different testing recommendations for infants born prematurely?

No. Testing should be completed at 2-6 months of age using a hepatitis C RNA test. No correction for age is needed for preterm infants.

59. What type of follow-up care do perinatally exposed infants need?

Perinatally exposed infants with a detectable hepatitis C RNA test at or after the age of 2 months, have hepatitis C infection and should be managed in consultation with a provider with expertise in pediatric hepatitis C management to receive related screenings, preventive services, interventions, and regular follow-up.

60. When can children with hepatitis C infection be treated?

Children diagnosed with hepatitis C infection should be referred to a pediatric gastroenterologist or infectious diseases specialist as promptly as possible for monitoring until the child is ≥ 3 years old when treatment is recommended.

PATIENT CONSENT FOR HEPATITIS C TESTING

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

No. There is no separate or special consent required for hepatitis C testing. The method used to obtain consent for other types of medical services (e.g., testing, screenings, procedures, etc.) may be used to consent for hepatitis C screening. For example, for

facilities using a general medical consent for medical services, this would cover hepatitis C testing.

62. Would verbal consent to hepatitis C testing suffice?

Yes, verbal consent is sufficient. See question 61 for additional information on consent.

63. 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 need to be specifically identified in the consent language. However, a person should be informed either verbally or in writing that they will be tested and that they may decline testing.

64. Is parental consent required for hepatitis C screening among people under 18 with a risk?

Yes, in New York State, parental consent is required for hepatitis C testing for persons younger than 18 years of age unless they meet the medical treatment of a minor exception criteria outlined in Public Health Law (PHL) §2504. https://www.nysenate.gov/legislation/laws/PBH/2504

INSURANACE COVERAGE AND REIMBURSEMENT FOR HEPATITIS C TESTING

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

New York State Medicaid, both fee-for-service and Medicaid Managed Care, covers hepatitis C screening for all adults, persons at risk and pregnant people. All billing and payments are subject to and paid in accordance with Medicaid regulation. For updates to New York State Medicaid, visit:

health.ny.gov/health care/medicaid/program/update/main.htm

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

Medicare also covers hepatitis C screening and hepatitis C treatment.

66. Does the law require insurance companies to pay for the hepatitis C test?

No, the law does not require insurance companies to pay for the test. However, the United State Preventive Services Task Force issued a B grade on screening for hepatitis C adults aged 18 to 79 years, including pregnant persons. The United States Preventive Services Task Force recommendation signifies that hepatitis C screening in this population will be covered by most public and private insurance. This is because the Affordable Care Act requires that private insurance plans cover United States Preventive Services Task Force A or B recommended services without cost sharing. Medicaid Managed Care plans must also cover these services. Hepatitis C testing is also covered by Medicare.

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

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.

68. Where can I find more information on the Patient Assistance Programs 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 resources for individuals who need help accessing free hepatitis C medications or other hepatitis C related services, including assistance with high co-pays. For more information go to:

https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis c/consumers/treatment information.htm

69. Will hepatitis C be added to the list of New York State sexually transmissible diseases included under New York Codes, Rules and Regulations Section 23.1.

No, New York State is not adding hepatitis C to its list of sexually transmitted diseases.

70. Will programs receiving free hepatitis C test kits through the NYS Hepatitis C Testing Program be required to meet the new hepatitis C screening requirements.

No, the New York State Hepatitis C Testing Program performs high impact testing only meaning they only test people at high-risk for hepatitis C such as people who inject drugs.

71. What are the proper CPT (Current Procedural Terminology) 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

72. Will there be a specific diagnosis code assigned for the testing?

The two ICD-10 codes for hepatitis C are 17.1 (acute) and 18.2 (chronic). The following Z codes can be used: Z11.59 (screen other viral), Z20.5 (exposure to hep), Z72.89 (problems related to lifestyle).

73. Does New York State Medicaid cover hepatitis C reflex testing?

New York State Medicaid reimburses laboratories for reflex testing without additional written orders from the physician. The preprinted requisition form must indicate that the test will be used in the reflex algorithm. For additional information:

https://www.health.ny.gov/health_care/medicaid/program/update/2015/august15_mu.pdf

PROVIDER REPORTING REQUIREMENTS FOR HEPATITIS C

74. Will the New York State Department of Health 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 data reporting requirements included in the law.

75. Are health care providers required to report hepatitis C cases?

Yes, in addition to labs reporting electronically to the local health department, providers are also required to report any suspect or confirmed acute or chronic hepatitis C case to the local health department in the county where the patient resides.

For more information on provider reporting for persons who live in New York State (outside of New York City):

https://www.health.ny.gov/professionals/diseases/reporting/communicable/.

For more information on provider reporting for persons who live in New York City: https://www.nyc.gov/site/doh/providers/reporting-and-services/notifiable-diseases-and-conditions-reporting-central.page

COMPLIANCE

76. What are the New York State Department of Health's expectations around compliance?

It is a requirement that all pregnant people be screened for hepatitis C during each pregnancy per New York State Public Health Law. If the pregnant person initially refuses hepatitis C screening, health care providers should continue to offer testing at subsequent prenatal visits, reaffirming the benefits of testing for the pregnant person's health and the health of their baby.

PROVIDER EDUCATION

77. Where can providers learn more about providing hepatitis C care and treatment?

The New York State Department of Health, AIDS Institute, Clinical Education Initiative offers training, intensive preceptorship programs, tele-education, technical assistance, and additional clinical tools to enhance provider capacity to deliver hepatitis C services. Visit: https://ceitraining.org

RESOURCES

New York State Department of Health Guidelines on the Management and Treatment of Persons Living with Hepatitis C: https://www.hivguidelines.org/collection/hepatitis-care/

Centers for Disease Control and Prevention Recommendations for Hepatitis C Screening Among Adults: https://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6902a1-H.pdf

Centers for Disease Control and Prevention Operational Guidance for Implementing Recommendations on Testing for Hepatitis C Virus Infection:

https://www.cdc.gov/mmwr/volumes/72/wr/mm7228a2.htm?s cid=mm7228a2 w

Hepatitis C Screening for Pregnant People - Provider Toolkit

https://ceitraining.org/documents/HCV%20Screening%20for%20Pregnant%20People%20-%20Provider%20Toolkit%20Nov%202023%20for%20Posting.pdf

Hepatitis C Reflex Testing

https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis c/providers/reflex testing.

New York State Department of Health AIDS Institute Provider Directory. This online directory provides a listing of hepatitis C providers in NYS. https://providerdirectory.aidsinstituteny.org

New York State Department of Health Hepatitis C Care and Treatment Programs. The New York State Department of Health provides funding to primary care sites across NYS to provide Hepatitis C care and treatment. In addition to primary care, these providers offer hepatitis C related services including hepatitis C treatment, education, care coordination, and support connecting with community resources:

https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis_c/docs/hcv_providers.pdf

Hepatitis C Testing Locations in New York City. Locations offering free and low-cost hepatitis C testing and treatment in New York City, as well as patient navigators who can provide support throughout the process can be found at www.nyc.gov/health/hepc.

New York State Hepatitis C Educational Materials for consumers can be found here: https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis c/educational materials.ht m

The Clinical Education Initiative (CEI), a New York State Department of Health AIDS Institute program, offers progressive continuing medical education to physicians, nurse practitioners, physician assistants, nurses, dentists, and pharmacists to enhance their capacity to deliver high-quality healthcare services and to improve patient health outcomes. We offer free, clinical education accredited, online and live trainings, conferences, intensive preceptorships, clinical technical assistance, and tools on HIV Primary Care and Prevention, Sexual Health, Hepatitis C treatment, and Drug User Health. https://ceitraining.org/

Podcasts

Universal Hepatitis C Screening among Pregnant Persons: The Time is Now

https://cei.podbean.com/e/universal-hepatitis-c-screening-among-pregnant-persons-the-time-is-now/