UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

ROBERT BARFIELD Plaintiff	)	CIVIL ACTION NO.:
V.	)	
SCOTT SEMPLE Defendant, in his official capacity As Commissioner of the Connecticut Department of Correction	)	JULY 19, 2018

VERIFIED CLASS ACTION COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Preliminary Statement

1. The Connecticut Department of Correction ("CT DOC") is refusing to provide life-saving treatment to an unknown number of incarcerated people with hepatitis C. This policy, practice, and custom has resulted in the suffering and probable death of numerous prisoners, and puts tens of thousands of other prisoners at serious risk of experiencing pain, liver failure, cancer, and death—despite the fact that there are medications that will cure almost all hepatitis C patients with little to no side effects, and the fact that the medical standard of care requires treatment for all such patients. The failure to provide treatment also creates the potential for further spreading of the disease to the general public. These actions amount to deliberate indifference to the serious medical needs of CT DOC prisoners with hepatitis C, in violation of the Eighth Amendment to the United States Constitution, and discrimination on the basis of

disability, in violation of the Americans with Disabilities Act and Rehabilitation Act. Accordingly, Plaintiffs seek declaratory and injunctive relief on behalf of all CT DOC prisoners with hepatitis C, so that they can receive the treatment that they desperately need.

Jurisdiction and Venue

2. Jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1331 in that this is a civil action arising under the Constitution of the United States.

3. Jurisdiction of the Court is invoked pursuant to 28 U.S.C. § 1343(a)(3) in that this action seeks to redress the deprivation, under color of state law, of rights secured to the Plaintiffs by the Constitution and laws of the United States.

4. Plaintiffs' claims for relief are predicated, in part, upon 42 U.S.C. § 1983, which authorizes actions to redress the deprivation, under color of state law, of rights, privileges, and immunities secured by the Constitution and laws of the United States, and upon 42 U.S.C. § 1988, which authorizes the award of attorneys' fees and costs to prevailing plaintiffs in actions brought pursuant to 42 U.S.C. § 1983. Plaintiffs' claims are also brought pursuant to the Americans with Disabilities Act (ADA), 42 U.S.C. § 12132, and the Rehabilitation Act (RA), 29 U.S.C. § 794, and pursuant to 42 U.S.C. § 12205, and 29 U.S.C. § 794a, which authorize an award of attorneys' fees and costs to the prevailing plaintiffs.

5. Declaratory and injunctive relief are authorized by 28 U.S.C. §§ 2201 and 2202, as well as Federal Rule of Civil Procedure 65.

6. Venue is proper in this district pursuant to 28 U.S.C. §1391(b) and § 1391(c), as Defendant does

business in this judicial district and division, and many of the events or omissions giving rise to the claims occurred in this judicial district and division.

7. Plaintiffs seek a preliminary and permanent injunction pursuant to Rule 65, Federal Rules of Civil Procedure.

Parties

8. Plaintiff Robert Barfield, inmate number 391969, is incarcerated in the CT DOC system as part of the Interstate Corrections Compact.

9. Plaintiff has exhausted all available administrative remedies.

10. Defendant Scott Semple is the Commissioner of the Connecticut Department of Correction (CT DOC). As such, he is responsible for the overall operation of the CT DOC, including the operation of Connecticut's prison system and compliance with the Constitution and federal laws. Defendant Semple has a non-delegable duty to provide constitutionally adequate medical care to all persons in his custody. He is sued in her official capacity for injunctive and declaratory relief. Defendant Semple may be referred to herein as the Connecticut Department of Correction or CT DOC.

11. Defendant Semple has statutory authority to implement the relief sought in the Compliant. See Conn. Gen. Stat. §§ 18-81 et seq.

12. Defendant Semple and his agents acted under color of state law and their actions constitute state action.

13. All staff members mentioned herein were employees or agents of Defendant and acted

within the scope of their employment or agency at all relevant times.

14. The CT DOC is a public entity under Title II of the ADA, and receives federal financial assistance within the meaning of the RA, and has at all relevant times.

General Factual Allegations

Hepatitis C and Its Symptoms

15. Hepatitis C is a blood borne disease caused by the hepatitis C virus (HCV). The virus causes inflammation that damages liver cells, and is a leading cause of liver disease and liver transplants.

16. HCV is transmitted by infected blood via several methods, including intravenous drug use and tattooing using shared equipment, blood transfusions with infected blood (typically before regular screening of donated blood began), and sexual activity. Intravenous drug use is the most common means of HCV transmission in the United States.

17. HCV can be either acute or chronic. In people with *acute* HCV, the virus will spontaneously clear itself from the blood stream within six months of exposure. *Chronic* HCV, on the other hand, is defined as having a detectable HCV viral level in the blood at some point six months after exposure. Fifty-five to eighty- five percent of people infected with HCV will develop chronic HCV.

18. Liver inflammation caused by chronic HCV can significantly impair liver function and damage its crucial role in digesting nutrients, filtering toxins from the blood, fighting infection,

and conducting other metabolic processes in the body. Liver inflammation can also cause fatigue, weakness, muscle wasting, skin rashes, and arthritis.

19. People with chronic HCV develop *fibrosis* of the liver, a process by which healthy liver tissue is replaced with scarring. Scar tissue cannot perform the job of normal liver cells, so fibrosis reduces liver function and results in the same symptoms mentioned above, but with greater intensity. Fibrosis can also lead to hepatocellular carcinoma (liver cancer).

20. When scar tissue begins to take over most of the liver, this extensive fibrosis is termed *cirrhosis*. Of those with chronic HCV, the majority will develop chronic liver disease and approximately 20% will develop cirrhosis in a 20-year timeframe.

21. Cirrhosis causes additional painful complications, including widespread itching, kidney disease, jaundice, fluid retention with edema, internal bleeding, varices (enlarged veins that develop in the esophagus or intestines, which can burst), easy bruising, ascites (fluid accumulation in the legs and abdomen), encephalopathy (mental confusion and disorientation), lymph disorders, increased risk of infection, seizures, and extreme fatigue. Most of these complications can occur before cirrhosis. If they go untreated, some can cause death, often from infection, bleeding, and fluid accumulation.

22. Abdominal ascites can require paracentesis, a procedure wherein a needle is inserted into the abdomen to drain the fluid. Without this periodic procedure, the fluid accumulation can decrease the available space for the patient's lungs, thus causing shortness of breath and difficulty breathing.

23. Moreover, once an HCV patient's liver has cirrhosis, it may not be reversible. Some patients with cirrhosis may have too much scar tissue in the liver, even if the liver can heal to some degree once the virus is eliminated by treatment. If scar tissue persists, the patient may still experience the complications of cirrhosis, including liver cancer.

24. Cirrhosis that is accompanied by serious complications is known as *decompensated* cirrhosis. Cirrhosis without serious complications is called *compensated* cirrhosis.

25. Thus, HCV is a physiological disorder or condition that affects one or more body systems, including but not limited to the digestive, gastrointestinal, immune, circulatory, cardiovascular, and hemic systems, and is therefore a physical impairment. This physical impairment substantially limits one or more major life activity, including but not limited to eating, walking, bending, lifting, concentrating, thinking, and communicating; the operation of major bodily functions such as digestive, gastrointestinal, immune, circulatory, cardiovascular, and hemic systems; and the operation of the liver.

26. For all CT DOC prisoners who have been diagnosed with HCV, there is a record of their impairment.

27. The CT DOC regards all prisoners with HCV as having a physical impairment that substantially limits one or more major life activity.

28. HCV is a serious medical need.

General Prevalence of Hepatitis C

29. Approximately 2.7 to 3.9 million Americans have chronic HCV.

30. In 2000, the United States Surgeon General called HCV a "silent epidemic," and estimated that as much as two percent of the adult U.S. population had HCV.

31. In 2013, HCV caused more deaths than sixty other infectious diseases combined, including HIV, pneumococcal disease, and tuberculosis.

32. Approximately 19,000 people die of HCV-caused liver disease every year in the United States.

33. HCV is the leading indication for liver transplants in the United States.

Hepatitis C in Prison

34. The prevalence of HCV in prison is much higher than in the general population. It is estimated that between 16% and 41% of the United States jail and prison population has HCV. Thus, incarceration is a risk factor for HCV.

35. CT DOC has no internal census of how many inmates have HCV.

36. Up until July 1, 2018, Correctional Managed Health Care (CMHC), a division of the University of Connecticut, provided health care for inmates under a Memorandum of Agreement (the "MOA") with the CT DOC.

37. Dr. Johnny Wu was medical director of CMHC from June 2012 to March 2017.

38. Upon information and belief, during his tenure, Dr. Wu never met with Defendant Semple to discuss HCV in CT DOC prisons.

39. Upon information and belief, during his tenure, Dr. Wu did not think HCV was a

problem.

40. Upon information and belief, CT DOC, during Dr. Wu's tenure, never did a study that sought to test all inmates for HCV.

41. Upon information and belief, CT DOC would hold monthly meetings about health issues that Dr. Wu would attend.

42. Upon information and belief, Dr. Wu, at these monthly meetings, would frequently ask for support from the CT DOC to perform a census of HCV in prisoners in CT DOC custody.

43. Upon information and belief, prior to his departure from CMHC, Dr. Wu had secured almost a $300,000 grant from Gilead Sciences, a pharmaceutical company that makes drugs to treat HCV, to perform a census of inmates with HCV.

44. Upon information and belief, Dr. Wu fought with CT DOC leadership over how to implement this grant.

45. Upon information and belief, Dr. Wu was under the impression that CT DOC wanted to control the census and handle it internally and not have CMHC involved in it. Thus neither the CT DOC nor CMHC ever obtained the $300,000.00 in funds to perform HCV testing on all inmates.

46. Upon information and belief, CT DOC did a study of the prevalence of HCV in the New Haven Correctional jail in 2015 and learned that 10-12 percent of the jail population at that one facility had HCV. As of December 1, 2015, a CT DOC inmate census indicated that there were 779 inmates at New Haven, meaning up to 93 inmates there are HCV positive.

47. Upon information and belief, CT DOC in or about 2016 began a study to see what numbers of prisoners entering CT DOC jails have HCV when entering the jails. The results of this study are not known.

48. Upon information and belief, Dr. Johnny Wright, a physician who works for the CT DOC at Osborn Correctional Institute, has testified that HCV is a problem in all CT DOC prisons, and in Osborn, five in ten people he sees as patients in custody have HCV. According to the July 1, 2018 CT DOC census, there are 1,331 prisoners at Osborn. Roughly extrapolating Dr. Wright's first-hand experience, that means that there could be almost 660 people in Osborn with HCV.

49. There is no clear estimate from the CT DOC as to how many people in CT DOC have HCV.

50. In a 2016 study by Yale University researchers canvassing the HCV population of inmates in prison systems of 41 states, CT DOC reported only four cases of HCV.[1] This report of four people with HCV was during the middle of Dr. Wu's tenure at CMHC.

51. According to a contradictory public statement in a BusinessInsider.com article from October 2014, CT DOC said it treats about 20 inmates a year with DAA drugs.[2] Dr. Wu was quoted as saying "My total budget is about $89 million to deliver healthcare for 16,200 people. That's mental health, dental, medical, consults, surgeries. To have a couple of million dollars tied up for hep C is a big portion of my budget."

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[1] https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2016.0296
SEE ALSO https://fivethirtyeight.com/features/prisoners-with-hep-c-get-cured-in-some-states-but-not-others/

[2] http://www.businessinsider.com/prisons-are-spending-millions-on-a-pricey-new-drug-2016-10

52. CT DOC and CMHC officials in public statements cannot even agree on how many HCV positive inmates exist and are treated annually.

Standard of Care for HCV

53. For many years, medical science lacked universally safe and effective treatments for HCV. The standard treatment prior to 2011, which included the use of interferon and ribavirin medications, sometime required injections, had a long treatment duration (up to 48 weeks), failed to cure most patients, and was associated with numerous side effects, including psychiatric and autoimmune disorders, flulike symptoms, gastrointestinal distress, skin rashes, and severe anemia. Moreover, not all drug regimens worked for all types of HCV, and many could not be given to patients with other comorbid diseases.

54. In 2011, however, the Food and Drug Administration (FDA) began approving new oral medications, called direct-acting antiviral (DAA) drugs, which have proven to work more quickly, cause fewer side effects, and treat chronic HCV much more effectively. At first, they were designed to work in tandem with the old treatment regimen. But beginning in 2013, the FDA began to approve DAA drugs that can be taken alone.

55. These DAA drugs—currently Sovaldi (sofosbuvir), Olysio (simeprevir), Harvoni (sofosbuvir/ledipasvir), Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir), Daklinza (daclatasvir), Technivie (ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazprevir), and Epclusa (sofosbuvir/velpatasvir)—have far fewer side effects, dramatically greater efficacy, a shorter treatment duration (12 weeks), and are administered orally (commonly a once-daily

pill) rather than by injections. These DAA drugs have truly revolutionized the way HCV is treated.

56. Most importantly, 90 to 95% of HCV patients treated with any of these DAA drugs are cured, whereas the old treatment regime only helped roughly one third of patients.

57. For HCV, a "cure" is defined as a sustained virologic response (SVR)— i.e., no detectable HCV genetic material in the patient's blood—for three months following the end of treatment.

58. In response to the revolutionary DAA medications, the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) formed a panel of experts to conduct an extensive, evidence-based review of the testing, management, and treatment of HCV. The results of that review have been published in a comprehensive document called the HCV Guidance, which is updated regularly and is available at www.hcvguidelines.org. The Centers for Disease Control and Prevention (CDC) encourages health care professionals to follow the evidence-based standard of care developed by the IDSA/AASLD.

59. The IDSA/AASLD guidelines set forth the medical standard of care for the treatment of HCV, which is now well-established in the medical community.

60. The IDSA/AALSD panel, through the HCV Guidance, recommends immediate treatment with DAA drugs for all persons with chronic HCV. This is the standard of care for the treatment of HCV, and it reflects the continuing medical research showing the safety, tolerability, efficacy, and dramatic benefits of the DAA drugs.

61. The CT DOC and CMHC, in the MOA, indicated that CMHC would implement Medicaid guidelines and clinical practice guidelines, and according to the state auditor's report, that had not been done. Thus, the CT DOC cannot determine what is medically necessary and therefore covered by the Medicaid program, including whether or not DAA medications for HCV should be approved for all adult patients with an HCV diagnosis.

62. Medicaid guidelines specifically eliminated any requirement that there be any evidence of hepatic fibrosis before covering DAA treatments. Thus, CT DOC has not recognized that the standard of care for HCV is to provide immediate treatment with DAA drugs to all patients with HCV, regardless of the stage of the disease.

63. Under the community standard of care, treatment with DAA drugs is expected to cure nearly all infected persons.

64. The benefits of immediate treatment include immediate decrease in liver inflammation, reduction in the rate of progression of liver fibrosis, reduction in the likelihood of the manifestations of cirrhosis and associated complications, a 70% reduction in the risk of liver cancer, a 90% reduction in the risk of liver-related mortality, and a dramatic improvement in quality of life.

65. Treatment must be provided timely to ensure efficacy. Delay in treatment increases the risk that the treatment will be ineffective.

Screening, Diagnosis, and Monitoring of HCV

66. Under the IDSA/AASLD guidelines, all persons with risk factors for HCV infection should

be offered testing for HCV. This includes all persons born between 1945 and 1965 and all persons who were ever incarcerated.

67. A person is generally diagnosed with HCV through a rapid blood test in which the blood is examined for HCV antibodies. A follow-up blood test determines whether the genetic material of HCV remains in the blood. A third blood test can determine which variation, or genotype, of HCV a person has.

68. Although the standard of care is to treat all persons with chronic HCV with DAA drugs, it is still useful to determine the progression of fibrosis and/or cirrhosis in the liver to choose the appropriate DAA drug, to treat other conditions or complications a person may be experiencing, to screen for liver cancer, to advise patients about contraindications and drugs to avoid, and to determine whether liver transplantation is necessary.

69. There are several methods used to determine the level of cirrhosis or fibrosis, along with an evaluation of the patient's symptoms. One such method is a liver biopsy, which is a surgery wherein a small sample of liver tissue is removed and histologically assessed. A typical biopsy evaluation method is a system called Metavir, which assigns a number corresponding to the amount of scar tissue on the liver, with 0 meaning no fibrosis and 4 meaning severe fibrosis or cirrhosis. A score of 2 or greater is considered significant fibrosis. Liver biopsies are generally regarded as the most accurate measure of fibrosis and cirrhosis, but they are not routinely recommended because they are invasive and potentially dangerous, and also because they are generally unnecessary, because the standard of care is to treat all HCV patients, regardless of disease progression.

70. Other methods of assessing fibrosis and cirrhosis include blood tests, such as the APRI (AST to Platelet Ratio Index) score. This score is a ratio derived by comparing the level of an enzyme in the blood called aspartate aminotransferase (AST) with the usual amount of AST in the blood of a healthy person and the number of platelets in the affected person's blood. Generally, an APRI score greater than 0.7 indicates significant fibrosis, and a score of 1.0 or greater indicates cirrhosis. But as explained below, a low APRI score does not necessarily indicate the absence of fibrosis.

71. Another blood test is called the FIB-4, which is a ratio derived using the level of two enzymes in the blood, AST and alanine aminotransferase (ALT), as well as platelet count and the person's age.

72. Standard ultrasounds or sonograms of the liver are unreliable indicators of the level of fibrosis, as advanced fibrosis may not be detected by these scans. But there is a more accurate version called FibroScan, which is a type of ultrasound known as transient elastography that uses sound waves to determine the amount of fibrosis present in the liver.

73. A FibroScan measures liver hardness by calculating the velocity of a vibration wave generated on the skin. The vibration wave velocity is determined by measuring the time the vibration wave takes to travel to a particular depth inside the liver.

74. According to the standard of care, a patient with chronic HCV and a liver stiffness of greater than 14 kilopascals (kPa) has approximately a 90% probability of having cirrhosis, while chronic HCV patients with liver stiffness greater than 7 kPa have around an 85% probability of

at least significant fibrosis.[3]

75. In assessing the level of fibrosis or cirrhosis, the entire clinical picture must be taken into account. There is no one blood test, scan, or symptom that will accurately determine the extent of liver damage, and therefore relying solely on strict numerical cutoffs of any test result is inappropriate. Any abnormal test result or symptom should be taken as a sign of fibrosis or cirrhosis, but normal results in isolation cannot rule out fibrosis or cirrhosis.

76. Relying solely on the APRI score to make treatment decisions is not adequate or appropriate because APRI has significant limitations. First, when an APRI score is extremely high, it has good diagnostic utility in predicting severe fibrosis or cirrhosis, but low and mid-range scores may miss many people who have significant fibrosis or cirrhosis. In fact, in more than 90% of HCV cases, an APRI score of at least 2.0 indicates that a person has cirrhosis, but more than half of people with cirrhosis will not have an APRI score of at least 2.0. Second, where a person has been diagnosed with cirrhosis or advanced fibrosis through some other means, a low APRI score does not negate the diagnosis—it should be presumed the patient has cirrhosis. Third, because AST levels fluctuate from day to day, a decreased or normalized level does not mean the condition has improved, and even a series of normal readings over time may

[3] Friedrich-Rust M, Ong MF, Martens S, et al. Performance of transient elastography for the staging of liver fibrosis: a meta-analysis. Gastroenterology 2008;134:960–74.

See also, Tsochatzis EA, Gurusamy KS, Ntaoula S, et al. Elastography for the diagnosis of severity of fibrosis in chronic liver disease: a meta-analysis of diagnostic accuracy. J Hepatol 2011;54:650–9.

fail to accurately show the level of fibrosis or cirrhosis.

77. A health care provider must also evaluate a patient's symptoms and determine whether the liver disease is compensated or decompensated. Once liver disease has advanced, scoring of the clinical degree of liver dysfunction is done using the Childs-Pugh (C-P) score, also termed the Child-Turcotte-Pugh score (CPT). Variables include the serum albumin and bilirubin, ascites, encephalopathy, and prothrombin time (a measure of how well the blood clots). The score ranges from 5 to 15. Patients with a score of 5 or 6 have CPT class A cirrhosis (well-compensated cirrhosis), those with a score of 7 to 9 have CPT class B cirrhosis (significant functional compromise), and those with a score of 10 to 15 have CPT class C cirrhosis (decompensated cirrhosis).

78. Once cirrhosis has developed, patients should also be followed with twice yearly alfa fetoprotein (AFP) screens, which is a serum marker for the development of liver cancer. Increases in AFP indicate the possible presence of liver cancer.

79. Individuals with comorbid HIV (or other immune disorders) and HCV are at a much greater risk for more rapidly progressive liver disease, and should be treated and closely followed.

CT DOC's Unlawful Policy and Practice of Denying Treatment for HCV

80. Despite the clear agreement in the medical community that all persons with chronic HCV should be treated with DAA drugs, the CT DOC does not provide these lifesaving medications to CT DOC prisoners with HCV. Instead, Defendant Semple has set a policy, custom,

and practice of not providing DAA medications to prisoners with HCV, in contravention of the prevailing standard of care and in deliberate indifference to the serious medical needs of prisoners with HCV.

81. This policy, practice, and custom has caused, and continues to cause, the unnecessary and wanton infliction of pain and an unreasonable risk of serious damage to the health of CT DOC prisoners with HCV.

82. Although Defendant Semple has a policy governing the treatment of prisoners with HCV, which is outlined in UCONN HEALTH CMHC Policy and Procedure Manual Number: G 2.04, Hepatitis C Management and Treatment (hereinafter "Policy G 2.04"), first promulgated on December 10, 2002 and revised on May 30, 2005, December 21, 2010, February 1, 2012, July 31, 2013, June 30, 2015 and June 30, 2016, in practice almost no prisoners receive DAA medications.

83. A true and correct copy of Policy G 2.04 is attached to this Complaint as Exhibit 1.

84. Policy G 2.04 created a special board of Infectious Disease (ID) experts who will evaluate all requests for treatment of Hepatitis C infection in CT DOC facilities.

85. Policy G 2.04 states: "Evaluation of candidates for treatment of Hepatitis C, as well as implementation of therapy, shall be performed by the ID specialists (IDS) that currently manage HIV and other infectious disease within CDOC facilities."

86. Policy G 2.04 created a Hepatitis C Utilization Review Board ("HepCURB") to review all requests for treatment, and, "In general, the HepCURB will follow the specific

recommendations of the … AASLD, … IDSA and the International Antiviral Society-USA (ISA-USA) regarding Hepatitis C management and treatment currently in force at the time of the inmate review."

87. Policy G 2.04 further states that "although they will not directly provide specific anti-viral drugs from Hepatitis C, CMHC Primary Care Physicians (PCPs) will provide appropriate supportive care to inmates with Hepatitis C, including management of their liver disease and its complications." Thus the policy itself contravenes the standard of care, since it states it will not provide DAAs.

88. Policy G 2.04 created a procedure that begins "When an inmate has been found to have a positive anti-HCV study, and there are clinical indication for treatment, the CMHC PCP shall conduct an initial evaluation using the Form HR 007A". Then the PCP should order appropriate testing of the inmate's HIV status and risk of future infection by Hepatitis A and B, and obtain a complete blood count (CBC) and liver function tests (LFTs) to assess hepatic inflammation.

89. Policy G 2.04 details the specific steps that PCPs should take:

> Additional diagnostic studies to assess the appropriateness of therapy for Hepatitis C infection in an inmate shall only be ordered by the IDS.
>
> The PCP shall inform the inmate of the diagnosis, provide the inmate with the approved CMHC Hepatitis C informational packet, and document the discussion in the inmate's health record on the Form HR 401, Clinical Record. For those inmates lacking protective antibodies against Hepatitis A and B, the PCP will offer active immunization.
>
> The PCP shall recommend follow-up in not less than 6 months, either within the CDOC or the community, with clinical re-evaluation and repeat measurement of complete blood count and liver function tests. If the inmate is still incarcerated

at the time of repeat testing, the PCP shall discuss the new findings with the inmate, and at that time shall either refer the inmate to the facility IDS for consideration of specific therapy, or shall counsel the inmate to continue monitoring of the disease either within the CDOC or in the community. If the inmate is referred to the IDS and has not been tested for HIV infection, the PCP will refer the inmate HIV testing. The follow-up visit shall be documented on Form HR 007B, Follow-Up Evaluation of Hepatitis C Infection by Primary Care Provider. This form is also to be used as the referral form if the PCP refers the inmate to the IDS.

The PCP shall withhold any referral to the IDS until court sessions have concluded and the inmate has been sentenced. The PCP shall also withhold any referral to the IDS until 2 CBCs and 2 LFTs, spaced at least 6 months apart and both performed within the CDOC, are available and are consistent with active liver disease.

It is expected that the CMHC PCP will continue to monitor the inmate regarding related health issues, such as the management of hepatic decompensation or intensive fluid retention, should these occur.

The PCP shall remain responsible for continuing care of the inmate, including the inmate's liver disease, regardless of whether anti-viral therapy is given.

90. The second procedural step of Policy G 2.04 provides a detailed framework for Assessment of the HCV by an On-Site Infectious Disease Specialist. The procedure is as follows:

• An inmate history that includes the following: drug and alcohol abuse history; suspected acute hepatitis episodes; hospitalizations related to hepatic disease or decompensation; any previous assessments or treatment for Hepatitis C; neuropsychiatric history including severe depression or suicidal ideation or attempts; past autoimmune disease; known immunosuppression, including HIV infection or solid organ transplant; current pregnancy; and any history of chronic disease (e.g. diabetes mellitus, cardiomyopathy) that requires special management as well as an assessment of how well this chronic disease is being controlled.

• A comprehensive evaluation of the inmate's hepatic status, including signs of

decompensation (ascites, wasting, persistent jaundice, variceal hemorrhage, hepatic encephalopathy); or a history of such decompensation, stigmata of hepatic disease.

• Review of laboratory tests already performed, as well as review of any available community records. If following this initial evaluation, the inmate appears to be a reasonable candidate for treatment, the IDS will counsel the inmate about the potential benefits and risks of treatment, and about CMHC's expectations about treatment adherence.

If the inmate wishes to proceed further, the IDS/designee shall ask the inmate to sign Form HR 307, Consent and Compliance Agreement for Hepatitis C Treatment, agreeing to comply with recommended treatment, including compliance with transient elastography testing (FibroScan), liver biopsy (if required), drug administration and laboratory testing, and stating an understanding that noncompliance with treatment will mean that therapy will stop and will not be offered again in the future.

This signed document shall be kept in the ID section of the inmate's Health Record (HR); refusal to agree to the terms of the Form HR 307, Consent and Compliance Agreement for Hepatitis C Treatment shall make the inmate ineligible for treatment.

If the inmate will not agree to the terms of the Consent and Compliance Agreement, the IDS shall ask the inmate to sign Form HR 301 Refusal of Health Services indicating her/his unwillingness to comply with the Agreement, and shall advise that no further evaluation for anti-viral treatment will be done, and shall return the inmate to the care of the PCP.

The IDS shall document the discussion in the inmate's Health Record on the Form HR 401, Clinical Record.

If the inmate signs the Consent and Compliance Agreement Form, agreeing to its terms, the IDS shall then use the Patient Safety System (PSS) to order the following laboratory studies using Hepatitis C Diagnostic Orders:

1) Liver function studies
2) CBC with differential
3) Chronic Hepatitis Profile (If not already done)
4) HAV IgG (If not already done)
5) Hepatitis C Genotype
6) HCV-RNA (quant. level by PCR)

7) Alpha-fetoprotein
8) ANA
9) TSH and free T4
10) Anti-mitochondrial Ab
11) Iron studies (Fe/TIBC/Transferrin)
12) HIV-Ab (If inmate's HIV Status unknown)
13) T4 count and HIV-1 viral load (If patient know to be HIV positive & if recent values not available)
14) PT / PTT
15) BUN / Creatinine
16) RPR

The IDS may omit any of these tests if recent values are available.

Prior to ordering an HIV-Ab study, standard pre-test counseling will be provided. The IDS/designee will then assist the inmate in completing Form HR 401D, Initial HCV Functional Status Report, and will place the completed form in the ID section of the inmate HR. In addition, the IDS shall order a mental health evaluation, to assess the psychological
risks of therapy:

- For inmates classified Mental Health 3, 4, or 5, a psychiatrist shall make an assessment of the inmate's present psychological status and current stability, advising the IDS regarding the risk of decompensation as a result of anti-Hepatitis C therapy. The psychiatrist shall summarize and document this evaluation on the Form HR 401, Clinical Record, the encounter to be identified as "MH Evaluation for HCV Treatment"
- For inmates classified Mental Health 1 or 2, a psychiatrist or psychologist will complete the mental health evaluation and document the findings, as outlined above.
- The IDS may refer a Mental Health 1 or 2 inmate directly to a psychiatrist, bypassing the above step, in selected cases.

If the results of the mental health assessment do not indicate any increased psychological risk, the IDS may then initiate a referral to the Hepatitis C Utilization Review Board.

The IDS/designee shall inform the inmate regarding Hepatitis C issues as the assessment progresses. Once the laboratory studies are completed and the IDS discussed treatment options with the inmate, if the inmate wishes to pursue

> treatment, the IDS shall placed a request to CMHC UR to schedule transient elastography (FibroScan).
>
> If at any point the IDS believes that treatment is inappropriate, but the inmate insists on therapy despite the advice of the IDS, the IDS does not need to perform the entire evaluation described above, but shall forward the inmate's request to the HepCURB, explaining why he or she does not believe that treatment is appropriate, and including whatever testing has been completed.

91. And again, despite this written policy of prioritization, in practice CT DOC provides almost no treatment with medications.

92. Policy G 2.04 holds that if the IDS determines after all the steps outlined above that the treatment should continue and the inmate wants to continue treatment, then the patient inmate's case is forwarded to the HepCURB, along with appropriate paperwork. The IDS, prior to forwarding the paperwork to the HepCURB, should inquire of the inmate about private health insurance, and "This will be documented in the inmate HR and included on Form HR 401C, IDS Hepatitis C Evaluation, including the name of the carrier and the policy number. The decision to treat or not treat shall be made without reference to third-party coverage, but if treatment is approved, the UCHC pharmacy will attempt to recover some or part of its costs through third-party payers."

93. Policy G 2.04 sets parameters for a Review by the HepCURB, which are as follows:

> The HepCURB will not generally approve Hepatitis C therapy unless there is a reasonable likelihood that the inmate will remain under CDOC supervision for the entire duration of treatment period.
>
> The HepCURB shall first determine if a liver biopsy should be performed prior to making a decision regarding the initiation of specific therapy for Hepatitis C where there is technical limitation of the transient elastography test (FibroScan)

In many circumstances the HepCURB may waive the requirement for a liver biopsy prior to the initiation of Hepatitis C therapy. If a liver biopsy is judged to be necessary, the HepCURB will notify the IDS through comments and internal messaging within the UR application. The IDS will inform the inmate that this is necessary and document this discussion in the inmate's HR on the Form HR 401, Clinical Record located in the ID section of the HR.

CMHC Central Office UR Unit shall schedule an appointment at UCHC for this purpose. If the liver biopsy is to be performed within the Interventional Radiology Department at John Dempsey Hospital, the inmate shall have a CBC, platelet count, PT, and PTT performed no more than 14 days prior to the date of the biopsy, and the results shall be available to the radiologist.

CMHC Central Office UR Unit shall notify the designated CMHC nurse at the CDOC facility of the timing of this. Once the HepCURB has either decided to forego the liver biopsy, or has obtained the pathology report regarding the liver biopsy in question, the HepCURB shall decide on treatment initiation.

To reduce the risk of re-infection following treatment, the HepCURB must have a reasonable expectation that the inmate will not engage in alcohol or drug abuse following release from the CDOC. For this reason, the HepCURB may insist that an inmate participate in the CDOC Addictions Program either before definitive therapy for Hepatitis C is initiated or simultaneous with such therapy. Prioritization for treatment is based on:

- Advanced hepatic fibrosis/cirrhosis Metavir stage F4
- Liver transplant patients
- HIV co-infection
- Comorbid medical conditions associated with HCV, e.g. crypglobulinemia and certain types of lymphomas; Hepatitis C related renal disease
- Continuity of care for newly incarcerated inmates who were being treated at the time of incarceration.

Treatment approvals will specify the most optimal therapy available at the time of treatment approval

94. Despite, or probably because of this policy, liver biopsies are generally not performed for CT DOC prisoners with HCV.

95. Since the change in management of inmate health care and the termination of the MOA, CT DOC has not released new guidelines for HCV treatment.

96. The prioritization for the DAA treatment as stated in Policy G 2.04, which places advanced HCV cases of hepatic fibrosis and liver transplant candidates at the top of the line is not in line with the standard of care. The Defendant's written policy (even if it was followed) of prioritizing treatment to patients with the most advanced stages of the disease amounts to deliberate indifference to serious medical needs in violation of the Eighth Amendment. Delaying treatment until a patient is extremely sick has the perverse effect of withholding treatment from the patients who could benefit from it most, because the treatment is less effective for patients with the most advanced stages of the disease.

97. If the HepCURB determines to initiate treatment and the HepCURB notifies the IDS of its approval, Policy G 2.04 prescribes the following steps:

> The IDS shall notify the inmate that treatment has been approved, and shall document this discussion on Form HR 401, Clinical Record, in the ID Clinic Section of the HR, and obtain the inmate's signature confirming the discussion on the URC computer generated report. The IDS will also obtain the inmate's signature on Form 305 Consent for Treatment.
>
> All treatments shall start on a standardized day of week and month in order to reduce errors by standardizing practice, to minimize side-effects interfering with inmate employment and programming during the week, and to 'batch' viral load testing to allow faster results. All treatment will start on the 3rd Friday of each month.
>
> The URC shall regularly furnish the CMHC Pharmacy Director and the CMHC Operations Administrator for Quality Assurance a list of inmates who have been approved for treatment.

> The CMHC Pharmacy Director shall coordinate the various steps in acquiring the medications, including any registration procedures with the pharmaceutical company involved.
>
> …
>
> When the medication is available, the IDS/designee will assist the inmate in completing Form HR 401E, HCV Functional Follow-up Status Report, and will place the completed form in the ID section of the inmate HR.

98. Because the accepted standard of care for HCV is to treat everyone, without regard to the stage of the disease or approval of any board or structure, Defendant's written policy (even if it was followed) of rationing treatment to patients who fit the elaborate criteria designed by CT DOC amounts to deliberate indifference to serious medical needs, in violation of the Eighth Amendment. It is not consistent with the standard of care. Delaying or preventing treatment until a patient manages the labyrinthine structure of approvals has the perverse effect of withholding treatment from the patients.

99. Even if the policy were adequate, the CT DOC does not follow it because it provides treatment to almost none of the HCV-positive prisoners in its custody. In practice, this procedure is not followed and chronic HCV patients do not receive appropriate care.

100. In fact, CT DOC's treatment rate is among the lowest in the country for which there is reported data.

101. And since 2013, the year the FDA approved DAA medications that cure HCV, an unknown number of CT DOC prisoners have died of chronic liver disease, cirrhosis, and other diseases of the digestive system. Since HCV is the most common cause of liver failure in the United States, it is likely that most of these deaths were due to chronic HCV. Upon information

and belief, past and current practices of the Defendant are resulting in deaths that could have been prevented through treatment of HCV.

102. Furthermore, assuming that prioritization were appropriate, Defendant's policy is also inadequate because it relies on an IDS' judgment instead of the community standard of care of providing treatment to everyone infected with HCV.

103. And assuming that Policy G 2.04 were appropriate, CT DOC has set the barriers so high that CT DOC precludes treatment for most inmates with HCV.

104. Further, assuming that Policy G 2.04 was appropriate and set appropriate standards or care, CT DOC is not even following the policy. CT DOC does not even have a census of people with HCV in its custody.

105. The CT DOC, through Policy G 2.04 unjustifiably delays providing HCV treatment, even though the standard of care requires treatment as early as possible. If DAA treatment is delayed until a patient has advanced fibrosis or cirrhosis, these medications can be significantly less effective. Moreover, if DAA treatment is delayed until a patient develops decompensated cirrhosis, a liver transplant preceded or followed by DAA treatment is the only way to cure the patient.

106. In practice, the CT DOC delays treatment for virtually all patients with HCV, regardless of their disease progression, until the patient is released from prison or dies.

107. "In a study performed at the Connecticut Department of Corrections during 2002 to 2006, investigators characterized major reasons for deferral of therapy, and inability to

complete therapy before inmate release was the most common reason for deferral; other major reasons included lack of indication for treatment, patient refusal, and unstable clinical conditions."[4] While these reasons may date back more than a decade, Plaintiff Barfield's experience and Policy G 2.04 demonstrate that the conclusions of this study remain relevant today.

108. Moreover, Defendant's policy does not address liver transplantation, the only possible cure for people with decompensated cirrhosis. Even if given DAA treatment, many of these patients will likely die without liver transplants.

109. Defendant's policy does not address the need for liver cancer screening, which is standard medical practice once individuals have progressed to advanced fibrosis or cirrhosis. Unless there is regular surveillance to find cancers early and remove them surgically, liver cancer has a very dismal prognosis. Contrary to the proper and necessary medical procedures and the community standard of care, Defendant has not screened Plaintiff, and, upon information and belief, other HCV-positive CT DOC prisoners with advanced fibrosis and cirrhosis, for liver cancer.

110. Defendant categorically withholds treatment from CT DOC prisoners with HCV, but does not categorically withhold treatment from prisoners with other similar diseases or conditions (such as HIV) or from other prisoners without similar diseases or conditions.

111. The CT DOC has enforced the above-described policies, practices, and customs despite

[4] https://www.hepatitisc.uw.edu/pdf/special-populations-situations/treatment-corrections/core-concept/all

knowing that the failure to provide DAA medications to prisoners with HCV subjects those prisoners to an unreasonable risk of pain, liver failure, cancer, permanent damage to their health, and even death. Defendant has acted with deliberate indifference to the serious medical needs of CT DOC prisoners with chronic HCV.

112. Defendant will continue its course of conduct unless enjoined by this Court. Plaintiffs have no adequate remedy at law.

Public Health Benefits of Treatment in Prison

113. Providing expanded HCV screening and DAA treatment in Connecticut's prisons would greatly reduce the number of new HCV cases in the community. Curing the disease while people are in prison would prevent prisoners from transmitting it when released, and testing would diagnose numerous individuals who were unaware they were infected, thus allowing them to seek treatment once released.

114. Studies have shown that providing DAA treatment to everyone with chronic HCV increases long term cost-savings. One study even found that restricting DAA treatment access until patients were in the later stages of fibrosis actually results in higher per-patient costs because, while it may be initially less expensive to delay administering DAAs, over the course of treatment, the follow-up care outweighs the initial costs.

115. Thus, early DAA treatment has the potential to both drastically reduce the incidence of HCV in the general population and also to reduce the costs associated with serious complications from untreated HCV, such as liver transplants and liver cancer.

Allegations Regarding Named Plaintiff Robert Barfield

116. Plaintiff Barfield was born March 21, 1970, and he has been incarcerated since 1994.

117. Plaintiff Barfield was transferred to the custody of the CT DOC in August 2012.

118. Plaintiff Barfield's release date on the convictions from Nevada is in 2026, while his release date for his convictions for offenses committed in Connecticut is 2023. Thus, while he is here on the Interstate Corrections Compact, he is also serving time in Connecticut prisons for offenses committed in Connecticut.

119. Plaintiff Barfield was diagnosed with Hepatitis C in 2006 while he was in Ely State Prison in Nevada.

120. Nevada prison authorities transferred him to Iowa soon thereafter, and his medical records in 2007 reflect his HCV infection.

121. Plaintiff Barfield has chronic HCV.

122. His chronic HCV is a physiological disorder or condition that affects one or more of his body systems, including but not limited to the digestive, gastrointestinal, immune, circulatory, cardiovascular, and hemic systems, and is therefore a physical impairment. This physical impairment substantially limits one or more major life activity, including but not limited to walking, bending, sitting, lifting, and thinking; the operation of major bodily functions such as his digestive, gastrointestinal, immune, circulatory, cardiovascular, and hemic systems; and the operation of his liver.

123. Plaintiff Barfield has a record of having an impairment that substantially limits one or

more major life activity, as he has a history of such an impairment, and the CT DOC has diagnosed him with HCV, and his symptoms are clear in his medical records.

124. Plaintiff Barfield is regarded by CT DOC as has having an impairment that substantially limits one or more major life activity, as CT DOC perceives him as having such an impairment, has diagnosed him with HCV, and his symptoms are written in his medical records.

125. Mr. Barfield meets the essential eligibility requirements for the receipt of services or the participation in programs or activities provided by CT DOC, including but not limited to medical services.

126. Since his transfer into the CT DOC, Plaintiff Barfield has continually requested treatment at every annual checkup, but to no avail. He was told that he was not sick enough to be treated.

127. Plaintiff Barfield has continually requested treatment for HCV then, and was told that he did not meet the requirements for treatment.

128. Mr. Barfield has filed numerous grievances, complaining of his symptoms and requesting treatment, and appealed them, yet they have all been denied.

129. Plaintiff Barfield has been housed in multiple CT DOC facilities, and his treatment for HCV has been universally poor across the facilities, and none of his treatment has matched what is prescribed in Policy G 2.04.

130. Mr. Barfield's medical records first show that he was screened for HCV on August 5, 2013. Dr. Gerald Valletta signed the HR007A form from that date. Dr. Valletta did not fully complete the form, including indicating that Plaintiff Barfield received the approved CMHC

Hepatitis C packet, whether or not Dr. Valletta ordered an Hepatitis A antibody test, despite the fact that Mr. Barfield Hepatitis A status was unknown.

131. During his incarceration with CT DOC, Mr. Barfield has received intermittent care for his HCV.

132. Plaintiff Barfield was transferred to Corrigan Correctional Institute in 2014.

133. While housed at Corrigan Correctional Institute, Plaintiff Barfield did not see a doctor for the entire year he was there. He saw nurses, but did not see a primary care provider. He did not receive any of the recommended routine HCV screenings, nor was the protocol in Policy G 2.04 followed while he was in Corrigan.

134. Plaintiff Barfield wrote request forms seeking treatment for his HCV while at Corrigan.

135. On August 22, 2015, Plaintiff Barfield had a visit with a nurse and requested lab work to check on his HCV.

136. On November 6, 2015, Mr. Barfield filed a grievance asking for lab work to be done on his HCV.

137. On December 12, 2015, Plaintiff Barfield had a medical visit in which he requested lab work to check on his HCV.

138. The written response to Mr. Barfield's November grievance, issued to him on January 4, 2016, indicated that no further action was needed because labs would be drawn on January 6, 2016.

139. No records in Mr. Barfield's medical file show the result of the CBC and LFT of blood and

laboratory work that may or may not have been done on January 6, 2016. However, a clinical field note on April 8, 2016 indicates that lab work was done in January 2016.

140. Inadequate record keeping is a violation of the standard of care.

141. On March 30, 2016, Plaintiff Barfield was transferred to Northern Correctional Institution. In his intake report, he reported acute chronic pain and weakness, typical symptoms of HCV.

142. On April 6, 2016, Plaintiff Barfield submitted an inmate request form seeking treatment for his HCV.

143. On April 8, 2016, a medical provider discussed HCV protocol with Mr. Barfield, and noted this as the response to the April 6, 2016 request form.

144. On April 14, 2016, Dr. Carson Wright ordered CBC and LFT laboratory work for Mr. Barfield to take place in July 2016.

145. On April 17, 2016, Plaintiff filed a grievance seeking treatment for numbness and tingling in his hand. Peripheral neuropathy like numbness in his feet is a standard symptom of HCV. Plaintiff had suffered a hand injury in March 2016, but his medical records do not show HCV as being considered as part of the diagnosis.

146. On April 19, 2016, Dr. Carson Wright conducted an Initial Evaluation of Hepatitis C Infection by Primary Care Provider, Form HR007A.

147. This April 19, 2016 HR007A form is not fully filled out, and there is no additional documentation in Mr. Barfield's file beyond this about his HCV.

148. This was the second HR007A in Mr. Barfield's medical file. Upon information and belief, there has never been an HR007B filed out for Mr. Barfield, nor has Mr. Barfield ever been brought through any of the steps in Policy G 2.04. Other than the HR007A, none of the other HCV forms pursuant to Policy G 2.04 are in Plaintiff Barfield's medical records.

149. On July 2, 2016, Plaintiff Barfield submitted another inmate request form regarding the numbness in his feet. The response stated that he was scheduled to see a doctor.

150. On July 5, 2016, Plaintiff Barfield submitted an inmate request form regarding unexplained weight gain, pain, and acid reflux. The response was to place him on a diet. Weight gain may be a symptom of HCV.

151. Also on July 5, 2016, Plaintiff Barfield submitted another inmate request form regarding the numbness in his feet. The response four days later was to order labs and have a doctor's appointment as a follow up.

152. On August 1, 2016, Plaintiff Barfield was transferred to Cheshire Correctional Institute.

153. On August 4, 2016, Plaintiff Barfield submitted an inmate request form regarding the results of the blood draws from Northern C.I. regarding his numb feet. The response stated that he was seen on August 5, 2016.

154. Also on August 4, 2016, Plaintiff Barfield filed another inmate request referring back to his requests from Northern C.I. to receive the DAA medications to cure his HCV. The response was that he was seen on August 5, 2016.

155. On August 5, 2016, Plaintiff Barfield during a medical exam requested medication for

HCV and complained of numbness in both feet.

156. On August 10, 2016, Plaintiff Barfield's Clinical Record demonstrates that he asked for HCV medication, but the treating physician noted that Mr. Barfield does not quite grasp the concept of CT DOC infectious disease protocol.

157. On September 19, 2016, Plaintiff Barfield's clinical medical record indicates that he saw a provider for numbness in his feet.

158. On September 26, 2016, Plaintiff Barfield submitted an inmate request form seeking treatment for his HCV. The response from Anita in medical on September 28, 2016 indicated that Plaintiff Barfield was scheduled for Hepatitis A and Hepatitis B vaccines for the end of October, and that "Protocol will be followed to monitor your Hep C."

159. Protocol was never followed for Plaintiff Barfield's HCV.

160. In Cheshire, Plaintiff Barfield complained about his Chronic HCV, and the medical staff there denied him treatment, and refused him access to DAAs.

161. On or about October 2016, Plaintiff Barfield was transferred to MacDougall Correctional Institution where he again initiated attempts to receive DAAs. In response, Plaintiff was met with a variety of refusals.

162. On October 21, 2016, Plaintiff Barfield's medical records indicate that his history is notable for HCV.

163. Plaintiff Barfield has been losing hair on his lower legs for some time, and nurses caring for him have remarked upon this development. Upon information and belief, this loss of hair is

a symptom of HCV and the poor circulation he suffers from.

164. The minimal treatment Plaintiff has received for his HCV has been to draw his blood every six months or so to monitor the progression of his condition.

165. On April 13, 2017, Dr. Omprakash Pillai received a Hepatitis C Virus RNA quantitative assay that showed Mr. Barfield had a viral load of 4,567,000 in his blood plasma as of April 7, 2017. A viral load of more than 800,000 is considered high. Barfield was told that his viral load was normal. Plaintiff Barfield's clinical medical records indicate that the Hepatitis B vaccine was ordered.

166. On April 20, 2017, Dr. Pillai received a Hepatitis C Virus RNA Quantitative assay that showed Mr. Barfield had a viral load of 4,731,000 in his blood plasma as of April 17, 2017. A viral load of more than 800,000 is considered high.

167. On May 11, 2017, Plaintiff Barfield's clinical medical record indicates that Dr. Pillai discussed the HCV protocol with Plaintiff, and Dr. Pillai wrote in the record a strategy of a cat scan and then a Fibroscan.

168. On May 21, 2017, Dr. Pillai received a Hepatitis C Virus RNA Quantitative assay that showed Mr. Barfield had a viral load of 4,313,000 in his blood plasma as of May 12, 2017. A viral load of more than 800,000 is considered high.

169. On June 1, 2017, Plaintiff Barfield's clinical medical record indicates that Dr. Pillai will request a Fibroscan.

170. On October 17, 2017, Plaintiff Barfield received Hepatitis A and Hepatitis B vaccines.

171. On December 11, 2017, Plaintiff Barfield filed an inmate request form seeking to know the status of his liver scan/test. The response, dated December 20, 2017, indicated that Plaintiff's request would be forwarded to the Utilization Review Committee nurse, and it also asked Mr. Barfield to "Please be patient with your health care team."

172. On December 20, 2017, Plaintiff Barfield's clinical medical records contain a notation that the inmate was seen regarding a FibroScan, but one was not yet scheduled.

173. On January 28, 2018, Plaintiff Barfield submitted an inmate request form complaining about the numbess in his feet and the pain in his feet. The response was that he had an appointment on February 2, 2018.

174. On February 11, 2018, Plaintiff Barfield submitted an inmate request form stating that he has been waiting seven months for a liver biopsy at UConn Health and has heard nothing and his overall health seems to be declining. The response by an unknown nurse on February 20, 2018 stated that there is a URC appointment for the second week of March 2018.

175. On February 11, 2018, Plaintiff Barfield submitted a second inmate request form seeking the names and identities of the people on the Hepatitis C Utilization Review Board to determine why he was being denied DAAs. The response, dated March 5, 2018, stated that the Health Services Administrator does not oversee that function and Plaintiff Barfield needed to go elsewhere.

176. On February 21, 2018, Plaintiff Barfield submitted an inmate administrative remedy form and demanded DAAs. The CT DOC response was that Plaintiff Barfield was scheduled for

an appointment on March 12, 2018.

177. Mr. Barfield had a FibroScan liver scan on March 12, 2018. Mr. Barfield's liver scan showed he had a median measurement of 8.7 kilopascals (kPa).

178. Mr. Barfield, then, appears to have an at least 85 % probability of at least significant fibrosis.

179. On April 26, 2018, Plaintiff Barfield submitted an inmate request form seeking to understand the situation regarding his HCV treatment, and inquiring why he has not been prescribed DAAs. The response from an unknown health services administrator, dated May 17, 2018, stated "That decision rests with the prescriber. You can file a health services review if you are dissatisfied with a Rx or Tx matter." That response is not in keeping with the Policy G 2.04.

180. On April 27, 2018, Plaintiff Barfield submitted another inmate request form seeking medical review about his pains and issues, and the response, dated May 17, 2018, stated that appointments were moving slower because CMHC was transitioning to an electronic record keeping system.

181. On May 20, 2018, Plaintiff Barfield filed an inmate request form seeking to understand the results of his liver biopsy from March 2018.

182. Also on May 20, 2018, Plaintiff Barfield filed an inmate request form complaining that Nurse Rose in medical has been deliberately frustrating his efforts to exhaust his remedies by refusing to respond to them or to respond to them in a timely manner and that CMHC was attempting to pawn the treatment costs into CT DOC.

183. On June 14, 2018, Plaintiff Barfield met with Dr. Pillai and a nurse for what they described as an HCV clinic. The two providers informed Plaintiff Barfield that he suffers from F2, moderate fibrosis on the scale of zero-to-four.

184. Dr. Pillai also informed Plaintiff Barfield that he would be considered for treatment, but that he would have to wait until the CT DOC fully transitioned medical care away from CMHC before the request for treatment could be considered. Dr. Pillai also stated to Plaintiff Barfield that the utilization review committee will no longer review requests for treatment, but that CT DOC would have denied Plaintiff treatment anyways in accordance with the standard parameters.

185. Plaintiff Barfield was recently transferred from McDougall-Walker to Corrigan again in mid-June 2018.

186. On or about June 30, 2018, Plaintiff Barfield met with a nurse practitioner at Corrigan. Plaintiff Barfield asked for DAAs again, and he was told that the medical staff at that institution does not provide them.

187. The CT DOC still has not completed its HCV protocol on Mr. Barfield.

188. The CT DOC's deliberate indifference to Mr. Barfield's serious medical needs caused his condition has been getting worse ever since.

189. He will continue to suffer, and will continue to suffer with HCV, unless he receives the DAA drug treatment.

Class Action Allegations

190. Pursuant to Federal Rule of Civil Procedure 23(b)(2), Plaintiffs seek to certify a class of all current and future prisoners in CT DOC custody who have been diagnosed, or will be diagnosed, with chronic HCV (the "Plaintiff Class").

191. Upon information and belief, Defendant can identify many more such similarly situated class members, through medical and other records in Defendant's possession.

192. Plaintiff Barfield seeks injunctive relief to force the CT DOC to determine the class members. Since CT DOC does not have an accurate census of all people infected with HCV in its custody, CT DOC should be made to determine all members of the class, since the action cannot properly be adjudicated without such a census.

193. The requirements of Rule 23(a) are satisfied:

a. *Numerosity.* The class is so numerous that joinder of all members is impracticable. While CT DOC has no census of HCV in its inmate population, Plaintiff Barfield can proffer reasonable estimates demonstrating joinder of all members of the class is impracticable. As of July 1, 2018, there were 13,400 inmates in CT DOC custody. Paragraph 34 supra suggests that between 16 and 41 percent of prisoners will have HCV, which means that between 2,144 and 5,494 people in CT DOC custody. Estimates based the 2015 CT DOC study (see ¶46, supra) at New Haven where 93 prisoners may have HCV, of Dr. Johnny Wright's testimony (see ¶48, supra) there may be 660 prisoners at Osborn, and of Dr. Wu's testimony that CMHC treated at least 20 people with DAAs (see ¶51, supra), there are more people with HCV than can be properly joined.

b. *Commonality.* There are questions of law or fact common to the class, including but not

limited to: 1) whether HCV is a serious medical need; 2) whether Defendant's policy and practice of not providing HCV treatment constitutes deliberate indifference to serious medical needs in violation of the Eight Amendment; 3) whether Defendant has knowingly failed to provide the necessary staging of HCV patients in accordance with the prevailing standard of care, including the pretreatment testing to determine the severity of the disease; 4) whether Defendant has knowingly employed policies and practices that unjustifiably delay or deny treatment for HCV; 5) whether Defendant has permitted cost considerations to improperly interfere with the treatment of HCV; 6) whether HCV is a disability under the ADA; 7) whether medical services in prison are a program or service under the ADA; and 8) whether Defendant has discriminated against CT DOC prisoners with HCV on the basis of their disability by categorically denying them medical treatment, while providing treatment for other diseases and conditions such as HIV.

c. *Typicality.* The claims or defenses of the class representative are typical of the claims or defenses of the class. The class representative has been diagnosed with chronic HCV but has been refused treatment, and suffer from the same kind of complications and substantial risk of serious harm that the class members suffer from.

d. *Adequacy.* The class representative and class counsel will fairly and adequately protect the interests of the class. The class representative is committed to obtaining declaratory and injunctive relief that will benefit himself as well as the class by ending Defendant's

unconstitutional policy and practice. Plaintiff Barfield interests are consistent with and not antagonistic to the interests of the class. The class representative has a strong personal interest in the outcome of this case and have no conflicts with class members. They are represented by experienced counsel who specialize in civil rights and class action litigation on behalf of prisoners.

194. The requirements of Rule 23(b)(2) are satisfied, as the party opposing the class has acted and refused to act on grounds generally applicable to the class so that final declaratory and injunctive relief would be appropriate to the class as a whole. Injunctive relief will end the policy and practice for all class members, allowing them to receive proper medical evaluation and treatment for HCV.

CAUSES OF ACTION

COUNT I Eighth Amendment to the U.S. Constitution via 42 U.S.C. § 1983

195. Defendant and its policymakers know about and enforce the policies and practices described herein. Defendant and its policymakers know of Plaintiffs' and the Plaintiff Class's serious medical needs, yet Defendant has intentionally failed and refused to provide treatment that will address those serious medical needs, knowing that those actions have resulted, and will continue to result, in Plaintiff and the Plaintiff Class's continued suffering and exposure to liver failure and its symptoms, liver cancer, and death.

196. Defendant has caused the wanton infliction of pain upon CT DOC prisoners with HCV, and has exhibited deliberate indifference to the serious medical needs of Plaintiffs and the Plaintiff Class, in violation of the Eighth Amendment.

197. Defendant knows, and has known, of the substantial risk of serious harm, and actual harms, faced by CT DOC prisoners with chronic HCV. Yet Defendant has disregarded, and continues to disregard, those risks and harms by failing to provide the very care and medication that would alleviate those risks and harms. Defendant has been deliberately indifferent to the substantial risk of serious harm to CT DOC prisoners with chronic HCV.

198. By denying Plaintiff and the Plaintiff Class their medically needed HCV treatment, Defendant has imposed punishment far in excess of that authorized by law, contrary to the Eighth Amendment.

199. Defendant's denial of Plaintiff and the Plaintiff Class's medically necessary HCV treatment violates all standards of decency, contrary to the Eighth Amendment.

200. Defendant's actions with respect to Plaintiffs and the Plaintiff Class amount to grossly inadequate care.

201. Defendant's actions with respect to Plaintiff and the Plaintiff Class is medical care so cursory as to amount to no medical care at all.

202. As a direct and proximate cause of this pattern, practice, policy, and deliberate indifference, Plaintiff and the Plaintiff Class have suffered, and continue to suffer from harm and violation of their Eighth Amendment rights. These harms will continue unless enjoined by

this Court.

COUNT II Americans with Disabilities Act, 42 U.S.C. § 12131, et seq.

203. This count is brought under Title II of the Americans with Disabilities Act (ADA), 42 U.S.C. § 12101, et seq. and 42. U.S.C. § 12131 – 12134, and its implementing regulations.

204. Defendant CT DOC is a "public entity" within the meaning of 42 U.S.C. § 12131(1) and 28 C.F.R. § 35.104.

205. Plaintiff and the Plaintiff Class have chronic HCV, which is a physiological disorder or condition that affects one or more body systems, including but not limited to the digestive, gastrointestinal, immune, circulatory, cardiovascular, and hemic systems, and is therefore a physical impairment. 42 U.S.C. § 12102(1) & (2); 28 C.F.R. § 35.108(a) & (b). This physical impairment substantially limits one or more major life activity, including but not limited to eating, walking, bending, lifting, concentrating, thinking, and communicating; the operation of major bodily functions such as digestive, gastrointestinal, immune, circulatory, cardiovascular, and hemic systems; and the operation of the liver. 42 U.S.C. § 12102(2); 28 C.F.R. § 35.108(c).

206. Plaintiff and the Plaintiff Class have a record of having an impairment that substantially limits one or more major life activity, as they have a history of such an impairment. 42 U.S.C. § 12102(1)(B); 28 C.F.R. § 35.108(a)(1)(ii) & (e).

207. Plaintiff and the Plaintiff Class are regarded by CT DOC as has having an impairment that substantially limits one or more major life activity, as CT DOC perceives them as having such an impairment. 42 U.S.C. § 12102(1)(C) & (3); 28 C.F.R. § 35.108(a)(1)(iii) & (f). Defendant CT DOC

has subjected them to a prohibited action because of an actual or perceived physical impairment.

208. Plaintiff and the Plaintiff Class are qualified individuals with a disability because they meet the essential eligibility requirements for the receipt of services or the participation in programs or activities provided by CT DOC, including but not limited to medical services. 42 U.S.C. § 12131(2); 28 C.F.R. § 35.104.

209. By withholding medical treatment from those with HCV, but not withholding medical treatment from those with other disabilities or those who are not disabled, Defendant CT DOC excludes Plaintiff and the Plaintiff Class from participation in, and denies them the benefits of CT DOC services, programs, and activities (such as medical services), by reason of their disability. 42 U.S.C. § 12132; 28 C.F.R. § 35.130(a).

210. By withholding medical treatment from those with HCV, but not withholding medical treatment from those with other disabilities or those who are not disabled, Defendant CT DOC subjects Plaintiff and the Plaintiff Class to discrimination. 42 U.S.C. § 12132; 28 C.F.R. § 35.130(a).

211. Defendant CT DOC fails to provide Plaintiffs and the Plaintiff Class with equal access and enjoyment of effective medical services. 28 C.F.R. § 35.130(b)(1).

212. Defendant CT DOC utilizes criteria or methods of administration that have the effect of subjecting Plaintiff and the Plaintiff Class to discrimination and that defeat or substantially impair accomplishment of the objectives of medical treatment for HCV. 28 C.F.R. §

35.130(b)(3).

213. Defendant has known about the violations noted herein but has failed to correct them, thereby exhibiting deliberate indifference to the rights of Plaintiff and the Plaintiff Class.

214. As a direct and proximate cause of these actions and omissions, Plaintiff and the Plaintiff Class have suffered and continue to suffer from harm and violation of their ADA rights. These harms will continue unless enjoined by this Court.

COUNT III Rehabilitation Act, 29 U.S.C. §§ 791 – 794a

215. This count is brought under Section 504 of the Rehabilitation Act (RA), 29 U.S.C. § 701, et seq. and 29 U.S.C. §§ 791 – 794, et seq., and it implementing regulations.

216. Defendant CT DOC is a program or activity receiving federal financial assistance. 29 U.S.C. § 794.

217. Defendant CT DOC excludes Plaintiff and the Plaintiff Class—all qualified individuals with disabilities—from participation in, and denies those individuals the benefits of programs or activities, solely by reason of the individuals' disabilities. 29 U.S.C. § 794(a); 28 C.F.R. § 42.503(a).

218. Defendant CT DOC subjects Plaintiff and the Plaintiff Class—all qualified individuals with disabilities—to discrimination. 29 U.S.C. § 794(a).

219. Defendant CT DOC denies Plaintiff and the Plaintiff Class—all qualified handicapped persons—the opportunity accorded others to participate in programs or activities. 28 C.F.R. §

42.503(b)(1).

220. Defendant CT DOC utilizes criteria or methods of administration that either purposely or in effect discriminate on the basis of handicap, and defeat or substantially impair accomplishment of the objectives of Defendant's programs or activities with respect to handicapped persons. 28 C.F.R. § 42.503(b)(3).

221. Defendant has known about the violations noted herein but has failed to correct them, thereby exhibiting deliberate indifference to the rights of Plaintiffs and the Plaintiff Class.

222. As a direct and proximate cause of this exclusion, Plaintiffs and the Plaintiff Class have suffered and continue to suffer from harm and violation of their RA rights. These harms will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand the following relief:

A. An order certifying this case as a class action, with the class defined under Rule 23(b)(2) as all current and future prisoners in CT DOC custody who have been, or will be, diagnosed with chronic HCV.

B. A judgment declaring that the Defendant has exhibited deliberate indifference to the serious medical needs of Plaintiffs and the Plaintiff Class and have violated Plaintiffs and the Plaintiff Class's right to be free from Cruel and Unusual Punishment, as secured by the Eighth Amendment to the U.S. Constitution;

C. A judgment declaring that Defendant has violated the rights of Plaintiffs and the Plaintiff Class under the Americans with Disabilities Act and the Rehabilitation Act;

D. A preliminary and permanent injunction ordering Defendant to, among other things, 1) immediately identify all people in CT DOC's custody who have HCV; 2) immediately provide direct-acting antiviral medications to Plaintiff and Plaintiff Class, and 3) develop and adhere to a plan to provide direct-acting antiviral medications to all CT DOC prisoners with chronic HCV, consistent with the standard of care;

E. A preliminary and permanent injunction requiring Defendant to, among other things, 1) properly screen, evaluate, monitor, and stage CT DOC prisoners with HCV (including screening for liver cancer where appropriate); 2) provide routine opt-out testing for HCV to all CT DOC prisoners; 3) develop and adhere to a policy allowing CT DOC prisoners with chronic HCV to obtain liver transplants if needed; and 4) modify the exclusions from HCV treatment based on

life expectancy and time remaining on sentence to reflect an appropriate individual assessment;

F. An order enjoining Defendant from taking any action to interfere with Plaintiffs' right to maintain this action, or from retaliating in any way against Plaintiffs for bringing this action;

G. An order retaining jurisdiction over this matter to ensure that the terms of any injunction are fully implemented;

H. An award of Plaintiffs' attorneys' fees, costs, and litigation expenses under 42 U.S.C. § 12205, 29 U.S.C. § 794a, and 42 U.S.C. § 1988; and

I. Such other relief as the Court may deem equitable and just under the circumstances.

Dated July 19, 2018

Respectfully submitted,

Attorney for Plaintiff

PLAINTIFF,
ROBERT BARFIELD

/s/ Kenneth J. Krayeske

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UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

ROBERT BARFIELD Plaintiff	CIVIL ACTION NO.:
V.	
SCOTT SEMPLE Defendant, in his official capacity As Commissioner of the Connecticut Department of Correction	JULY 18, 2018

DECLARATION OF ROBERT BARFIELD

I, Robert Barfield, pursuant to 28 U.S.C. § 1746, make this Unsworn Declaration Under Penalty of Perjury, and declare that the statements made below are true, and state:

My name is Robert Barfield. I have reviewed the Verified Complaint set forth above and I find the facts contained therein which pertain to me to be true and accurate to the best of my knowledge and belief.

I understand that a false statement in this declaration will subject me to penalties for perjury.

I declare under penalty of perjury that the foregoing is true and correct.

Date: 7/18/18

Robert Barfield

EXHIBIT 1

UCONN HEALTH
CORRECTIONAL MANAGED HEALTH CARE
POLICY AND PROCEDURE MANUAL
FOR USE WITHIN THE CONNECTICUT DEPARTMENT OF CORRECTION

NUMBER: G 2.04 **Page 1 of 9**

HEPATITIS C: MANAGEMENT & TREATMENT

Effective Date: 12/10/02

POLICY:

UConn Health, Correctional Managed Health Care (**CMHC**) shall create a special board of Infectious Disease (**ID**) experts who shall evaluate all requests for treatment of Hepatitis C infection in inmates in Connecticut Department of Correction (**CDOC**) facilities.

Hepatitis C assessment and treatment management is complex and shall be under the direct supervision of a board-certified or board eligible infectious disease specialist (**IDS**) employed by CMHC with experience in the management of this disease.

Evaluation of candidates for treatment of Hepatitis C, as well as implementation of therapy, shall be performed by the ID specialists (IDS) that currently manage HIV and other infectious diseases within CDOC facilities.

A Hepatitis C Utilization Review Board (**HepCURB**) shall review all requests for treatment. This review board shall be chaired by the CMHC Director of Medical Services, and shall consist of board-certified or eligible specialists in infectious diseases who are conversant with management of hepatitis C and with correctional health care concerns and practice. In general, the HepCURB will follow the specific recommendations of American Association for the Study of Liver disease (AASLD), Infectious Diseases Society of America (IDSA), and the International Antiviral Society-USA (ISA-USA) regarding Hepatitis C management and treatment currently in force at the time of the inmate review.

Although they will not directly provide specific anti-viral drugs for Hepatitis C, CMHC Primary Care Physicians (PCPs) will provide appropriate supportive care to inmates with Hepatitis C, including management of their liver disease and its complications.

PROCEDURE:

1. Hepatitis C Evaluation/Referral by the CMHC Primary-Care Physician (PCP)

When an inmate has been found to have a positive anti-HCV study, and there are clinical indication for treatment, the CMHC PCP shall conduct an initial evaluation using the **Form HR 007A, Initial Evaluation of Hepatitis C Infection by Primary Care Provider**.

Unless the information is already available, the PCP will order appropriate testing of the inmate's HIV status and risk of future infection by Hepatitis A and B, and shall obtain a complete blood count (CBC) and liver function tests (LFTs) to assess hepatic inflammation. (These may be omitted if recent values drawn within the CDOC are available.) Additional

diagnostic studies to assess the appropriateness of therapy for Hepatitis C infection in an inmate shall only be ordered by the IDS.

The PCP shall inform the inmate of the diagnosis, provide the inmate with the approved CMHC Hepatitis C informational packet, and document the discussion in the inmate's health record on the **Form HR 401, Clinical Record.** For those inmates lacking protective antibodies against Hepatitis A and B, the PCP will offer active immunization.

The PCP shall recommend follow-up in not less than 6 months, either within the CDOC or the community, with clinical re-evaluation and repeat measurement of complete blood count and liver function tests. If the inmate is still incarcerated at the time of repeat testing, the PCP shall discuss the new findings with the inmate, and at that time shall either refer the inmate to the facility IDS for consideration of specific therapy, **or** shall counsel the inmate to continue monitoring of the disease either within the CDOC or in the community. If the inmate is referred to the IDS and has not been tested for HIV infection, the PCP will refer the inmate HIV testing. The follow-up visit shall be documented on **Form HR 007B, Follow-Up Evaluation of Hepatitis C Infection by Primary Care Provider.** This form is also to be used as the referral form if the PCP refers the inmate to the IDS.

The PCP shall withhold any referral to the IDS until court sessions have concluded and the inmate has been sentenced. The PCP shall also withhold any referral to the IDS until 2 CBCs and 2 LFTs, spaced at least 6 months apart and both performed within the CDOC, are available and are consistent with active liver disease.

It is expected that the CMHC PCP will continue to monitor the inmate regarding related health issues, such as the management of hepatic decompensation or intensive fluid retention, should these occur.

The PCP shall remain responsible for continuing care of the inmate, including the inmate's liver disease, regardless of whether anti-viral therapy is given.

2. Hepatitis C Assessment by the On-Site ID Specialist (IDS)

Assessment of Hepatitis C-infected inmates by the IDS shall include the following:

- An inmate history that includes the following: drug and alcohol abuse history; suspected acute hepatitis episodes; hospitalizations related to hepatic disease or decompensation; any previous assessments or treatment for Hepatitis C; neuropsychiatric history including severe depression or suicidal ideation or attempts; past autoimmune disease; known immunosuppression, including HIV infection or solid-organ transplant; current pregnancy; and any history of chronic disease (e.g. diabetes mellitus, cardiomyopathy) that requires special management as well as an assessment of how well this chronic disease is being controlled.

- A comprehensive evaluation of the inmate's hepatic status, including signs of decompensation (ascites, wasting, persistent jaundice, variceal hemorrhage, hepatic encephalopathy); or a history of such decompensation, stigmata of hepatic disease.

- Review of laboratory tests already performed, as well as review of any available community records.

If following this initial evaluation, the inmate appears to be a reasonable candidate for treatment, the IDS will counsel the inmate about the potential benefits and risks of treatment, and about CMHC's expectations about treatment adherence.

If the inmate wishes to proceed further, the IDS/designee shall ask the inmate to sign **Form HR 307, Consent and Compliance Agreement for Hepatitis C Treatment,** agreeing to comply with recommended treatment, including compliance with transient elastography testing (FibroScan), liver biopsy (if required), drug administration and laboratory testing, and stating an understanding that noncompliance with treatment will mean that therapy will stop and will not be offered again in the future.

This signed document shall be kept in the ID section of the inmate's Health Record (HR); refusal to agree to the terms of the **Form HR 307, Consent and Compliance Agreement for Hepatitis C Treatment** shall make the inmate ineligible for treatment.

If the inmate will not agree to the terms of the Consent and Compliance Agreement, the IDS shall ask the inmate to sign **Form HR 301 Refusal of Health Services** indicating her/his unwillingness to comply with the Agreement, and shall advise that no further evaluation for anti-viral treatment will be done, and shall return the inmate to the care of the PCP.

The IDS shall document the discussion in the inmate's Health Record on the **Form HR 401, Clinical Record.**

If the inmate signs the Consent and Compliance Agreement Form, agreeing to its terms, the IDS shall then use the Patient Safety System (PSS) to order the following laboratory studies using **Hepatitis C Diagnostic Orders:**

1) Liver function studies
2) CBC with differential
3) Chronic Hepatitis Profile (If not already done)
4) HAV IgG (If not already done)
5) Hepatitis C Genotype
6) HCV-RNA (quant. level by PCR)
7) Alpha-fetoprotein
8) ANA
9) TSH and free T4
10) Anti-mitochondrial Ab
11) Iron studies (Fe/TIBC/Transferrin)
12) HIV-Ab (If inmate's HIV Status unknown)
13) T4 count and HIV-1 viral load (If patient know to be HIV positive & if recent values not available)
14) PT / PTT
15) BUN / Creatinine
16) RPR

The IDS may omit any of these tests if recent values are available.

Prior to ordering an HIV-Ab study, standard pre-test counseling will be provided.

The IDS/designee will then assist the inmate in completing Form HR 401D, Initial HCV Functional Status Report, and will place the completed form in the ID section of the inmate HR. In addition, the IDS shall order a mental health evaluation, to assess the psychological risks of therapy:

- For inmates classified Mental Health 3, 4, or 5, a psychiatrist shall make an assessment of the inmate's present psychological status and current stability, advising the IDS regarding the risk of decompensation as a result of anti-Hepatitis C therapy. The psychiatrist shall summarize and document this evaluation on the **Form HR 401, Clinical Record**, the encounter to be identified as "MH Evaluation for HCV Treatment"
- For inmates classified Mental Health 1 or 2, a psychiatrist or psychologist will complete the mental health evaluation and document the findings, as outlined above.
- The IDS may refer a Mental Health 1 or 2 inmate directly to a psychiatrist, bypassing the above step, in selected cases.

If the results of the mental health assessment do not indicate any increased psychological risk, the IDS may then initiate a referral to the Hepatitis C Utilization Review Board.

The IDS/designee shall inform the inmate regarding Hepatitis C issues as the assessment progresses.

Once the laboratory studies are completed and the IDS discussed treatment options with the inmate, if the inmate wishes to pursue treatment, the IDS shall placed a request to CMHC UR to schedule transient elastography (FibroScan).

If at any point the IDS believes that treatment is inappropriate, but the inmate insists on therapy despite the advice of the IDS, the IDS does not need to perform the entire evaluation described above, but shall forward the inmate's request to the HepCURB, explaining why he or she does not believe that treatment is appropriate, and including whatever testing has been completed.

3. Referral to the Hepatitis C Utilization Review Board (HepCURB)

Once the above assessment is complete, the IDS shall discuss treatment options with the inmate. If the IDS recommends treatment and the inmate wishes to pursue this, the IDS shall make a formal referral to the HepCURB by entering the request in the UR application.

At the same time, the following documents should be faxed to the Central Office Utilization Review (UR) Unit, utilizing **Form HR 924C, HepCURB Referral Fax Cover Sheet and Checklist.**

- **Form HR 007A, Initial Evaluation of Hepatitis C Infection by Primary Care Provider**

- **Form HR 007B, Follow-Up Evaluation of Hepatitis C Infection by Primary Care Provider**
- **Form HR 307, Consent and Compliance Agreement for Hepatitis C Treatment**
- **Form HR 401C, IDS Hepatitis C Evaluation**
- **Form HR 401D, Initial HCV Functional Status Report**
- **Form HR 504, Mental Health Screening**
- Psychiatrist's written opinion (if obtained)
- IDS clinical documentation record
- Written report of any prior liver biopsy or transient elastography (FibroScan)

As part of the referral process, the IDS/designee will inquire about any private health insurance. This will be documented in the inmate HR and included on **Form HR 401C**, **IDS Hepatitis C Evaluation**, including the name of the carrier and the policy number. The decision to treat or not treat shall be made without reference to third-party coverage, but if treatment is approved, the UCHC pharmacy will attempt to recover some or part of its costs through third-party payers.

4. <u>Review by HepCURB</u>

The HepCURB shall review the submitted materials and make a decision regarding further assessment and/or treatment.

Hepatitis C is a chronic disease that requires ongoing infection for a number of years before the development of end-stage liver disease and cirrhosis. The duration of therapy is also substantial (up to 12 months) and complex. The HepCURB will not generally approve Hepatitis C therapy unless there is a reasonable likelihood that the inmate will remain under CDOC supervision for the entire duration of treatment period.
The HepCURB shall first determine if a liver biopsy should be performed prior to making a decision regarding the initiation of specific therapy for Hepatitis C where there is technical limitation of the transient elastography test (FibroScan)

In many circumstances the HepCURB may waive the requirement for a liver biopsy prior to the initiation of Hepatitis C therapy.

If a liver biopsy is judged to be necessary, the HepCURB will notify the IDS through comments and internal messaging within the UR application. The IDS will inform the inmate that this is necessary and document this discussion in the inmate's HR on the **Form HR 401, Clinical Record** located in the ID section of the HR.

CMHC Central Office UR Unit shall schedule an appointment at UCHC for this purpose.

If the liver biopsy is to be performed within the Interventional Radiology Department at John Dempsey Hospital, the inmate shall have a CBC, platelet count, PT, and PTT performed no more than 14 days prior to the date of the biopsy, and the results shall be available to the radiologist.

CMHC Central Office UR Unit shall notify the designated CMHC nurse at the CDOC facility of the timing of this.

Once the HepCURB has either decided to forego the liver biopsy, or has obtained the pathology report regarding the liver biopsy in question, the HepCURB shall decide on treatment initiation.

To reduce the risk of re-infection following treatment, the HepCURB must have a reasonable expectation that the inmate will not engage in alcohol or drug abuse following release from the CDOC. For this reason, the HepCURB may insist that an inmate participate in the CDOC Addictions Program either before definitive therapy for Hepatitis C is initiated or simultaneous with such therapy.

Prioritization for treatment is based on:

- Advanced hepatic fibrosis/cirrhosis Metavir stage F4
- Liver transplant patients
- HIV co-infection
- Comorbid medical conditions associated with HCV, e.g. crypglobulinemia and certain types of lymphomas; Hepatitis C related renal disease
- Continuity of care for newly incarcerated inmates who were being treated at the time of incarceration.

Treatment approvals will specify the most optimal therapy available at the time of treatment approval

5. <u>Treatment Selection and Initiation Process</u>

Once the HepCURB approves an inmate for Hepatitis C treatment, it shall notify the appropriate IDS/designee through comments and internal messaging within the UR application. The IDS shall notify the inmate that treatment has been approved, and shall document this discussion on **Form HR 401, Clinical Record,** in the ID Clinic Section of the HR, and obtain the inmate's signature confirming the discussion on the URC computer-generated report. The IDS will also obtain the inmate's signature on **Form 305 Consent for Treatment.**

All treatments shall start on a standardized day of week and month in order to reduce errors by standardizing practice, to minimize side-effects interfering with inmate employment and programming during the week, and to 'batch' viral load testing to allow faster results. All treatment will start on the 3rd Friday of each month.

The URC shall regularly furnish the CMHC Pharmacy Director and the CMHC Operations Administrator for Quality Assurance a list of inmates who have been approved for treatment.

The CMHC Pharmacy Director shall coordinate the various steps in acquiring the medications, including any registration procedures with the pharmaceutical company involved.

Inmates on Hepatitis C therapy will not be allowed to transfer to certain CDOC facilities while receiving Hepatitis C therapy, or may be required to transfer from their current facility to one with greater clinical capability. Halfway houses shall not be considered suitable sites for administering Hepatitis C therapy. Therefore, inmates approved for therapy shall be placed on a "medical hold." The IDS/designee will complete **Form HR 106, Health-Related**

Transfer Hold, place it in the HR (uppermost left hand-side). The ID nurse will notify the CDOC Counselor Supervisor and request that the patient be kept at the approved facility as long as treatment continues (and if necessary, be moved to that approved facility before the onset of treatment.)

When the medication is available, the IDS/designee will assist the inmate in completing **Form HR 401E, HCV Functional Follow-up Status Report,** and will place the completed form in the ID section of the inmate HR.

6. Patient Management During Hepatitis C Therapy

Side effects may require modification of an inmate's medication dosage or even discontinuation of therapy.
HCV viral load need to be drawn prior to treatment, at 4 weeks in to treatmentand at the end of treatment, as well as either 12 or 24 weeks after treatment completion for those with undetectable end of treatment viral loads.

Relevant measurements including lab test and drug dosage will be documented on **Form HR 107, Hepatitis C Treatment Flow Sheet,** located in the ID Section of the HR. Medication administration shall be documented on the inmate's monthly Medication Administration Record (MAR), or on an MAR designed specifically for Hepatitis C medications.

7. Patient Follow-Up upon Completion Of Therapy

The IDS/designee shall also inform the CDOC Counselor Supervisor, who shall notify population management to release the medical hold.

The IDS shall also arrange to have another HCV viral load drawn three (3) months following completion of the therapy. The results of this assay will determine if the inmate has successfully responded to therapy (i.e. whether they can be classified as a long-term responder) or has failed therapy.

The managing IDS shall document these results in the inmate's HR and also convey the results directly to both the inmate and the HepCURB.

8. Treatment Denials

If the HepCURB denies a request for Hepatitis C therapy, the official report generated by the HepCURB will outline the specific reasons why the inmate was denied the therapy. Copies of the HepCURB decision will be sent to the IDS who initiated the request, who will then personally communicate the decision to the inmate involved, and document this notification in the inmate's HR. The inmate must also sign to acknowledge that he/she has been notified.

An IDS who disagrees with the HepCURB decision may file an appeal for reconsideration, and may appear at a scheduled HepCURB meeting to discuss the case in person if so desired.

If the HepCURB does not authorize treatment for Hepatitis C, the inmate's hepatitis care and monitoring shall again become the responsibility of the PCP, rather than the IDS. The PCP may make another referral to the IDS if a change in the inmate's condition justifies it.

If the HepCURB denies care for patients with advanced hepatitis, such patients shall be continually be monitored by the IDS and PCP

Treatment denial due to release date, such inmate shall be referred to the facility based discharge planner for a timely referral to an appropriate community based health care provider.

9. Protocol for Continuation of Therapy Begun Before Incarceration

As soon as the health services staff becomes aware that a newly admitted inmate has been receiving treatment for Hepatitis C in the community at the time of incarceration, the staff should attempt to have the inmate's medication brought in from home at once. By the morning after admission, the facility ID nurse must contact the patient's pharmacy, ascertaining whether the patient has faithfully been picking up the medication and documenting the date of most recent medication pickup, and the patient's physician, ascertaining whether the patient has been appearing for follow-up visits as ordered, and documenting the date of the most recent follow up. The staff must also inventory whatever medication was brought in by the patient, and ascertain whether and how and for how long the patient's friends or family would be able to continue supplying the medications. The facility staff must put this information into an email addressed to the facility IDS, to the CMHC Director of Medical Services, and the CMHC Pharmacy Director. Any patient who can be shown to have been off the treatment schedule for more than 14 days will be deemed to have been off treatment, and will not be continued on treatment while in DOC unless and until that inmate later meets CMHC criteria for HepC treatment.

The inmate shall be referred promptly to the IDS, who shall review the inmate's history and obtain health records from the outside physician. Such health records shall include the same type of information required when initiation of treatment is contemplated within the CDOC, as well as the dosage, treatment side effects, and results (if any) of Hepatitis C PCR assay done while on treatment.

This information shall be forwarded to the HepCURB for consideration at their next meeting. Until that meeting, the inmate shall generally be continued on the same therapy regimen as given prior to incarceration.

To receive temporary approval for treatment, the IDS should contact the CMHC Director of Medical Services by phone to discuss the case, and should submit a non-formulary exception request form. Until the medication is obtained through the CMHC pharmacy, the inmate's own medication brought from home (if available) may be administered under the direction of the IDS, in compliance with **CMHC Policy D 2.16, Inmate Personal Medication: Identification.**

Readmission:

When an inmate is admitted and identifies completion of previous Hepatitis C treatment, the inmate should be referred to the ID Case Manager for scheduling with the IDS to have an HCV RNA/REFLEXHCV GT drawn to determine if the inmate is reinfected.

REFERENCES:

An Update on Treatment of Genotypy 1 Chronic Hepatitis C Virus Infection: 2011 Practice Guideline by the American Association for the Study of Liver Diseases. Ghany et al. Hepatology, vol 51, No 4, pp 1433 ff, October 2011

Recommendations for Testing, Managing, and Treating Hepatitis C.American Association for the Study of Liver Diseases and the Infectious Diseases Society of America . http://www.hcvguidelines.org/node/141 (2015) Updated: February 24, 2016. Changes made: April 25, 2016.

Approved: UConn Health	**Date:**
Title: CMHC Executive Director, Robert Trestman MD PhD	_____
Title: CMHC Director of Medical Services, Johnny Wu MD	_____
Title: CDOC Director Health Services, Kathleen Maurer MD	_____

Revision Dates: 05/30/05, 12.21.10; 02/28/11; 02/01/12; 07/31/13; 06/30/15; 06/30/16