



HEPATITIS C

By: James Orlando, Associate Attorney
Alexander Reger, Legislative Analyst II
Timothy Bleasdale, Legislative Fellow

This report addresses a series of questions on hepatitis C.

1. What are the symptoms and effects of hepatitis C and how is it treated?

[According to the Centers for Disease Control and Prevention \(CDC\)](#), hepatitis C is a blood-borne virus that infects the liver and can cause liver cirrhosis, cancer, and liver failure. If untreated, hepatitis C can cause death. The virus often goes unnoticed by patients until it begins to cause more significant health complications, which can take years to develop. Acute hepatitis C generally lasts a short time and is less severe. This form of the disease can clear on its own, but often develops into chronic hepatitis C. Chronic hepatitis C can require expensive treatments and may make a liver transplant necessary.

Hepatitis C is contracted by [contact with infected blood](#). Drug users that share needles are considered to have an elevated risk of contracting the virus. Since hepatitis C screening was not introduced until 1992, people receiving organ transplants or blood transfusions before then may have contracted the virus through these procedures. Many people have no symptoms until the virus begins to cause liver damage or have other complications. These symptoms could include fatigue, joint pain, abdominal pain, itchy skin, sore muscles, dark urine, and jaundice (a yellowing of the skin and eyes).

Information about hepatitis C treatments is provided in answering question 8.

2. Provide a summary of the 2013 New York law requiring hepatitis C screening for a certain population.

In 2013, New York enacted legislation generally requiring hospitals and primary care providers to offer a hepatitis C screening or diagnostic test to patients born between 1945 and 1965 (N.Y. L. 2013, Ch. 425, N.Y. Pub. Health Law § 2171). The law took effect January 1, 2014.

The requirement applies for patients receiving (1) inpatient care at a general hospital, (2) primary care services at a hospital outpatient department or a diagnostic and treatment center, or (3) primary care services (in any setting) from a physician, physician assistant, or nurse practitioner.

The requirement does not apply when the health care practitioner reasonably believes that the individual (1) is being treated for a life threatening emergency, (2) has previously been offered or had a hepatitis C screening test (except a test must be offered if otherwise indicated), or (3) lacks capacity to consent.

The law defines "hepatitis C screening test" as any laboratory screening test or tests that detect the presence of hepatitis C virus antibodies in the blood. If someone accepts the offer of such a test and the test is reactive, the provider must offer follow-up care or refer the individual to another provider who can provide such care. The follow-up care must include a hepatitis C diagnostic test (laboratory testing to confirm whether the individual has a hepatitis C virus infection).

Among other things, this law also specifies that:

1. the offering of hepatitis C screening testing must be culturally and linguistically appropriate in accordance with rules and regulations and
2. it does not affect any health care practitioner's scope of practice or diminish the practitioner's authority or obligation to offer such a screening or diagnostic test or provide services related to such tests.

3. What is the New York Department of Health's role with this new law and what educational efforts does it have planned or implemented?

According to the department, its role involves (1) educating providers about the law and assisting them to ensure the law's effective implementation, (2) evaluating the law's effectiveness, and (3) compliance issues.

Education and Guidance. The department has undertaken various initiatives to educate providers about the screening law. The department has:

1. issued a "[Dear Colleague](#)" letter to inform providers about the law;
2. issued a detailed [list](#) of questions and answers about the law;
3. held regional stakeholder meetings to review the law, provide background information, and answer questions; and
4. provided briefings to provider membership organizations and other groups.

The department also plans to host a statewide webcast and will continue to serve as a resource to providers to help them implement the law.

Evaluation. The screening legislation requires the New York health commissioner, by January 1, 2016, to evaluate and report on the legislation's impact as to the number of people (1) screened for hepatitis C and (2) who have accessed care after a positive test.

Enforcing Compliance. The department can:

1. issue a statement of deficiencies against a department-regulated health care facility that fails to comply with the law and
2. impose a fine of up to \$2,000 per violation against any person or entity to which the law applies, under § 12 of the Public Health Law.

4. What Northeastern states have hepatitis C screening laws or proposed legislation?

New York is the only state with a hepatitis C screening law, but Massachusetts and New York have laws requiring the state Department of Health to provide educational materials to veterans, doctors, and other high risk persons on hepatitis C diagnosis, treatment, and prevention ([Mass. Gen. Laws ch. 111, § 4M](#), N.Y. Pub. Health Law § 2170).

In addition, three states (Massachusetts, New Jersey, and Pennsylvania) currently have proposed legislation with similar requirements as [SB 257](#) in Connecticut.

Massachusetts

The Massachusetts legislature is currently considering two hepatitis C bills. [H.2021](#) would require the state Department of Health to conduct a needs assessment to

determine the incidence and prevalence of hepatitis B and C. Under the bill, the department must also: (1) create and implement a plan to prevent further hepatitis infections; (2) develop and implement an educational outreach program; (3) develop educational materials targeted at health care providers, individuals born between 1945 and 1965, and members of at-risk populations; and (4) establish a hepatitis B and C surveillance program. The bill was reported out of the Public Health Committee and referred to the Health Care Financing Committee where it awaits further action.

[S.1045](#) requires the state Department of Health to create a program to mitigate the impact of hepatitis C. The program must provide screening, information, education, and treatment components, as well as increase public awareness of hepatitis C. The program must also provide information to health care providers about the risks, available prevention methods, and treatment options for hepatitis C. The bill was referred to the Public Health Committee where it awaits further action.

New Jersey

The New Jersey General Assembly proposed two bills ([A2555](#) and [S876](#)) that generally require health care providers to offer individuals born between 1945 and 1965 a hepatitis C screening test when receiving inpatient care. If an individual accepts the test and has a positive result, the provider must offer follow-up health care or refer him or her to a provider who offers appropriate follow-up services. These bills have been introduced and referred to the appropriate legislative health committees where they await action.

Pennsylvania

The Pennsylvania legislature has proposed a bill ([HB 2003](#)) that is substantially similar to the New Jersey bills. The bill was referred to the Health Committee, where it was reported out on March 10, 2014.

5. What are the CDC's and the U.S. Preventative Services Taskforce's (USPTF) recommendations regarding hepatitis C screening?

Both the [CDC](#) and the [USPTF](#) recommend:

1. one-time hepatitis C screening for adults born between 1945 and 1965, regardless of a prior risk assessment;
2. routine screening for members of at risk populations, including
 - a. HIV infected patients;
 - b. individuals who have ever injected illegal drugs;

- c. individuals with select medical conditions or who received specific medical treatments;
- d. certain recipients of blood transfusions and organ transplants;
- e. children born to hepatitis C-positive women; and
- f. those who work in the healthcare, emergency medical, and public safety environments.

In addition, the CDC recommends that anyone testing positive for hepatitis C should receive alcohol screening and intervention, and be referred to appropriate care.

6. Does Medicaid/Medicare currently cover the cost of hepatitis C screenings?

The Connecticut Medicaid program covers hepatitis C screening, but Medicare does not. However, the [Centers for Medicare and Medicaid Services \(CMS\)](#) is considering a proposal that would extend Medicare coverage for hepatitis C screening tests to high risk adults and those born between 1945 and 1965. The public comment period on the [proposal](#) ends April 3, 2014, after which CMS has 60 days to render a decision.

Under the Affordable Care Act (§ 2713), health insurance plans must cover items or services that have a grade "A" or "B" rating from USPTF. One-time hepatitis C screening for individuals born between 1945 and 1965 is a ["B" rated recommendation](#).

7. What is the cost of hepatitis C testing?

According to the National Institutes of Health, the cost of testing for hepatitis C can [vary greatly](#), ranging from [\\$50 to \\$700](#). There are [three basic types of tests](#) used by doctors to determine whether a patient has been exposed to or infected by hepatitis C. These are antivirus tests, RNA tests, and genotype tests. All three types of tests would qualify as one of the test types (screening or diagnostic) required by the [New York](#) law and [Connecticut](#) bill. Home test kits are also available.

Antivirus Test

A hepatitis C antivirus test uses a blood sample to test for the presence of hepatitis C antibodies. If the antibodies are found, it means the patient has been exposed to hepatitis C, but does not necessarily mean the patient is currently infected. Cost estimates vary but are generally between [\\$50 and \\$150](#).

RNA Test

An RNA test is a blood test that looks for the genetic material of the virus in the patient's blood to determine whether the patient is currently infected with hepatitis C. In contrast to the antivirus test, the RNA test shows the actual presence of the virus in the blood rather than mere past exposure to the virus. Cost estimates vary but are generally between [\\$240 and \\$500](#).

Genotype Test

A genotype test is a blood test to determine the type of hepatitis C a patient has, which can determine how the patient should be treated. This can determine the mix of medication given to the patient as well as the length of treatment. Cost estimates for this test fall between [\\$200 and \\$700](#).

A patient may choose to have an antivirus screening test first to determine whether he or she has ever been exposed to hepatitis C. If no antiviruses appear in this test, then it may not be necessary to undergo a more expensive diagnostic test, such as an RNA test.

Home Test Kit

It is also possible to buy a home test kit in some drug stores. One example is the [Home Access Hepatitis C Check kit](#), which can be bought online for between \$60 and \$80. This kit comes with a lancet to draw a small amount of blood from the patient's fingertip. The blood is placed on a collection paper and mailed to a laboratory for testing. Generally, the patient has to call the lab after a waiting period of about two weeks to receive the results of the test. These tests appear to be a form of the antivirus test.

8. What are the typical costs associated with treating chronic hepatitis C?

The cost of treating chronic hepatitis C varies greatly, based on the patient's individual health condition, [genotype of the hepatitis C](#) the patient has, and treatment plan. Estimates range from \$16,000 to more than \$577,100.

Standard Treatment

For example, United Healthcare reports the current standard treatment for hepatitis C is a 24- or 48-week course of weekly pegylated interferon injections and oral ribavirin twice-a-day. This treatment [costs between \\$16,000 and \\$32,000 per course of treatment](#); however, these drugs have significant side effects that often

require additional medications and have had a low success rate in treating hepatitis C. The U.S. Food and Drug Administration (FDA) has approved new treatments in recent years that are more effective but with higher costs.

Newer Treatment

In 2011, the FDA approved two new drugs, [telaprevir](#) (brand name Incivek) and [boceprevir](#) (brand name Victrelis), that are used in combination with the standard injection therapy described above. According to United Healthcare, treatment with either drug [adds about \\$49,200 to the cost of treatment](#), but in some cases may shorten the length of treatment by as much as 50%. In 2013, the [FDA approved a new oral drug](#) treatment that can be used instead of the standard injection treatments. The new drug, sofosbuvir (brand name Sovaldi), [costs \\$1,000 per pill](#) with the typical treatment lasting 12 weeks, for a total cost of \$84,000. This cost may be higher if the patient requires other companion drugs. However, sofosbuvir is considered to be a more effective cure for the disease and may not have side effects as severe as the more traditional treatments.

Liver Transplant

In more extreme cases, a patient may require a liver transplant. The waiting list for liver transplants is [grouped by blood type and prioritized based on the severity of the illness](#), with sicker patients within each blood type receiving priority. In the United States, there are [more people in need of transplants](#) than there are donors. Transplant cost estimates vary widely by source, due in part to the inclusion or exclusion of certain expenses as a part of the transplant cost, such as pre-transplant screening or post-transplant treatments. At the lower end, [United Healthcare](#) estimated in 2011 the average cost was about \$280,000 in the first year after the transplant takes place. On the higher end, the [United Network for Organ Sharing](#) (UNOS), which manages the national organ transplant system under contract with the federal government, estimated the average cost of a liver transplant in 2011 as \$577,100.

9. What efforts are the Connecticut Department of Public Health (DPH) currently involved in regarding hepatitis C, and what resources does DPH currently dedicate to the disease?

According to DPH, public health funding in Connecticut for hepatitis C is extremely limited. DPH previously had a federally funded Hepatitis B and C Surveillance Program that ended in 2012 due to CDC directing the funding elsewhere. The federal funding supported three epidemiologists who closely monitored the burden of hepatitis B and C in the state, including reports that are on DPH's [website](#). DPH

reports that in the absence of that federal funding, they no longer have the capacity to closely monitor the burden of hepatitis C since the vast majority of their staff are funded on federal categorical grants.

DPH reports that they still have a small federal grant from the CDC that funds 75% of an Adult Viral Hepatitis Prevention Coordinator’s salary. This coordinator provides technical expertise to manage and coordinate activities to prevent viral hepatitis infections and integrate viral hepatitis prevention services into health care settings and public health programs (e.g., sexually transmitted diseases, HIV, immunization, correctional health, substance abuse treatment, and syringe exchange) that serve adults at risk for viral hepatitis. These activities include promoting the CDC recommendation to test all baby boomers for hepatitis C. DPH has integrated hepatitis C testing into many of its HIV prevention programs, including syringe exchange, that reach injection drug users who are the highest risk category for hepatitis C.

10. How many people have hepatitis C?

The [incidence rate for acute hepatitis C](#) is approximately 0.3 cases per 100,000 people, or about 850 new cases a year. Between 60-85% of individuals infected with acute hepatitis C will develop a chronic infection, and an estimated [3.2 million people](#) in the United States are living with chronic hepatitis C.

Table 1 compares the number of deaths attributable to chronic hepatitis C in the United States to the other top chronic diseases that cause death.

Table 1: Total Deaths Attributable to Some Chronic Diseases – 2010

| Chronic Disease | United States Deaths |
|-------------------------------------|-----------------------------|
| Heart Disease | 597,689 |
| Cancer | 574,743 |
| Chronic Lower Respiratory Diseases | 138,080 |
| Alzheimer's Disease | 83,494 |
| Diabetes | 69,071 |
| Chronic Liver Disease and Cirrhosis | 31,903 |
| Parkinson’s Disease | 17,011 |
| Chronic Hepatitis C Infection | 15,106* |

Sources: <http://www.cdc.gov/nchs/fastats/lcod.htm>,
 *<http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm>

11. What is the current policy for treating the state prison population with hepatitis C?

The Department of Correction (DOC) has a partnership with the UConn Health Center's (UCHC) [Correctional Managed Health Care](#) to provide medical services to inmates. UCHC's policy and procedures [manual](#) for treating inmates requiring special needs or services addresses hepatitis C (see G 2.04, on page 48).

The manual sets protocols for evaluation, assessment, and treatment, and requires requests for treatment to be approved by a Hepatitis C Utilization Review Board. Hepatitis C assessment and treatment management is under the direct supervision of an infectious disease specialist (IDS). Primary care physicians (PCPs) provide supportive care to inmates with hepatitis C, although they do not directly provide anti-viral drugs.

Among other things, the manual:

1. provides that the review board will not generally approve hepatitis C therapy unless there is a reasonable likelihood that the inmate will be under DOC supervision for the entire treatment period;
2. allows the board to require an inmate to participate in an addiction services program either before beginning definitive hepatitis C therapy or along with such therapy;
3. allows an IDS to appeal if the board denies a treatment request;
4. provides that if a treatment request is denied, the PCP resumes responsibility for the inmate's hepatitis care and monitoring; and
5. establishes a protocol to continue treatment begun before incarceration.

The manual includes a Hepatitis C information sheet for inmates (see page 59).

RESOURCES

Agency for Healthcare Research and Quality, Testing for Hepatitis C Virus, <http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=1697&pageaction=displayproduct>, last visited on March 12, 2014.

California Pacific Medical Center, MELD and the Waiting List for Liver Transplant, <http://www.cpmc.org/advanced/liver/patients/topics/MELD.html>, last visited on March 12, 2014.

Centers for Disease Control and Prevention, Hepatitis C FAQs for Health Professionals, <http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm#a4>, last visited on March 12, 2014.

Centers for Disease Control and Prevention, Hepatitis C Information for Health Professionals, <http://www.cdc.gov/hepatitis/HCV/GuidelinesC.htm>, last visited on March 12, 2014.

Centers for Disease Control and Prevention, Hepatitis C Information for the Public, <http://www.cdc.gov/hepatitis/c/cfaq.htm>, last visited on March 12, 2014.

Centers for Disease Control and Prevention, Viral Hepatitis Surveillance – United States, 2010, <http://www.cdc.gov/hepatitis/statistics/2010surveillance/Commentary.htm>, last visited on March 12, 2014.

Centers for Medicare and Medicaid Services, National Coverage Analysis (NCA) Tracking Sheet for Screening for Hepatitis C Virus (HCV) in Adults, <http://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=272>, last visited on March 12, 2014.

Centers for Medicare and Medicaid Services, Proposed Decision Memo for Screening for Hepatitis C Virus (HCV) in Adults, <http://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=272>, last visited on March 12, 2014.

Connecticut Department of Public Health, Viral Hepatitis, <http://www.ct.gov/dph/cwp/view.asp?a=3135&q=393226>, last visited on March 12, 2014.

Food and Drug Administration, Approval of Incivek (telaprevir), a direct acting antiviral drug (DAA) to treat hepatitis C (HCV), <http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/ucm256328.htm>, last visited on March 12, 2014.

Food and Drug Administration, Approval of Victrelis (boceprevir) a direct acting antiviral drug (DAA) to treat hepatitis C virus (HCV), <http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/ucm255413.htm>, last visited on March 12, 2014.

Food and Drug Administration, Approval of Sovaldi (sofosbuvir) tablets for the treatment of chronic hepatitis C, <http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/ucm377920.htm>, last visited on March 12, 2014.

The Hastings Center, Organ Transplantation, <http://www.thehastingscenter.org/Publications/BriefingBook/Detail.aspx?id=2198>, last visited on March 12, 2014.

Healthcare Bluebook, Laboratory Services, https://www.healthcarebluebook.com/page_Results.aspx?SearchTerms=hepatitis, last visited on March 12, 2014.

Home Access Health Corporation, The Home Access Hepatitis C, http://www.homeaccess.com/hepatitis_c_test.asp, last visited on March 12, 2014.

MedlinePlus, Hepatitis C, <http://www.nlm.nih.gov/medlineplus/ency/article/000284.htm>, last visited on March 12, 2014.

National Public Radio, "\$1,000 Pill For Hepatitis C Spurs Debate Over Drug Prices," <http://www.npr.org/blogs/health/2013/12/30/256885858/-1-000-pill-for-hepatitis-c-spurs-debate-over-drug-prices>, last visited on March 12, 2014.

New York Department of Health, "Dear Colleague" letter, https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis_c/rapid_anti_body_testing/docs/2013-11-18_dcl_hepc_testing.pdf, last visited on March 12, 2014.

New York Department of Health, NYS Hepatitis C Testing Law Frequently Asked Questions, https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis_c/rapid_anti_body_testing/faqs.htm, last visited on March 12, 2014.

NORC at the University of Chicago, The Cost-Effectiveness of Birth Cohort and Universal Hepatitis C Antibody Screening in U.S. Primary Care Settings, http://www.norc.org/PDFs/Cost-effectiveness%20of%20BC%20Screening%20Technical%20Report_v7.pdf, last visited on March 12, 2014.

UConn Health Center, Correctional Managed Health Care, <http://cmhc.uhc.edu/>, last visited March 26, 2014.

UConn Health Center, Correctional Managed Health Care, Policies and Procedures: G - Special Needs and Services, <http://cmhc.uhc.edu/pdfs/policies/G%20-%20Special%20Needs%20and%20Services.pdf>, last visited March 26, 2014.

United Healthcare, Hepatitis C Breakthrough Promises First-Ever Clinical Cure, <http://www.uhcpharmacyinfocus.com/article/hepatitis-c-breakthrough-promises-first-ever-clinical-cure>, last visited on March 12, 2014

United Network for Organ Sharing, Costs, <http://www.transplantliving.org/before-the-transplant/financing-a-transplant/the-costs/>, last visited on March 12, 2014.

United States National Library of Medicine, HCV Testing Cost-Effective Alternative To Treating Advanced Disease, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3571002/>, last visited on March 12, 2014.

United States Preventive Services Task Force, Screening for Hepatitis C Virus Infection in Adults, <http://www.uspreventiveservicestaskforce.org/uspstf/uspshepc.htm>, last visited on March 12, 2014.

United States Preventive Services Task Force, USPSTF A and B Recommendations, <http://www.uspreventiveservicestaskforce.org/uspstf/uspsabrecs.htm>, last visited on March 12, 2014.

Washington Post, "Costly hepatitis drug Sovaldi rattles industry" http://www.washingtonpost.com/national/health-science/costly-hepatitis-drug-sovaldi-rattles-industry/2014/03/01/86cab0b4-a091-11e3-9ba6-800d1192d08b_story.html, last visited on March 12, 2014.

JO/AR/TB:ro