UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

CHARLES GRAHAM aka CHARLES STEVENSON and RUSSELL L. DAVIS, on behalf of themselves and all others similarly situated,	)	
Plaintiffs,	)	
v.	)	**No. _____**
TONY C. PARKER, Commissioner, Tennessee Department of Corrections; DR. MARINA CADRECHE, Assistant Commissioner of Rehabilitative Services, Tennessee Department of Corrections; and DR. KENNETH WILLIAMS, Medical Director, Tennessee Department of Corrections, in their official capacities,	)	
Defendants.	)	

CLASS ACTION COMPLAINT

Plaintiffs Charles Graham aka Charles Stevenson and Russell L. Davis bring this complaint against Defendants Tony C. Parker, Dr. Marina Cadreche, and Dr. Kenneth Williams in their official capacities as Commissioner, Assistant Commissioner, and Medical Director, respectively, of the Tennessee Department of Corrections, for declaratory and injunctive relief on behalf of themselves and all others similarly situated, and would allege as follows:

INTRODUCTION

1. Plaintiffs bring this action under 42 U.S.C. § 1983 to uphold the Eighth and Fourteenth Amendments of the United States Constitution. Plaintiffs and members of the putative class are inmates in the custody of the Tennessee Department of Corrections ("Department") who are infected with the Hepatitis C virus ("HCV"). Hepatitis C is a viral

infection that causes liver inflammation, leading to a host of medical complications, and ultimately death. Despite knowledge of Plaintiffs' HCV infection and the fatal effects of the disease, the Department has consistently and systematically denied them treatment. The Department's HCV policies, written and unwritten, and its implementation of those policies constitute deliberate indifference to the suffering of Plaintiffs and the putative Class and violates their right to be free of cruel and unusual punishments as guaranteed by the U.S. Constitution.

JURISDICTION AND VENUE

2. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1343(a).

3. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(b) because Defendants have their official residence in this district.

PARTIES

4. Plaintiff Russell L. Davis is an inmate in the Department's Northwest Correctional Complex, 960 Negro Graveyard Road/State Route 212, Tiptonville, Tennessee 38079. He was diagnosed with HCV in 2009 while an inmate in another Department facility. Since that time, Defendants have refused to provide Mr. Davis with any form of treatment for his illness, despite his repeated requests for medical care.

5. Plaintiff Charles Graham aka Charles Stevenson[1] is an inmate in the Department's Hardeman County Correctional Facility, 2520 Union Springs Rd, Whiteville, Tennessee 38075. He was diagnosed with HCV in 2005 while an inmate in another Department facility. Since that time, Defendants have refused to provide Mr. Stevenson with any form of treatment for his illness, despite his repeated requests for medical care.

6. Defendant Tony C. Parker is the Department's Commissioner. In that capacity,

[1] Plaintiff's legal name is Charles Graham. However, his name appears as Charles Stevenson in most of the Department's internal documentation. For ease of reference, Plaintiff will refer to himself as "Charles Stevenson" in the remainder of the Complaint.

he has authority over all aspects of the management and governance of all Tennessee penitentiaries, including the provision of constitutionally adequate medical, mental health, and dental care for all prisoners committed to the custody of the Department. The Department's primary business location is 320 Sixth Avenue North, Nashville, Tennessee 37243, and Defendant Parker serves in his official capacity at this location.

7. Dr. Marina Cadreche is the Department's Assistant Commissioner of Rehabilitative Services. In that capacity, she has authority over all aspects of health care for inmates in the Department's custody. The Department's primary business location is 320 Sixth Avenue North, Nashville, Tennessee 37243, and Defendant Cadreche serves in her official capacity at this location.

8. Dr. Kenneth Williams is the Department's Medical Director. In that capacity, he has authority over various aspects of medical care for inmates in the Department's custody. Specifically Dr. Williams has direct control over the TDOC Advisory Committee on HIV and Viral Hepatitis Prevention and Treatment ("TACHH"), which works to establish and update Department policies on HCV treatment in Tennessee penitentiaries. The Department's primary business location is 320 Sixth Avenue North, Nashville, Tennessee 37243, and Defendant Williams serves in his official capacity at this location.

9. In their official and related capacities, Defendants act under color of state law. *See* Tenn. Code Ann. § 4-6-101 *et seq*.

FACTS

10. Defendants commit themselves to offering quality health care to inmates that meets "the community standard of care." They claim to do so through "performance-based monitoring," which involves "extremely detailed and exhaustive reviews of offender treatment

and health records." *See* Offender Health Care, Tennessee Department of Corrections, *available at* https://www.tn.gov/correction/topic/The Department-rehabilitation-offender-health-care#sthash.4lktEXst.STBmeP4D.dpuf (last reviewed July 13, 2016).

11. In reality, Defendants ignore the medical needs of Plaintiffs and Class members in order to save costs. Defendants' written policies for HCV diagnosis, assessment and treatment utilize outdated standards of care and normalize the practice of refusing treatment for unjust and medically unsound reasons. Defendants' unwritten policies, customs, and actual practices in diagnosing and treating HCV fall short even of the outdated and unreasonable written protocols.

12. Prior to 2013, HCV infection was treated with interferons, which are proteins that work on the immune system. Interferon treatment lasts 48 weeks, has a low rate of effectiveness, and causes debilitating side effects similar to chemotherapy treatment.

13. The medical community has achieved amazing advances in the treatment of HCV infection in the last few years. In late 2013, the U.S. Food and Drug Administration approved the use of direct-acting anti-viral drugs ("DAAs") for the treatment of HCV infection. DAA treatment lasts 12 weeks, has a high rate of effectiveness in curing HCV infection without the harsh side effects of interferon treatment, and is effective at any stage of the disease.

14. In order to guide medical professionals in the rapidly developing world of HCV treatment, the American Association for the Study of Liver Disease ("AASLD") and the Infectious Disease Society of America ("IDSA"), the two relevant professional medical associations concerned with the study of HCV, formed the HCV Guidance Panel in mid-2013. The AASLD/IDSA HCV Guidance Panel sets standards for the diagnosis and treatment of HCV infection. Those standards are widely accepted throughout the medical community as the current standard of care and result in a 90+% cure rate depending on genotype and other factors.

15. In its first report, issued in March 2014, the HCV Guidance Panel stated that the 48-week interferon treatment "has been superseded by treatments incorporating DAAs and should not be used." Recommendations for Testing, Managing and Treating Hepatitis C, March 17, 2014, http://www.hcvguidelines.org/sites/default/files/full_report.pdf, at p. 20.

16. The HCV Guidance Panel has updated its recommendations several times since its initial report to reflect newly approved DAAs entering the market. The current guidance was issued on July 6, 2016 and definitively establishes a 12-week treatment regimen with DAAs as the medically accepted standard of care. Recommendations for Testing, Managing, and Treating Hepatitis C, July 6, 2016, http://hcvguidelines.org/sites/default/files/HCV-Guidance_July_2016_b.pdf. Each iteration of the Panel's guidance has consistently stated that 48-week interferon treatment is "inferior" to DAA treatment and is "not recommended."

17. Defendants are keenly aware of the epidemic levels of HCV infection among inmates in Tennessee and nationally. The Department has faced intense media and legislative scrutiny over the epidemic levels of HCV infection in its facilities during the past 6 months. The Department's current HCV protocol recognizes that HCV is a "silent epidemic" which disproportionately affects "correctional populations." *See* Tennessee Department of Corrections, Chronic HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C (January 1, 2016), attached hereto as Exhibit A (hereinafter the "Protocol"). In March 2016, the Department placed the number of its inmates testing positive for HCV at 3,487, or nearly 1 in 6 prisoners, while conceding that this number is likely far below true infection rates due to a lack of routine testing and inaccurate testing. *See, e.g.*, Letter from Schofield to Tennessee House Finance, Ways and Means Committee, March 9, 2016, attached hereto as Exhibit B. The

Department further acknowledges that nearly half of the inmates tested in 2015 for HCV showed positive test results, a statistic that puts the likely number of inmates infected near 10,000.

18. Defendants are also keenly aware of the community standard of care in the treatment of HCV infection in the prison setting. The Department's Protocol references the guidance of the AASLD/IDSA HCV Guidance Panel as well as Federal Bureau of Prisons ("FBOP") guidance, which is consistent with the Guidance Panel's recommendations. Defendants also acknowledge that the Guidance Panel advises treating all HCV positive individuals, a recommendation that has been adopted by the U.S. Department of Veteran's Affairs and Medicare. Tennessee Department of Corrections, Management of Chronic Hepatitis C Virus (HCV), May 20, 2016, attached hereto as Exhibit C (hereinafter "Management Guidance"), at p. 7. Defendants further acknowledge that the FBOP's current policy is to screen all inmates for HCV infection and treat them with DAAs. *See* Management Guidance at p. 8.

19. Despite Defendants' knowledge of the epidemic rates of HCV infection in their facilities and their knowledge of the standard of care for treatment of HCV infection, Defendants fail to provide medically accepted care to the vast majority of HCV+ inmates. In fact, as of May 2016, only eight (8) of the 3,487 diagnosed inmates were receiving treatment with DAAs.

20. Defendants' HCV Protocol establishes an endless loop of procedures and eligibility criteria not based on sound medicine with the end goal of denying inmates treatment. The Protocol establishes a convoluted, multi-step assessment procedure between diagnosis and treatment lasting roughly 45 months. Protocol at pp. 18-20. In practice, that wait time is greatly extended by delays in making appointments, receiving the results of laboratory tests, etc.

21. During this assessment period, a sick inmate risks losing eligibility – and either not receiving treatment or having to start the process over again – for a variety of missteps, none

of which are based on sound medical reasoning. For example, an inmate who has been disciplined becomes ineligible to continue the process to receive treatment. So does an inmate who has received a tattoo, who has used drugs or alcohol, or who is generally considered by the Department a behavioral risk. Inmates who are not capable of giving informed consent and those with certain mental illnesses will be denied treatment. An inmate who does not understand the multiple pages of technical consent forms will be denied treatment. *Id*.

22. Defendants conduct this assessment and provide treatment only at certain approved facilities. Inmates housed in other facilities are ineligible for treatment.

23. Further, the Protocol states that an inmate who does not have at least 27 months left on his sentence will be denied treatment. This policy, in addition to being indifferent to the suffering of sick inmates and arbitrary in light of the 12-week course of treatment, creates the risk of an HCV pandemic among the general population, as HCV positive inmates will be released into the broader Tennessee community and will likely infect others.

24. Even if an inmate perseveres and is able to receive treatment, the treatment offered by Defendants falls far below community standards of care. For example, Defendants consider drawing blood to be an appropriate form of HCV treatment. Defendants also consider provision of the hepatitis B vaccine to be an appropriate form of HCV treatment. The Protocol specifically contemplates use of interferons, even though those drugs are widely considered "inferior" and are disfavored for treatment of HCV infection.

25. Defendants have no written policies governing treatment of inmates with DAAs, and instead have intentionally omitted DAA treatment from the Protocol and other policies in order to justify their routine denial of treatment with these life-saving medications.

26. The Protocol, as well as the policies, recommendations, and guidance established by Defendants and/or the TACHH, govern the management, diagnosis and treatment of HCV infection in all Tennessee penitentiaries. The Protocol and other policies and practices established by Defendants apply both to the Department and all of its vendors, such as Corrections Corporation of America, Corizon, and Centurion.

27. Plaintiffs have been fighting an uphill battle with Defendants to receive treatment for their HCV infection for years without success.

28. Defendants transferred Plaintiff Davis to DeBerry Special Needs Facility in order for him to receive treatment for his HCV infection in 2013. However, he was subsequently transferred out of DeBerry, without explanation, to a different Department facility that does not offer HCV treatment. Since that time, Defendants have denied Plaintiff Davis treatment, explaining to him that the Department has no protocols in place for HCV treatment.

29. Defendants have also denied Mr. Stevenson treatment, although they have refused to provide an explanation for that denial. Instead, Defendants repeatedly tell Mr. Stevenson to schedule an appointment to assess his medical needs, although assessment never progresses to treatment after his appointments.

30. Defendants' willful indifference to Plaintiffs' disease causes Plaintiffs prolonged physical and mental pain. Plaintiffs are forced to endure the physical effects of HCV, including pain, cramping, and fatigue. Plaintiffs' physical suffering is exacerbated by the mental anguish of knowing that the infection will continue indefinitely and the disease will eventually kill them.

31. Both Plaintiffs suffer from constant fatigue due to their infection. Mr. Davis also suffers from acute symptoms, such as diarrhea, constipation, and gastrointestinal pain. Plaintiffs and potential Class members will suffer irreversible harm, such as liver damage, due to

Defendants' indifference. Many HCV+ inmates have already died from the disease left untreated while in Department custody.

32. Plaintiffs have filed and exhausted all grievance procedures available to them related to Defendants' failure to provide adequate treatment to them for HCV. In the event Plaintiffs' exhaustion efforts suffer from some unknown defect, the relief sought is still warranted absent complete exhaustion to prevent irreparable injury to Plaintiffs and the Class.

CLASS ALLEGATIONS

33. Plaintiffs bring this claim on behalf of themselves and, pursuant to Fed. R. Civ. P. 23(b)(1) and (b)(2), a class of

> **All persons currently incarcerated in any facility under the supervision or control of the Tennessee Department of Corrections or persons incarcerated in a public or privately owned facility for whom the Tennessee Department of Corrections has ultimate responsibility for their medical care and who have at least twelve weeks or more remaining to serve on their sentences and are either currently diagnosed with Hepatitis C infection or are determined to have Hepatitis C after an appropriate screening test has been administered by The Department of Corrections.**

34. This class of persons shall hereinafter be referred to as the "Inmate Class." Excluded from the Inmate Class are Defendants and any members of their immediate family, as well as immediate family members of the judges.

35. Plaintiffs seek relief from the wrongdoing of Defendants for themselves and for all members of the Inmate Class through Rule 23 of the Federal Rules of Civil Procedure. The putative classes meet the statutory prerequisites of Fed. R. Civ. P. 23(a), as set forth herein.

36. As of May 2016, there were 3,487 known prisoners with Hepatitis C. However, with more than 20,000 inmates currently in Department custody, Plaintiffs believe that the actual

number of individuals infected with HCV could be three times the number of known cases. Therefore, members of the class are so numerous that joinder would be impracticable.

37. The number and identity of putative class members is easily ascertainable through discovery. Any notice to class members could be given through the already-established channels Defendants use to communicate with individuals in their custody.

38. Plaintiffs' claims are typical of the claims of the Class, as Defendants' policies and practices apply to all HCV positive prisoners in Department facilities. Plaintiffs will fairly and adequately represent the interests of all Class members and do not have any interests antagonistic to those of the Class. Plaintiffs have retained counsel with competence and experience in class action and Constitutional litigation.

39. Inmate Class members' claims involve common questions of both law and fact. The facts relevant to this action are limited simply to the evidence of Defendants' written policies and unwritten policies, practices and customs regarding the diagnosis and treatment of HCV infection. The injuries sustained by Plaintiffs and all putative class members flow from a common nucleus of operative facts – Defendants' willful failure to offer adequate medical care. Similarly, this action raises common questions of law regarding the rights of Plaintiffs and Class members to receive adequate medical care and specific contours of Defendants' obligations under the Eighth Amendment of the U.S. Constitution.

40. This action is maintainable as a class action pursuant to Fed. R. Civ. P. 23(b)(1) because the number of class members is at least 3,487 and may be as much as three times that amount, and the prosecution of separate actions by individuals would create a risk of inconsistent and varying adjudications, which in turn would establish incompatible standards of conduct for Defendants. Additionally, the prosecution of separate actions by individual members could result

in adjudications with respect to individual members that, as a practical matter, would substantially impair the ability of other members to protect their interests.

41. This action is also maintainable as a class action pursuant to Fed. R. Civ. P. 23(b)(2) because Defendants' policies and practices that form the basis of this complaint are common to and apply generally to all members of the Inmate Class, regardless of what entity runs the particular facility where an inmate is housed or what entity provides medical care in that facility. All Class members have sustained uniform injury – a lack of adequate medical care – and that injury can be remedied by the Class-wide injunctive and declaratory relief sought.

CAUSE OF ACTION

42 U.S.C. § 1983
VIOLATION OF THE EIGHTH AMENDMENT

42. Plaintiffs hereby re-allege and incorporate each and every allegation set forth above as if fully set forth herein.

43. The Eighth Amendment to the United States Constitution, made applicable to states by the Fourteenth Amendment, guarantees all citizens, including Plaintiffs and the Inmate Class, the right to be free from cruel and unusual punishments.

44. By their policies and practices described herein, Defendants subject Plaintiffs and the members of the putative Class to a substantial risk of serious harm and ultimately death from inadequate medical care. These policies and practices have been and continue to be implemented by Defendants and their agents, officials, employees, and all persons acting in concert with them under color of state law, in their official capacities, and are the proximate cause of the Plaintiffs' and Class members' ongoing deprivation of rights secured by the United States Constitution under the Eighth Amendment.

45. Defendants have been and are aware of all the deprivations complained of herein,

have adopted policies and practices that institutionalize those deprivations, and have been and are deliberately indifferent to the deprivations.

46. Under 42 U.S.C. § 1983, Plaintiffs and the Class are entitled to a declaration that the Defendants' written policies and unwritten policies, customs and practices are unconstitutional and an injunction requiring Defendants to adopt policies and practices consistent with the accepted standard of care for HCV infection and the public interest.

47. Plaintiffs and Inmate Class members have no adequate remedy at law to redress the wrongs suffered as set forth in this complaint. Plaintiffs have suffered and will continue to suffer irreparable injury, both in the form of physical and mental harm and deprivation of Constitutional rights, as a result of the unlawful policies, and practices of Defendants, as alleged herein, unless Plaintiffs Inmate Class members are granted the relief they request.

WHEREFORE, Plaintiffs and the Class pray for the following relief:

1. Declaration that the suit is maintainable as a class action pursuant to Federal Rule of Civil Procedure 23(a) and 23(b)(1) and (2);

2. Declaration that the policies and practices of Defendants, and their agents, employees, officials, and all persons acting in concert with them, as described herein, are in violation of the rights of Plaintiffs and members of the Inmate Class under the Eighth Amendment to the U.S. Constitution, which prohibits Defendants from inflicting cruel and unusual punishments under color of state law;

3. Preliminarily and permanently enjoin Defendants, their agents, employees, officials, and all persons acting in concert with them under color of state law, from subjecting Plaintiffs and the Inmate Class to the unconstitutional policies and practices described herein;

4. Order Defendants and their agents, employees, officials, and all persons acting in concert with them under color of state law, to develop and implement, as soon as practical, a plan to eliminate the substantial risk of serious harm that prisoner Plaintiffs and members of the Plaintiff Class suffer due to Defendants' inadequate diagnosis, assessment and treatment of HCV infection. Defendants' plan shall comport with the community standard of care and the advice of medical experts.

5. Award Plaintiffs the costs of this suit, and reasonable attorneys' fees and litigation expenses pursuant to 42 U.S.C. § 1988, and other applicable law;

6. Retain jurisdiction of this case until Defendants have fully complied with the orders of this Court, and there is a reasonable assurance that Defendants will continue to comply in the future absent continuing jurisdiction; and

7. All other relief, legal or equitable, that the Court deems just and proper.

Dated: July 25, 2016

Respectfully submitted,

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TN Department of Correction

Chronic HCV Guidance:

Recommendations for Testing, Managing, and Treating Hepatitis C

EXHIBIT

1

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Introduction

Viral Hepatitis has been labeled “the silent epidemic” by the United States Department of Health and Human Services, but we in correctional healthcare have known little silence from this prevalent disease. (HHS) Hepatitis C Virus (HCV) Infection has become the most common cause of death from a viral illness in the United States surpassing HIV. Correctional populations have a much higher burden of disease related to HCV infection than the general population. Many who are affected may exhibit little to no symptoms of the infection. This guideline will assist providers in screening, diagnosis, and managing chronic hepatitis C patients within the Tennessee Department of Corrections. This document will serve as a replacement of the Pre-Treatment HCV Program last updated in April 2014.

Disease Progression

Those affected by HCV often progress gradually through different stages of disease. About 15-25% may resolve the initial infection and resolve the infection. Another 75-85% will progress to chronic hepatitis C infection. This is the main target patient population for this guideline.

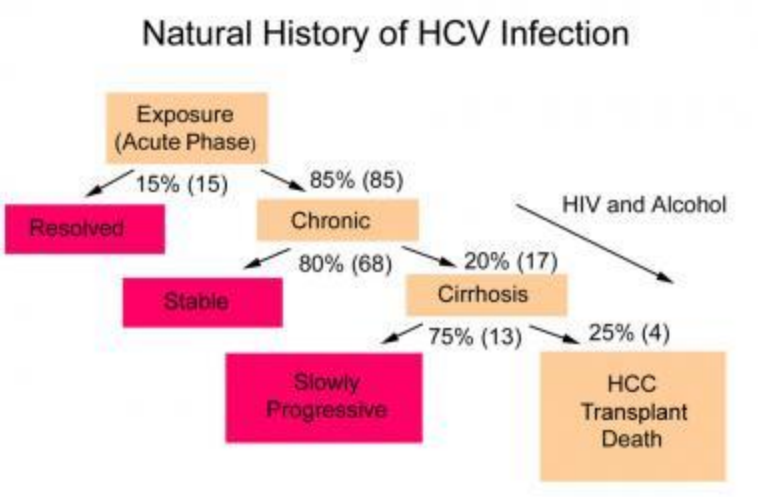


Figure 1 Natural Progression of HCV Infection

Reference: Medscape: http://emedicine.medscape.com/article/177792-overview

Acute Hepatitis C infection also known as “acute phase” should be treated on a case by case basis with supportive treatment being paramount. Some patients may need an admission into infirmary with serial laboratories drawn and IVF. Those patients that go on to resolution (Negative HCV RNA 6 months or more out from initial infection) should be followed like any other inmate in a preventative health program but should not be enrolled in Q90 day hepatitis C chronic care program, so long as he or she has no cirrhosis, complications, or related comorbidities. They should have clearly documented on the problem list that Hepatitis C has resolved and the date of resolution documented on CR Form 1894 Major Medical Conditions Problem List.

HCV Infection: Screening Criteria, Risk Factors, and Recommended Testing

Screening Criteria for testing for HCV infection is recommended for:

- Sentenced inmates with risk factors for HCV infection
- All inmates with certain clinical conditions
- Inmates who request testing.

Testing for HCV infection at the prevention baseline visit is recommended for sentenced inmates who have the following risk factors:

- Ever injected illegal drugs or shared equipment (including intranasal use of illicit drugs)
- Received tattoos or body piercings while in jail or prison, or from any unregulated source
- HIV or chronic hepatitis B virus (HBV) infection
- Received a blood transfusion or an organ transplant before 1992, or received clotting factor transfusion prior to 1987
- History of percutaneous exposure to blood
- Ever received hemodialysis
- Born to a mother who had HCV infection at the time of delivery

HCV testing is recommended for all inmates with the following clinical conditions, regardless of sentencing status:

- A reported history of HCV infection without prior medical records to confirm the diagnosis
- chronic hemodialysis – screen alanine aminotransferase (ALT) monthly and anti-HCV semiannually
- Elevated ALT levels of unknown etiology
- Evidence of extrahepatic manifestations of HCV – mixed cryoglobulinemia, membranoproliferative glomerulonephritis, porphyria cutanea tarda, vasculitis

The preferred screening test for HCV infection is an immunoassay that measures the presence of antibodies to HCV antigens, referred to as HCV Ab or anti-HCV.

Note: Unless clinically indicated (see clinical conditions under Screening Criteria above), screening should ordinarily not be pursued for asymptomatic, highly mobile, nonsentenced inmates.

Refusal of testing of sentenced inmates who have risk factors for HCV infection, but who refuse testing at the baseline visit, should be counseled about and offered HCV testing during periodic preventive health visits

Initial Evaluation of HCV+

Initial evaluation of anti-HCV positive (antibody positive) inmates includes:

- a baseline history and physical examination
- lab tests (see below)
- calculation of the APRI score to determine fibrosis
- Assessment of the need for preventive health interventions such as vaccines and screenings for other conditions
- Counseling on information related to HCV infection[1]

Recommended Lab Tests [2]:

- Complete blood count (CBC); prothrombin time (PT) with International Normalization Ratio (INR); liver panel (albumin, total and direct bilirubin, serum alanine aminotransferase [ALT] and aspartate aminotransferase [AST], and alkaline phosphatase); serum creatinine; and calculated glomerular filtration rate (GFR).
- Hepatitis B surface antigen (HBsAg) and HIV antibody (anti-HIV or HIV Ab).
- Quantitative HCV RNA viral load testing to determine if the inmate has active or resolved HCV infection.
- Ordinarily, testing for HCV genotype may be deferred until the time of pretreatment evaluation.
- Unless otherwise clinically indicated, testing for other causes of liver disease—e.g., antinuclear antibody (ANA), ferritin, iron saturation, ceruloplasmin—are not routinely ordered in the evaluation of a positive HCV Ab test.

All inmates who are anti-HCV positive should be evaluated to assess the need for the preventive health interventions, including the following:

- Hepatitis B vaccine: Indicated for susceptible inmates with chronic HCV infection. For foreign-born inmates, consider prescreening for hepatitis B immunity prior to vaccination.
- Inmates with evidence of liver disease should be priority candidates for hepatitis B vaccination.
- Hepatitis A vaccine: Indicated for susceptible inmates with chronic HCV infection who have other evidence of liver disease. For foreign-born inmates, consider prescreening for hepatitis A immunity prior to vaccination.
- Influenza vaccine: Offer to all HCV-infected inmates annually.
- Inmates with cirrhosis are high priority for influenza vaccine.

Assess for Hepatic Cirrhosis and Decompensation

Cirrhosis is a condition of chronic liver disease marked by inflammation, degeneration of hepatocytes, and replacement with fibrotic scar tissue. The natural history of HCV is such that 50–80% of HCV infections become chronic. (FBOP, 2015) Progression of chronic HCV infection to fibrosis and cirrhosis may take years in some patients and decades in others—or, in some cases, may not occur at all.

[1] See Attachment I
[2] See Attachment II

STAGES OF FIBROSIS — Noninvasive tests of hepatic fibrosis attempt to predict the stage of hepatic fibrosis that would be seen histologically. There are several histologic scoring systems for chronic liver disease. Many use five-point scales such as the METAVIR score. Many authors will drop the "F" prefix and simple call F3, for example, Stage 3.

- F0: No fibrosis
- F1: Portal fibrosis without septa
- F2: Few septa
- F3: Numerous septa without cirrhosis
- F4: Cirrhosis

Patients are typically considered to have significant fibrosis if their fibrosis score is ≥F2. (UpToDate)

Most complications from HCV infection occur in people with cirrhosis. Patients with advanced hepatic fibrosis (primarily stage 3) have a 10% per year rate of progressing to cirrhosis (stage 4). Those with cirrhosis have a 4% per year rate of developing decompensated cirrhosis, and a 3% per year rate of developing hepatocellular carcinoma.

Physical exam in a hepatitis C patient may be normal until end-stage disease. Some common findings of end-stage disease include:

- Skin changes: Spider angiomata, palmar erythema, jaundice, scleral icterus, ecchymoses, caput medusa, hyperpigmentation
- Hepatomegaly (small liver in end-stage disease)
- Splenomegaly if portal hypertension
- Central obesity
- Abdominal fluid wave, shifting dullness if ascites
- Gynecomastia
- Dupuytren contractures
- Pretibial, presacral pitting edema and clubbing (especially in hepatopulmonary syndrome)
- Asterixis; mental status changes
- Muscle wasting, weakness

Assessing for cirrhosis is important for prioritizing inmates for treatment of HCV and in determining the need for additional health care interventions.

Cirrhosis may be diagnosed in several ways:

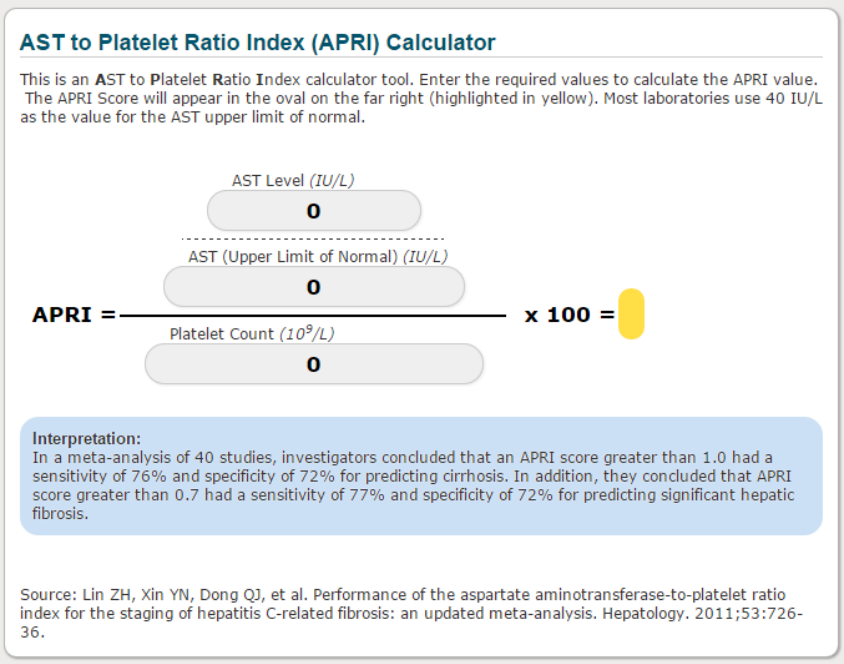
- Symptoms and signs that support the diagnosis of cirrhosis may include: low albumin or platelets, elevated bilirubin or INR, ascites, esophageal varices, and hepatic encephalopathy. However, isolated lab abnormalities may require additional diagnostic evaluation to determine the etiology.
- The AST to Platelet Ratio Index (APRI) or APRI score has been used by both the AASLD and BOP as the preferred method for non-invasive assessment of hepatic fibrosis and cirrhosis:
    - The APRI score, a calculation based on results from two blood tests (the AST and the platelet count), is a less invasive and less expensive means of assessing fibrosis than a liver biopsy. The formula for calculating the APRI score is [(AST/AST ULN) x 100 / (platelet count x 103/µL / 1,000).
    - An APRI score ≥ 2.0 may be used to predict the presence of cirrhosis. At this cutoff, the APRI score has a sensitivity of 48%, but a specificity of 94%, for predicting cirrhosis. Inmates with an APRI score ≥ 2.0 should have an abdominal ultrasound performed to identify other findings consistent with cirrhosis (see

abdominal imaging studies below in this list). Lower APRI scores have different sensitivities and specificities for cirrhosis. For example, an APRI score ≥ 1 has a sensitivity of 77% and a specificity of 75% for predicting cirrhosis.

- An APRI score is not necessary for diagnosing cirrhosis if cirrhosis has been diagnosed by other means.

- The APRI may also be used to predict the presence of significant fibrosis (stages 2 to 4, out of 4). Using a cutoff of ≥ 1.5, the sensitivity is 37% and specificity is 95% for significant fibrosis.

- APRI calculators (click here for APRI Score) are readily available on the Internet at: http://www.hepatitisc.uw.edu/page/clinical-calculators/apri. This is an **A**ST to **P**latelet **R**atio **I**ndex calculator tool. Enter the required values to calculate the APRI value. The APRI Score will appear in the oval on the far right (highlighted in yellow). Most laboratories use 40 IU/L as the value for the AST upper limit of normal.



Source: http://www.hepatitisc.uw.edu/page/clinical-calculators/apri

- Abdominal imaging studies such as ultrasound or CT scan may identify findings consistent with or suggestive of cirrhosis (nodular contour of the liver), portal hypertension (ascites, splenomegaly, varices), or hepatocellular carcinoma (HCC).
  - Initiation of a referral for assessment for cirrhosis by onsite ultrasound will be necessary.
- A Liver biopsy is no longer required to confirm diagnosis unless otherwise clinically indicated. However, the presence of cirrhosis on a prior liver biopsy may be used to meet the criteria for HCV treatment.

Decompensation of liver disease has been closely linked to prognosis. Decompensation can be differentiated from compensated through the following method:

- The AASLD and FBOP have used the Child-Turcotte-Pugh (CTP) score as a tool to help determine the severity of cirrhosis and is used by to distinguish between compensated and decompensated liver disease. (AASLD)
  - CTP calculators are readily available on the Internet at: http://www.hepatitisc.uw.edu/page/clinical-calculators/ctp
  - Once cirrhosis has been determined, the CTP can assess the severity of cirrhosis and help in distinguishing between compensated and decompensated liver disease.
  - The CTP score includes five parameters (albumin, bilirubin, INR, ascites, and hepatic encephalopathy), each of which is given a score of 1, 2, or 3. The sum of the five scores is the CTP score, which is classified as shown in the table below:

CTP Score	CTP Class	Hepatic Compensation
5–6	Class A	Compensated cirrhosis
7–9	Class B	Decompensated cirrhosis
≥ 10	Class C	

  - A CTP score of 5 or 6 is considered to be compensated cirrhosis, while a score of 7 or greater is considered decompensated. Please note CTP class or CTP grade can be used interchangeably.
  - It is recommended that cases of decompensated cirrhosis be managed in consultation with a clinician experienced in the treatment of this condition because the dosages of DAA medications are not well-established with severe hepatic impairment. These cases should be referred to the TACHH[3].
  - Inmates with CTP Class C decompensated cirrhosis may have a reduced life expectancy and should be considered for medical furlough in accordance with current TDOC Policy Medical Furloughs(Policy# 511.01.1)
  - Consider all patient with a CTP >7 for medical furlough as prognosis increases with increased score.
  - On all patient with CTP>7 please provide MELD score for further prognosis
    - Prognosis for patient with liver disease can be estimated based on CTP and MELD score
    - Found at: http://www.hepatitisc.uw.edu/page/clinical-calculators/meld

Prognosis	
CTP Score	**½ year Survival**
Total 5-6 = Class A or well compensated:	100%/85%
Total 7-9 = Class B or significant functional compromise:	80%/60%
Total 10-15 = Class C or decompensated:	45%/35%

[3] TDOC Advisory Committee on Hepatitis C and HIV

- Consider all patient with a CTP >7 for medical furlough as prognosis increases with increased score.
- On all patient with CTP>7 please provide MELD score for further prognosis

- The Model for End Stage Liver Disease (MELD) predicts survival for patients with advanced liver disease. It has been used to estimate 3-month mortality for severe liver disease patients.
  - Prognosis for patient with liver disease can be estimated based on CTP and MELD score
  - Source found at: http://www.hepatitisc.uw.edu/page/clinical-calculators/meld
- The estimated 3-month mortality is based on the MELD score. The higher the score the higher likelihood of mortality within the time range.

MELD Scoring	
MELD Score	**Mortality Risk**
40 or more	71.3% mortality
30-39	52.6% mortality
20-29	19.6% mortality
10-19	6.0% mortality
<9	1.9% mortality

Source: Kamath PS, Kim WR; Advanced Liver Disease Study Group. The model for end-stage liver disease (MELD). Hepatology. 2007;45:797-805

Special Considerations for Patients with Cirrhosis:

- Pneumococcal vaccine: Offer to all HCV-infected patients with cirrhosis who are 19 through 64 years of age
- Hepatocellular carcinoma (HCC) screening: Liver ultrasound is recommended every six months for patients with both cirrhosis and chronic HCV infection.
- Esophageal varices screening: Screening for esophageal and gastric varices with esophagogastroduodenoscopy (EGD) is recommended for patients diagnosed with cirrhosis. Initiation of a referral to GI or Hepatology will be necessary.

Other healthcare interventions recommended for patients with cirrhosis may include:

- Nonselective beta blockers for prevention of variceal bleeding in patients with esophageal varices.
- Antibiotic prophylaxis if risk factors are present for spontaneous bacterial peritonitis.
- Optimized diuretic therapy for ascites.
- Lactulose and rifaximin therapy for encephalopathy.

In general, NSAIDs should be avoided in advanced liver disease/cirrhosis, and metformin should be avoided in decompensated cirrhosis. The detailed management of cirrhosis is beyond the scope of these guidelines. Other resources should be consulted for more specific recommendations related to this condition.

TDOC Criteria for HCV Treatment[4]

Priority Level 1- Highest

- Cirrhotics
- CTP 7-9 are highest priority
- Liver transplant candidates
- Hepatocellular Carcinoma*
- Comorbid conditions like certain lymphomas, hematologic malignancies and cryoglobulinemia with renal disease or vasculitis
- Continuity of Care for those already on medications prior to incarceration

Priority Level 2- High Priority

- APRI ≥ 2.0 without other clinical findings
- HBV
- HIV
- Comorbid liver disease
- Advanced fibrosis of F3 (Metavir Stage, bridging fibrosis) or worse

Priority Level 3- Intermediate Priority

- Stage 2 Fibrosis on liver biopsy
- APRI score 1.5 to < 2
- DM
- Porphyria cutanea tarda

Priority Level 4- Routine Priority

- Stage 0 to Stage 1 fibrosis on liver biopsy
- All other cases of HCV infection meeting the eligibility criteria for treatment.

[4] Based on FBOP Priority Levels (FBOP, 2015)

Pretreatment Assessment

Recommended Treatment Regimens for HCV continue to evolve, but still depend on several factors:

- HCV genotype
- Prior HCV treatment history
- Compensated vs. decompensated liver disease

Pretreatment assessment should be accomplished within three months of the projected start of treatment and should include the following:

- Laboratory tests including CBC, PT/INR, liver panel, serum creatinine, calculated GFR, quantitative HCV RNA viral load sensitive to ≤ 25 IU/ml, HCV genotype, and urine drug screen.
- Calculation of the APRI score using results from the pretreatment labs. (An APRI score is not needed if there is confirmed cirrhosis.)
- Calculation of current CTP score for inmates with known or suspected cirrhosis.
- Assessment for significant drug-drug interactions and current/prior medication adherence.
- Review of incident report history for high-risk behaviors (alcohol/drug possession/use; tattooing).
- For ribavirin-containing regimens: In addition to the above, a pretreatment ECG is recommended for inmates with preexisting coronary heart disease.
- For interferon-containing regimens: In addition to the above, pretreatment evaluation should include a WBC with differential, TSH/free T4. Such regimens should also include a mental health evaluation.

Antiviral Treatment[5]

Patient should be referred to the TDOC Advisory Committee on Hep C and HIV (TACHH) for antivirals. Those patients found to qualify for treatment will be referred to our hepatitis C consultant. Preferred treatment regimens are beyond the scope of this document and will be determined by the TACHH and hepatitis C consultant. Please refer to the AASLD/IDSA/IAS-USA guidelines (www.hcvguidelines.org) for recommended treatment regimens.

Based on the Centurion Guideline, updated on March 2015, patients currently being considered for antiviral treatments will be qualified based on fibrosis and staging. (Centurion, 2015) Those that have moderate to high risk for advanced hepatic fibrosis are worked up and staged using APRI/FIB4 and other modalities to ensure proper staging. Those with F3 to F4 staging should be referred to the TACHH to be qualified for antiviral administration.

[5] Review information noted in the Attachment III: HEPATITIS C TREATMENT CONSENT/AGREEMENT

Special Consideration for antiviral treatment. Patient should have:

- No contraindications to or significant drug interactions with any component of the treatment regimen
- GFR ≥ 30
- Not to be pregnant, especially for riba and IFN regimen
- Life expectancy of greater than 18 months
- Willingness and ability to adhere to a rigorous treatment regimen and abstain from risky behaviors
- At least 9 months on prison sentence from the start of medications

Contraindications to antivirals treatment include (at the time of medication administration):

- GFR less than 30.
- Contraindications to, or significant drug interactions with, any component of the treatment regimen
- Life expectancy of less than 18 months
- Less than 9 months remaining on their sentence in the TDOC to complete a course of treatment (relative contraindication).
- Pregnancy is a relative contraindication, especially for any regimen that would require ribavirin or interferon
- Received a tattoo within the last year
- Caught using/or in possession of illicit drugs, non-prescribed medications, alcohol or injectable drug apparatus in the last year
- Inability to give informed consent
- Solid organ transplant recipient
- Non-compliant or prefers to continue risky behavior
    - Demonstrate an unwillingness and an inability to adhere to a rigorous treatment regimen and to abstain from high-risk activities while incarcerated

On-Treatment Monitoring

On-treatment monitoring should include the following:

- *An outpatient clinic visit* at 2 weeks and 4 weeks after starting therapy, and monthly thereafter; more frequently as clinically indicated.
- *Labs drawn 4 weeks after the start of therapy* should include CBC, creatinine, calculated GFR, liver panel, and quantitative HCV viral load; others as clinically indicated.
- *For regimens containing interferon and/or ribavirin:* A CBC should also be drawn 2 weeks after starting therapy, then at 4 weeks, then monthly; more frequently as clinically indicated. Interferon and/or ribavirin dosage adjustments may be required.
- *Increases in the ALT may require more frequent monitoring or early discontinuation.* Early discontinuation of HCV treatment is recommended if ALT increases by tenfold, or by a less than tenfold increase if accompanied by symptoms related to hepatic dysfunction. Asymptomatic ALT increases of less than tenfold should be monitored approximately every 2 weeks.

- If the quantitative HCV viral load is detectable after 4 weeks of treatment, it should be repeated 2 weeks later. Early discontinuation of HCV treatment is recommended only if there is > 1 log increase from the nadir in HCV viral load after 6 weeks or more of treatment.

Note: HCV viral load testing is no longer required at the end of treatment, but should be obtained in all cases that failed to achieve undetectable levels during treatment.

- A test for thyroid stimulating hormone (TSH) is recommended every 12 weeks only for patients receiving regimens containing interferon. For a 12-week regimen, a TSH should be drawn at the end of treatment, in addition to the pretreatment baseline.
- *Pregnancy testing is required prior to treatment with ribavirin-containing regimens*, and then periodically during and after treatment—usually monthly during treatment and for 6 months after completion of treatment.
- Testing for HCV drug-resistant mutations is not routinely recommended at this time.

Post-Treatment Monitoring

- A quantitative HCV RNA viral load assessment is recommended at 12 weeks after completion of treatment; if HCV is undetectable, it defines a sustained virologic response (SVR).
- If the HCV viral load is again undetectable at 6 to 12 months after the end of treatment, the inmate may be removed from the chronic care clinic, so long as he or she has no cirrhosis, complications, or related comorbidities.
- *Recurrent viremia following an SVR may be due to relapse or reinfection. To help distinguish between the two in such cases, an HCV genotype, along with subtyping for genotype 1, should be obtained.*

Ongoing Monitoring

Periodic monitoring is recommended for all those with active infection, including acute HCV infection, HCV treatment failures, relapse of HCV infection or reinfection, and those with chronic HCV infection who are not yet treated.

- *For cases without advanced fibrosis, cirrhosis, or complications,* annual evaluation is appropriate. This evaluation should include a focused review of systems and patient education relevant to HCV, vital signs and a focused physical examination, and lab monitoring (CBC, PT/INR, liver panel, serum creatinine, calculated GFR, and calculation of the APRI score).
- *For patients with cirrhosis or significant comorbidities*, evaluation is recommended at least every six months; more frequently as clinically indicated.
- *In cases of acute HCV infection*, monitoring for spontaneous clearance of the infection with ALT and quantitative HCV RNA levels every four to eight weeks, for six to twelve months, is recommended. If viremia persists after that time, continue to monitor and manage the case as a chronic infection.
- In most cases of acute HCV infection, treatment may be deferred to allow for spontaneous clearance of viremia. However, in some cases there may be a compelling reason to treat the acute infection in order to prevent severe complications, e.g., HCV infection superimposed on established cirrhosis or advanced fibrosis.

Appendix

- Attachment I: Hepatitis C Patient Counseling
- Attachment II: Initial Lab Studies to Order
- Attachment III: Hepatitis C Treatment Consent/Agreement
- Attachment IV: Hepatitis C Pre-Treatment Evaluation Work Sheet
- Attachment V: Hepatitis C Treatment Algorithm
- Attachment VI: Hepatitis C Treatment Monitoring Schedule

Attachment I

HEPATITIS C PATIENT COUNSELING

1. Information on Disease Natural History:

- ☐ Most people with Hepatitis C can remain healthy, manage the disease and lead full, active lives.
- ☐ The risk of developing serious liver disease is small ranging from 5% to 25% over a period of 25-30 years in most cases.
- ☐ It is difficult to predict which HCV-infected persons will develop cirrhosis or who will respond to treatment.

2. Information on Evaluation:

- ☐ The provider may have to extract a sample of the patient's liver with a needle to determine the extent of liver damage. In most instances, there are no complications, however rarely internal bleeding may occur, as well as leak of bile from the liver and gallbladder.
- ☐ It is mandatory that the patient makes it to his/her scheduled provider visits as well as allow for blood draws during evaluation and treatment. Patients who refuse a blood draw will be terminated from the treatment program.
- ☐ Patient may undergo random blood or urine testing for illegal substances and that any positive test may result in stopping, or loss of eligibility for, treatment.
- ☐ Certain medical-mental health conditions/medication intolerance/pregnancy many prevent a patient from being treated safely and effectively.
- ☐ An adequate amount of time must be available to safely and effectively treat the patient while incarcerated to maximize good patient outcomes while minimizing side effects.

3. Information on Treatment:

- ☐ Current treatment is very effective with some risk of serious side effects.
- ☐ Initial (first few weeks) side effects may include flu-like symptoms with some drug regimens, but should gradually improve.
- ☐ Current treatment regimens include a medication that may be injected every week for up to 48 weeks.
- ☐ Adherence to the drug regimen is mandatory to increase the likelihood of cure. Patients who are non-compliant will be terminated from the treatment program.
- ☐ Treatment will continue to evolve over the next few years as experts develop new medications that will work even better, and better tolerated by the patient.

4. Prevention:

- ☐ The infection can be spread even if the patient "feels fine".
- ☐ Patient should not shoot drugs, use alcohol, have sex with other inmates, get a tattoo or body piercing.
- ☐ Patient should not share personal items that might have be tainted with blood, such as; tooth brushes, nail files, clippers or razors.
- ☐ Patient should cover cuts and skin sores to keep blood from contacting other people.

My signature below signifies my understanding of, and agreement to comply with the information above. I understand that failure to comply may result in loss of eligibility for treatment or discontinuation of treatment in progress. Reconsideration for treatment is not guaranteed but may occur on a case by case basis if activity is stopped.

Patient Name: _____TDOC ID#_____

Patient Signature: _____

Clinician Name: _____

Clinician Signature: _____Date_____/_____/_____

Attachment II

INITIAL LAB STUDIES TO ORDER *

1.	CBC with Differential • Includes red blood cell indices (MCV) and platelet count
2.	CMP (Complete Metabolic Profile) • Includes creatinine, alkaline phosphatase., total bilirubin, ALT, AST and albumin (Calculated GFR)
3.	PT/INR
4.	TSH
5.	Hep C Antibody
6.	If Hep C antibody is positive then check for below: • Hepatitis B Antigen ○ If not done in previous 6 months. Do not repeat if previously positive • HIV Antibody Screen ○ If not done in previous 6 months. Do not repeat if previously positive
7.	• HCV RNA

*** If not obtained within last 90 days**

Note: see attachment VI for recommendations for labs pre-treatment and during antiviral therapy.

Attachment III

HEPATITIS C TREATMENT CONSENT/AGREEMENT

Treatment of Hepatitis C is reserved for eligible patients who understand the commitment to therapy, will tolerate and comply with the course of treatment, and agree to avoid all activities that may worsen their liver disease or infect themselves or others with the Hepatitis C virus or other blood borne pathogens. Every patient who is considered for treatment must complete this agreement before a liver biopsy is performed and/or before initiation of therapy.

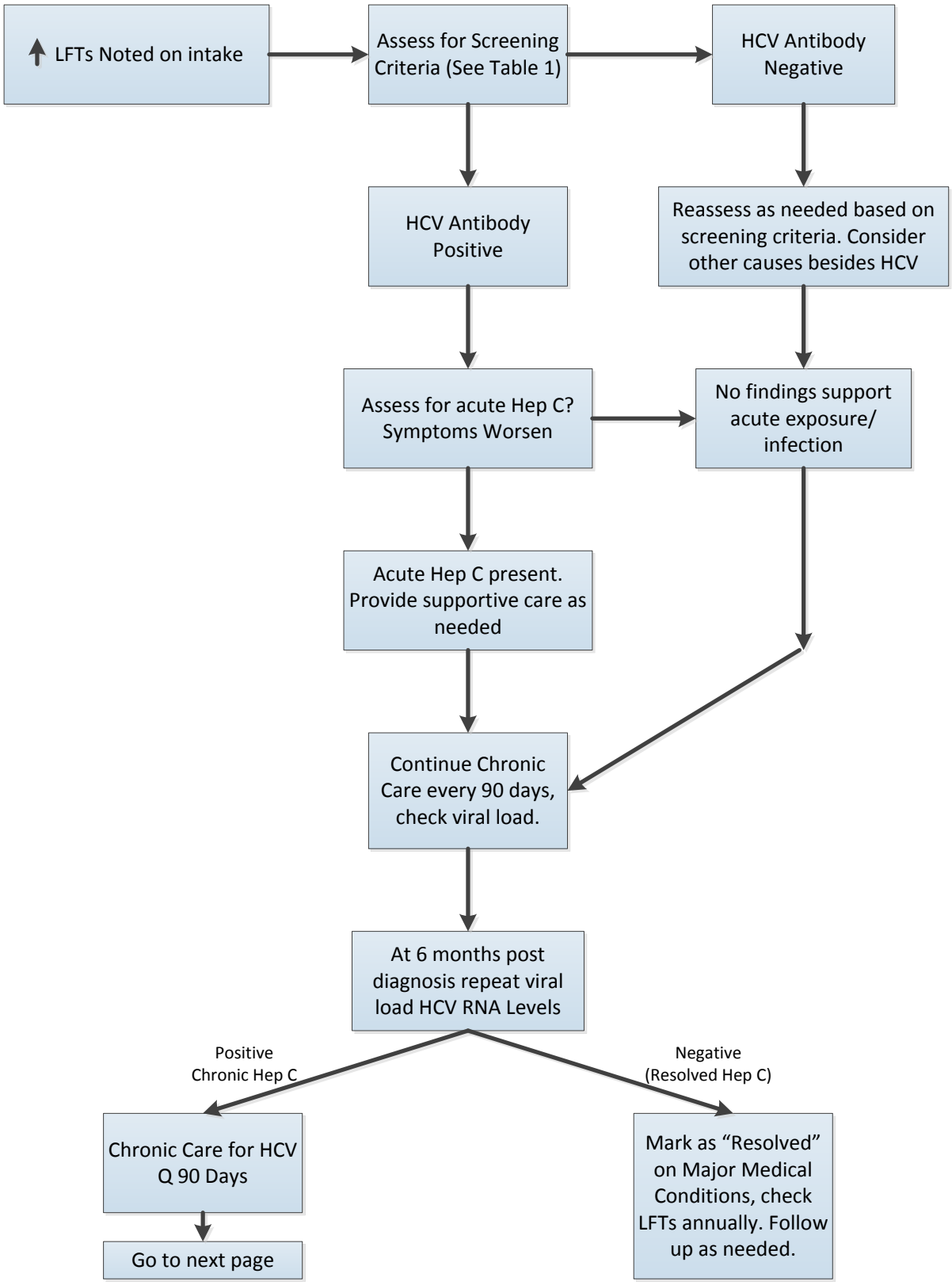
Patient's Initials	
	I understand that the therapy may be of no benefit to me, and that it may not free or clear me of the Hepatitis C infection.
	I have been informed that side effects of treatment of Hepatitis C may include fatigue, body aches and other serious side effects that may continue throughout my treatment with the medication.
	I understand that I may be tested for HIV before beginning treatment as the presence of the HIV virus could seriously affect my Hepatitis C infection and its treatment.
	I understand that the treatment with medication may continue for up to 12 months and that frequent blood testing will be needed to check for side effects or other problems.
	I understand that treatment for Hepatitis C may cause mental health side effects, especially depression.
	I understand that I must not become pregnant or attempt to impregnate my partner during my Hepatitis C antiviral treatment or for 6 months after stopping treatment. I understand that I must use two forms of birth control during heterosexual activity while taking medication, and for 6 months after medication ends.
	I understand that my failure to comply with the medication, blood testing, or regular appointments may result in my provider stopping the therapy.*
	I understand that alcohol injures the liver and drinking alcohol is forbidden.
	I understand that I must abstain from any activity that may transmit the Hepatitis C virus or other blood borne pathogens. This includes tattooing, sexual activity in prison, IV drug use and intranasal drug use. This activity may result in loss of eligibility for treatment or stopping treatment in progress.*
	I understand that I may be required to undergo random blood and urine testing for illegal substances and that any positive test may result in stopping, or loss of eligibility for treatment . *
	I understand that completion of this agreement does not guarantee that I will be approved for Hepatitis C treatment.
	My initials and my signature below signify my understanding of, and agreement to comply with the requirements. I understand that failure to comply may result in loss of eligibility for treatment or discontinuation of treatment in progress. *

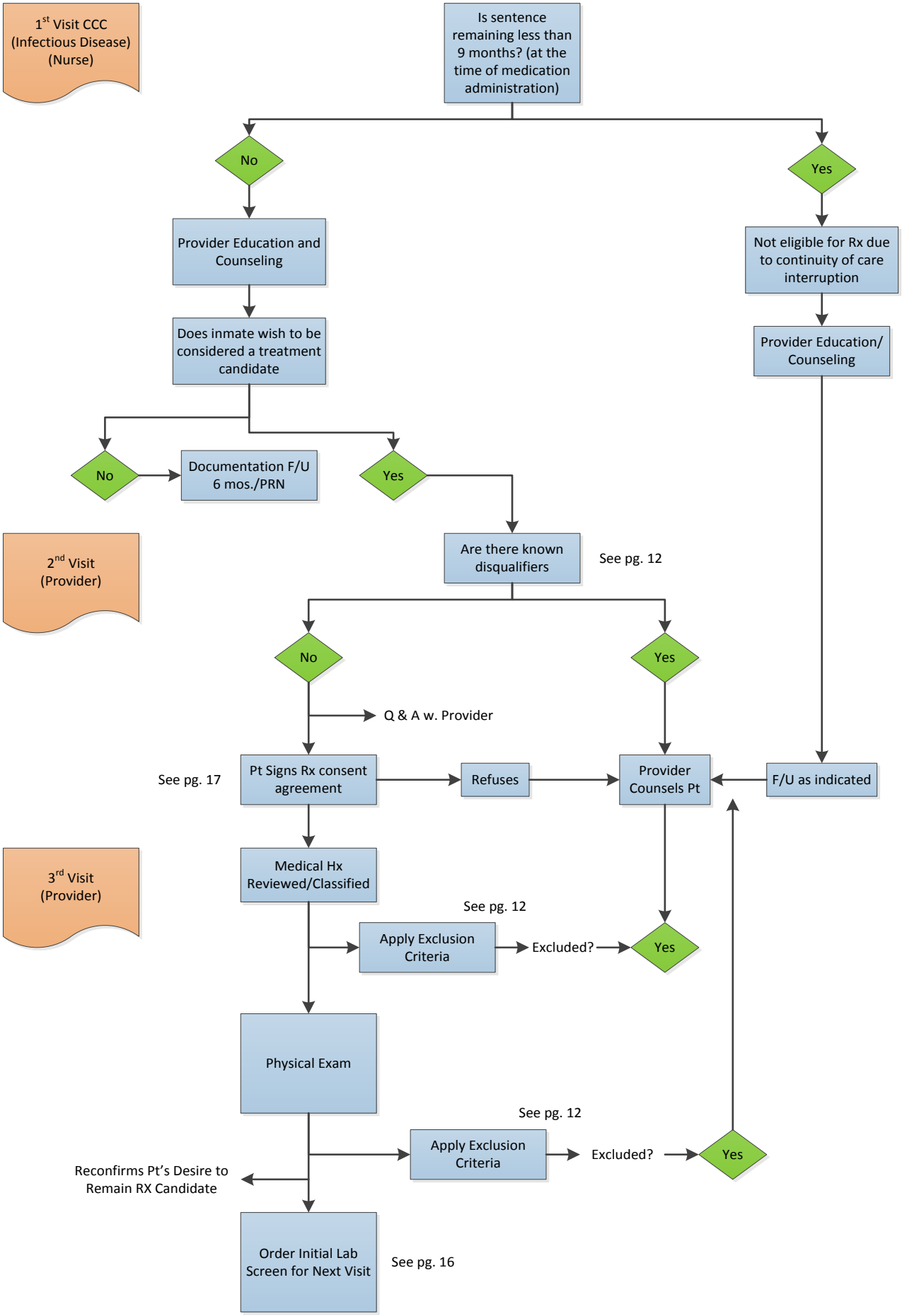
*** Loss of eligibility or treatment stopped for minimum of 1 year. Reconsideration for treatment not guaranteed, but may occur on case by case basis if activity is stopped.**

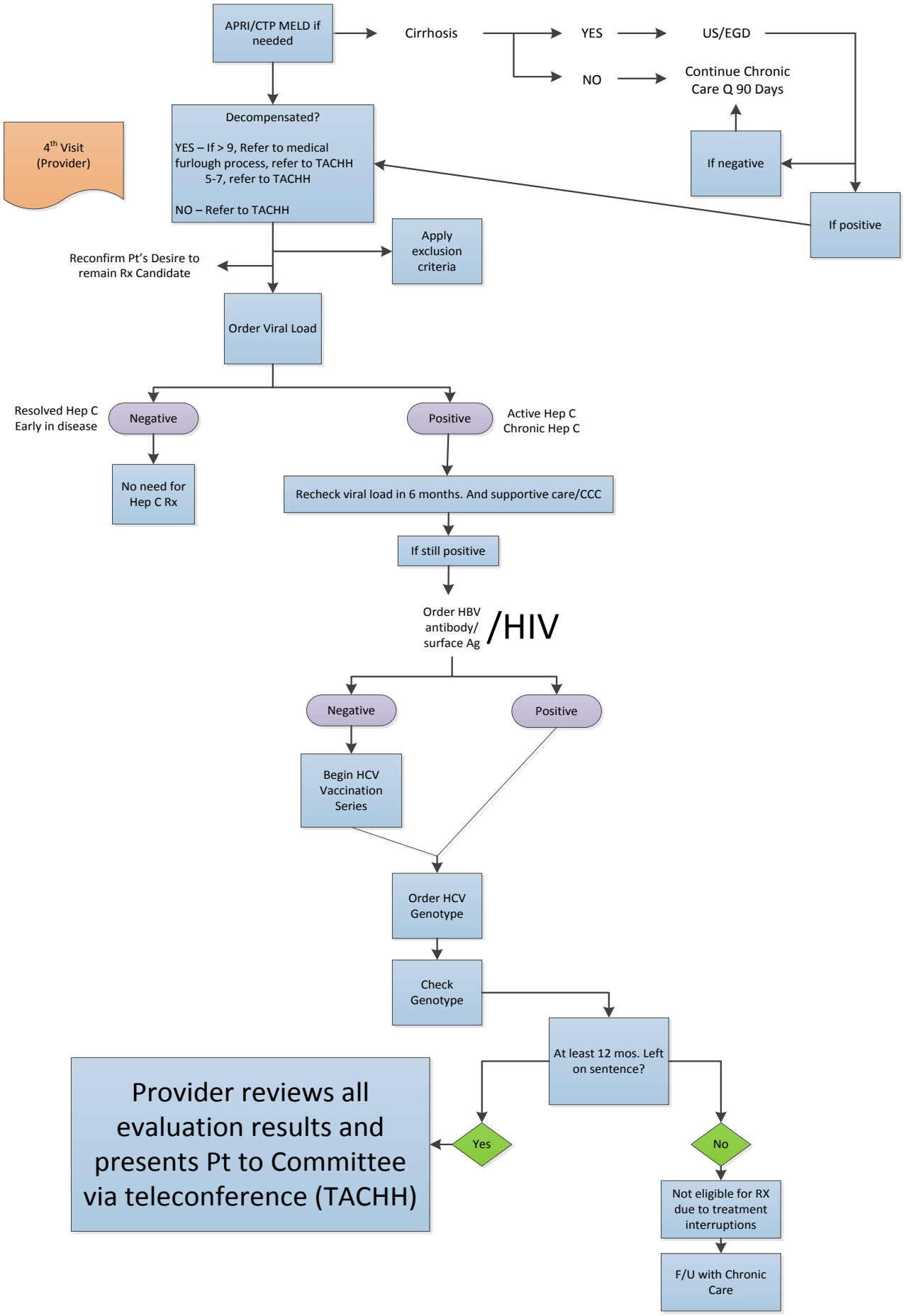
Patient Name Last:_____ First: _____MI_____ TDOC# _____ D.O.B._____	Patient Signature:_____ Clinician Name:_____ Date:___/___/___ Clinician Signature:_____

Attachment IV

Recommended Initial Pathway for HCV Management




1st Visit CCC (Infectious Disease) (Nurse)
Is sentence remaining less than 9 months? (at the time of medication administration)
No
Yes
Provider Education and Counseling
Not eligible for Rx due to continuity of care interruption
Does inmate wish to be considered a treatment candidate
Provider Education/ Counseling
No
Documentation F/U 6 mos./PRN
Yes
2nd Visit (Provider)
Are there known disqualifiers
See pg. 12
No
Yes
Q & A w. Provider
See pg. 17
Pt Signs Rx consent agreement
Refuses
Provider Counsels Pt
F/U as indicated
3rd Visit (Provider)
Medical Hx Reviewed/Classified
See pg. 12
Apply Exclusion Criteria
Excluded?
Yes
Physical Exam
See pg. 12
Apply Exclusion Criteria
Excluded?
Yes
Reconfirms Pt's Desire to Remain RX Candidate
Order Initial Lab Screen for Next Visit
See pg. 16


APRI/CTP MELD if needed
Cirrhosis
YES
US/EGD
NO
Continue Chronic Care Q 90 Days
If negative
If positive
4th Visit (Provider)
Decompensated?
YES – If > 9, Refer to medical furlough process, refer to TACHH 5-7, refer to TACHH
NO – Refer to TACHH
Apply exclusion criteria
Reconfirm Pt's Desire to remain Rx Candidate
Order Viral Load
Resolved Hep C Early in disease
Negative
Positive
Active Hep C Chronic Hep C
No need for Hep C Rx
Recheck viral load in 6 months. And supportive care/CCC
If still positive
Order HBV antibody/ surface Ag
/HIV
Negative
Positive
Begin HCV Vaccination Series
Order HCV Genotype
Check Genotype
At least 12 mos. Left on sentence?
Yes
No
Not eligible for RX due to treatment interruptions
F/U with Chronic Care
Provider reviews all evaluation results and presents Pt to Committee via teleconference (TACHH)

Attachment V

HEPATITIS C PRE-TREATMENT EVALUATION WORK SHEET

Submit with request for consult TDOC Advisory Committee on Hepatitis and HIV (TACHH)

Patient Name:_____ (Last Name, First Name) TDOC #:_____	Date of Projected Parole/Sentence expiration _____	Previous Antiviral Treatment (Y/N)? If so, what med? How long?

Refer to Pre-Treatment Evaluation Flow Chart

1.0	Patient educated and counseled about Hepatitis treatment		Yes/No
2.0	Consent Form signed		Yes/No
3.0	HIV/HBV co-infection or other liver disease?		Yes/No
	Labs ordered		Yes/No
	Medical History reviewed/Exclusion criteria applied ☐ Sentenced inmate with 9 months remaining on sentence to complete a course of treatment prior to hallway house (RRC), home confinement, or GCT/Full Term release. ☐ No sanctions for drug or alcohol/intoxicant possession/use, or tattooing within previous 1 year. ☐ No documented non-adherence to prior therapy, failure to complete pretreatment evaluation process, or unwillingness to commit or consent to HCV treatment. ☐ No contraindications or drug interactions with requested treatment regimen ☐ No uncontrolled or unstable medical or mental health conditions ☐ No current pregnancy		Yes/No
	Physical Completed		Yes/No
4.0	Age: DOB: Race:		
	TSH: PT-INR:		
	Albumin (g/dl): Bilirubin (MG/dl): Creatinine:		
	Platelets Count: AST:		
	APRI: APRI Date:	Stage (0-5) : _____ ☐N/A ☐None Amount of Fibrosis: ☐Portal ☐ Periportal ☐ Bridging ☐Cirrhosis	
	Child-Turcotte-Pugh Score (CTP):	MELD:	Yes/No
	Viral load ordered Viral load: EQ/ml		Yes/No
5.0	Hepatitis B antibody/surface antigen ordered		Yes/No
	Hepatitis B vaccine given		Yes/No
	Genotype:		

6.0	TDOC HIV-HEP C Advisory Committee	Yes/No
	Liver biopsy Fibroscan Fibrotest Date:	Yes/No
	Treatment Approved	Yes/No

Required Documentation – include copies of the following with this request:

- ☐ CBC, serum creatinine and eGFR, liver panel, INR (dated within 90 days of request)
- ☐ HCV RNA viral load (reported as IU/ml) and genotype (dated with 90 days of request)
- ☐ HIV Ab – if positive, include CD4 and HIV viral load (dated within 90 days of request) and current antiretroviral medication regimen
- ☐ Hepatitis B serology (sAb and sAg) – if sAg reactive, include eAg, eAb, and HBV DNA viral load
- ☐ Liver biopsy report (if performed)
- ☐ For regimens with peginterferon include WBC differential, TSH & free T4 (dated within 90 days of request) and a mental health assessment (dated within 6 months of request)
- ☐ If cirrhosis (defined by pathology or clinical findings), include abdominal US or CT and EGD
- ☐ Pregnancy test if woman with child-bearing potential (dated within 90 days of request)
- ☐ Signed consent to Hepatitis C Treatment form

Comments: (other pertinent diagnosis or facts that will affect Treatment)

Submit with request for TACHH/Hepatitis C consultant

Attachment VI

Hep C Treatment Monitoring Schedule

Evaluation*	Baseline (anti-HCV positive)	Pretreatment (Within 90 days of Tx)	On-Treatment Monitoring (by week of treatment)**							12 wks post-treatment	6–12 mos post-treatment
			2	4	8	12	16	20	24		
Clinician evaluation	X	X	X	X	X	X	X	X	X	X	X
HIV Ab, HBsAg, HBsAb, Anti-HAV (IgG)	X										
Prothrombin Time / INR	X	X									
CBC	X	X	X	X	every 4 weeks during treatment						
Serum creatinine + eGFR	X	X		X						X	X
ALT, AST, bilirubin, alkaline, phosphatase, albumin	X	X									
APRI & CTP scores***	X	X									
HCV RNA, quantitative****	X	X		X	See footnote					X	X
HCV genotype		X									
Assess for drug-drug interactions & adherence		X	At each clinician evaluation during treatment								
Review incident report history for high risk behavior (alcohol / drug possession / use; tattooing)		X	if indicated								
Urine drug screen		X	if indicated								
Urine pregnancy test (if childbearing potential)		X		X	X	X	X	X	X	monthly x 6 mos	

* Conduct further diagnostic evaluations as clinically warranted to identify other potential causes of the patient's liver disease such as hemochromatosis, Wilson's disease, or autoimmune hepatitis (e.g., serum iron, serum copper,ANA/ ESR). If any of these conditions are diagnosed or are strongly suspected, a liver biopsy should be considered prior to treatment.

** More frequent monitoring may be required if clinically indicated.

*** A CTP score is calculated only for cases with known or suspected cirrhosis.

****For treatment regimens recommended in this document, the routine schedule of HCV RNA testing includes baseline and pretreatment testing, after 4 weeks on treatment, 12 weeks after completion of therapy, and if undetectable, again 6 to 12 months after completion of treatment . If the quantitative HCV viral load is detectable after 4 weeks of treatment, it should be repeated 2 weeks later. An HCV RNA is no longer necessary at the end of treatment unless undetectable levels were not achieved during treatment.

RIBAVIRIN-CONTAINING REGIMENS: A pretreatment ECG is recommended for inmates with preexisting coronary heart disease. A CBC should be obtained two weeks after starting treatment in addition to the routine monitoring schedule.

INTERFERON-CONTAINING REGIMENS: Pretreatment evaluation should include a WBC with differential, TSH / free T4 and a mental health evaluation. During treatment, a WBC with differential should be included with all CBCs, and TSH / free T4 should be checked every 12 weeks.

Source: FBOP Guidance on Evaluation and Management of Chronic HCV Infection

Note: TDOC guidance follows baseline labs evaluation with the addition of TSH

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TN Department of Correction | Office of the Commissioner

March 9, 2016

The Honorable Charles M. Sargent
House Finance, Ways and Means Committee
206 War Memorial Building
Nashville, TN 37243

Dear Chairman Sargent:

SUBJECT: Response to Questions Raised During the Hearing

First, let me thank you for the opportunity to speak before the House Finance, Ways and Means Committee on February 24, 2016. I always appreciate the chance to share the good work of the 6,000 correctional professionals who make up the Tennessee Department of Correction.

Second, during the hearing there were a few questions that arose which required a bit of research, ranging from a particular facility's staff to inmate ratio to the number of inmates with Hepatitis C. I wanted to ensure that the answers to these questions were provided in a timely manner for the committee.

Many of the questions were about staffing. During the first half of FY16 (July 1 through January 31), the turnover rate for the correctional security series was 17 percent. We believe this is due to the self-funded 5 percent assignment differential and the focus on recruitment and retention of officers. In 2015, the department also self-funded a one-time retention bonus for all Correctional Officers and increased our mentorship program to help new officers during their first year.

Additionally, the Department has instituted a Referral Incentive Program and a $600 Sign-On Bonus for new Correctional Officers. The Department has paid approximately $12,000 in referral bonuses and $300,000 in signing bonuses in the past year. Just over 70 percent of the Department's 6,458 employees were eligible for Performance Based increases this year as well.

Also if you look at the entire security series and the average facility population from FY15, the Department has a ratio of 4.55 inmates to every 1 officer. During the hearing, we were asked about two facilities in particular. West Tennessee State Penitentiary has a 4.67-to-1 ratio and Turney Center Industrial Complex ratio is 5.15:1.

There were also inquiries about the Department's treatment of inmates with Hepatitis C. Currently, TDOC offers the most up-to-date treatment available for Hepatitis C. Testing positive does not necessarily mean a person still has Hepatitis C or needs to be treated with medication. Once people have been infected, they will always have antibodies in their blood. This is true if even if they have cleared the Hepatitis C virus. A reactive antibody test requires an additional, follow-up test to determine if a person is currently infected with Hepatitis C.

In TDOC 3,487 people preliminarily tested positive for the Hep C virus. However, not everyone needs or can benefit from treatment. The doctor on site determines the most appropriate medical care. Decisions about starting treatment are based on many factors, such as the type of virus, the condition of the liver, and other health conditions. Those patients that are identified as being Hepatitis C positive are then enrolled in chronic care clinics to ensure their disease process is followed.

The Department has also established the Tennessee Advisory Committee on HIV and Viral Hepatitis Prevention and Treatment Committee. This is an additional layer of oversight to ensure that the most serious cases are prioritized and treated appropriately. This means they meet with a medical professional every 90 days or as clinically indicated.

Finally, there were a few questions about the Department's proposed budget. The first question dealt with why the budget has grown since FY11. Over the last five years, three significant events have contributed to the budget growth. These events include the addition of Community Supervision to TDOC, the offender population increase, and the expansion of Bledsoe County Correctional Complex.

In FY12 Community Supervision moved from the Board of Parole to TDOC. This included the addition of the staff and their caseloads. The Department went from supervising approximately 20,000 inmates behind bars to supervising more than 100,000 offenders both behind bars and in the community. As you can see, this increase in responsibilities required an obvious increase in funding. Later Bledsoe County Correctional Complex expanded to become a state-of-the-art intake and diagnostic facility for the state. These three important and significant achievements were not only in line with industry best practices but were necessary as Tennessee pushes forward to be a leader in offender management.

Chairman, the Tennessee Department of Correction is always happy to answer questions from members of the General Assembly. We are always excited to share the good work that we do and enjoy the opportunity to tell you about how the 6,000 Tennesseans who work in our Department are committed to enhancing public safety. As always, if you have any additional questions, please do not hesitate to contact me.

Sincerely,

Derrick D. Schofield
Commissioner

DDS:NT

TN Department of Correction

CustomerFocused GOVERNMENT
Great People. Great Service.

EXHIBIT 1

Management of Chronic Hepatitis C Virus (HCV)

Prepared for
Commissioner Derrick Schofield

May 20, 2016

TN Department of Correction

AGENDA

Customer Focused GOVERNMENT
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- Purpose
- End State
- Background
- Current Status
- Challenges
- Discussion

TN Department of Correction

PURPOSE

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Discuss HCV disease process and progression.

Review current national recommendations.

Review current guidelines employed by other DOC.

Review current TDOC guidelines.

Review current TDOC status.

Discuss national and TDOC challenges.

TN Department of Correction

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END STATE

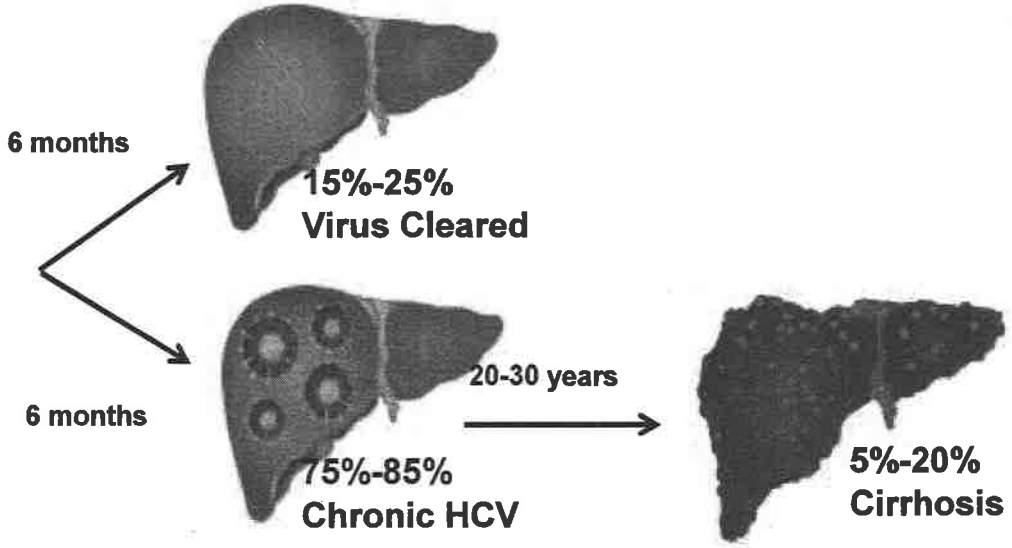
Accessible quality healthcare to enhance public health.

BACKGROUND

- Approximately 2% world population has chronic HCV.
- Approximately 3.2 million US population (7 million).
- About 12,000 deaths per year.
- 23% - 41% of incarcerated population
- 5% - 11% Veterans
- Yale University: 0.17% incarcerated currently Tx

Pathology & Progression

- 6 months: 15 -25 % clear virus (w/o Tx)
- 6 months: 75- 85% chronic Dz
- 20-30 years: 5-20 % Cirrhosis



National Guidelines

- US Preventive Task Force Recommendations

In June 2013, the USPSTF issued its final recommendations regarding HCV screening:

  - Those at high risk for HCV infection
  - Those born from 1945 to 1965 (one-time screening of "Baby Boomers", regardless of risk)

- AASLD (American Association for the Study of Liver Disease)
  - Tx everyone

- Veterans Administration
  - Tx everyone

National Guidelines

- FBOP (Federal Bureau of Prisons (4/2016)
  - Screen all inmates, certain conditions, IM request
  - Inmate education
  - Co-infection testing (HIV, HBV, HepA)
  - DAA primary regimen

DOC Guidelines

- 28 states: Tx by fibrosis
- 16 states: liver failure
- 29 states: remaining sentence
- 4 states: chance of recidivism
- 8 states: chance of re-infection
- 2 states: stability of mental/physical health
- Several states consider disciplinary infractions in previous year

TN Department of Correction

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TDOC Guidelines

- Policy/Procedure
  - Coalition of Correctional Health Authorities
  - Updated HCV Treatment Guidelines (1/16)
    - Next revision 7/16 (FBOP 5/17/16)
  - Established TACHH, TDOC Advisory Committee on Hepatitis C and HIV
    - CMO, AMD, Centurion CMO, Centurion MD, Centurion AMD, CCA CMO, Hepatology consultant, ID consultant

TDOC Guidelines

- Screen:
  - Inmates w/ risk factors
  - Certain Clinical conditions (HBV, HIV,IV drug, dialysis, HCV + mother, abnormal lab)
  - Inmate request

TDOC Guidelines

- Priority:
  - Liver Failure
  - Fibrosis/Cirrhosis
  - Remaining sentence
  - Infractions

- Regimens:
  - FDA approved regimens

Management of Chronic HCV

TDOC Current Status

Department of Correction

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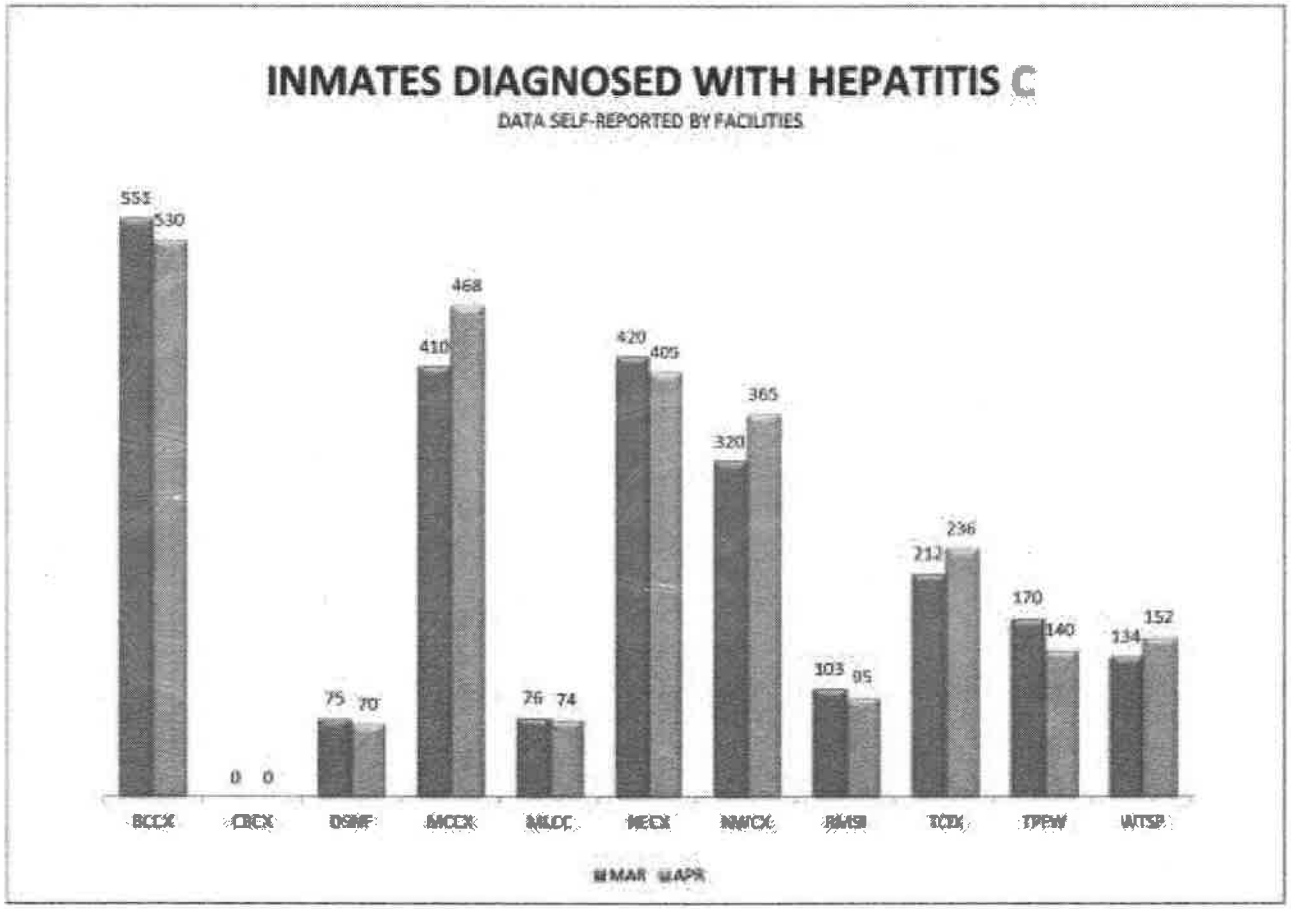

MARCH 2016: 2471 APRIL 2016: 2535
2015 YTD MONTHLY AVERAGE: 2495.3
2016 YTD MONTHLY AVERAGE: 2626.6
YTD TOTAL: 10507

Management of Chronic HCV

TDOC Current Status

TN Department of Correction

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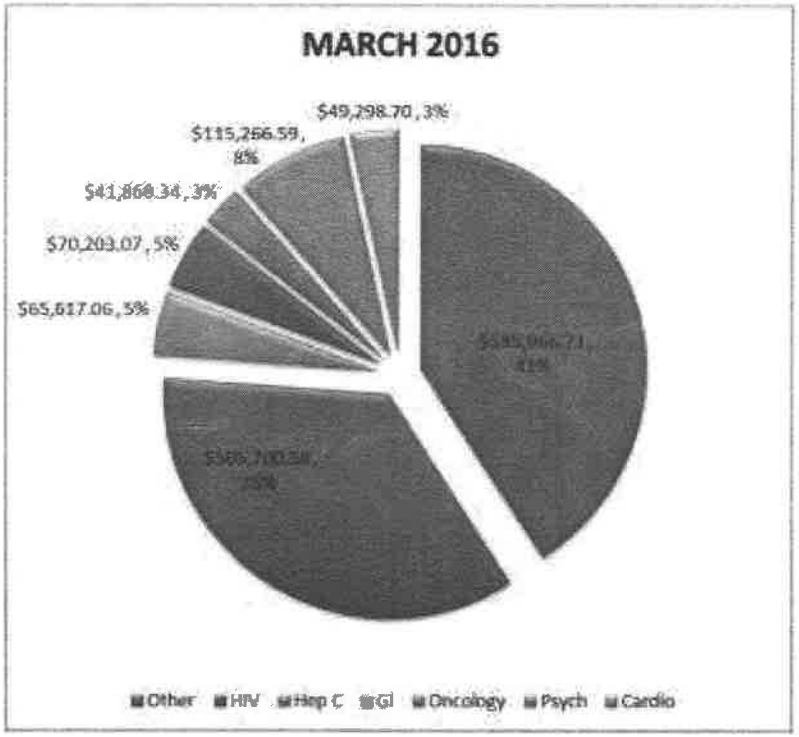
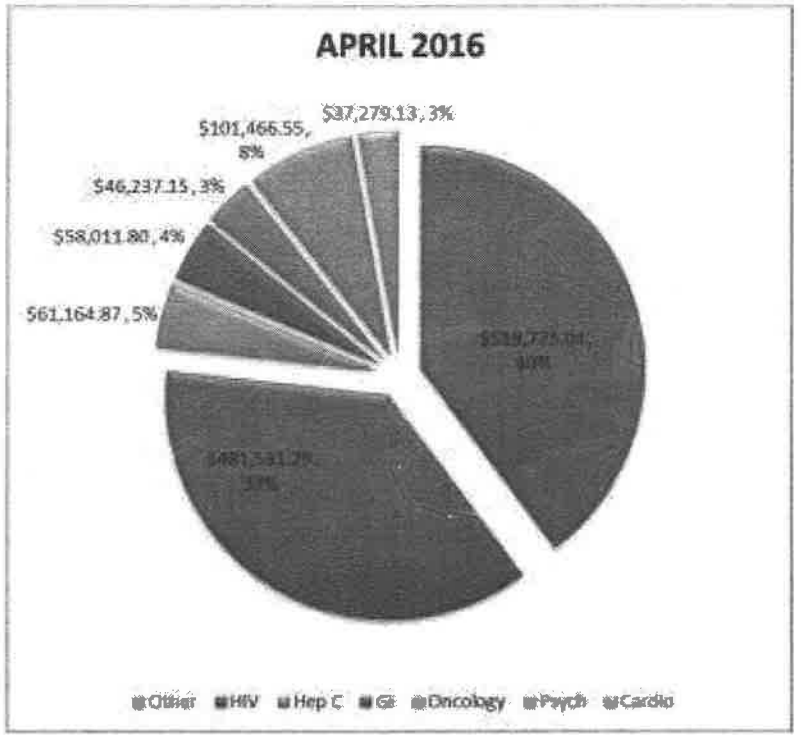
PHARMACEUTICAL COSTS[5]

DATA PROVIDED BY CENTURION TN





MARCH 2016: $1,433,921.05

APRIL 2016: $1,305,465.83

2015 YTD MONTHLY AVERAGE: $1,271,398.78

2016 YTD MONTHLY AVERAGE: $1,332,178.11

[4+5]see page 13

TDOC Current Status

12 week Regimens			
Medication	Current Pricing	Primary Wholesale Pricing	Retail Pricing
Sovaldi	$74,493	$82,320	$100,800
Harvoni	$54,969	$92,610	$113,400
24 week Regimens			
Medication	MMCAP Pricing	Primary Wholesale Pricing	Retail Pricing
Sovaldi	$148,986	$164,640	$201,600
Harvoni	$109,938	$185,220	$226,800

Challenges

- Testing:
  - Risk Vs Benefit
  - Partnerships
- Resources:
  - $167,215,698.00
  - Line item budget request ($1 million => $600K)
  - Cost sharing w/ vendor (50%)

Discussion

THE HONORABLE JOHN C. COUGHENOUR

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

B.E. and A.R., on their own behalf and on behalf of all similarly situated individuals,

Plaintiffs,

v.

DOROTHY F. TEETER, in her official capacity as Director of the Washington State Health Care Authority,

Defendant.

CASE NO. C16-227-JCC

ORDER GRANTING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

This matter comes before the Court on Plaintiffs' motion for a preliminary injunction (Dkt. No. 18), Defendant's opposition to both motions (Dkt. No. 29), and Plaintiffs' reply (Dkt. Nos. 35). Having thoroughly considered the parties' briefing and the relevant record, the Court finds oral argument unnecessary and hereby GRANTS the motion for the reasons explained herein.

I. BACKGROUND

Plaintiffs in this action are Washington Medicaid enrollees who have contracted Hepatitis C ("HCV"), a chronic, contagious liver disease, but have not received the life-altering medication they have been prescribed, known as Direct-Acting Antivirals ("DAAs"). (Dkt. No. 1 at 3.) Plaintiffs bring this case on behalf of others similarly situated.

As it progresses, HCV causes severe liver damage, among the many other effects

including heart attacks, diabetes, fatigue, joint and muscle pain, depression, nerve damage, and jaundice. (Dkt. No. 19 at 2.) The virus's progressive damage, known as "fibrosis," is scored on an ascending fibrosis score of F0 (no liver damage) through F4 (cirrhosis of the liver). (*Id.* at 3.) HCV is both widespread and deadly: over 20,000 people in the United States die every year due to liver disease caused by HCV. (*Id.* at 2.)

Before DAAs were available, the main treatment for HCV was a three-drug course of treatment that resulted in, at most, a 70% cure rate, and was accompanied by significant adverse side effects. (Dkt. No. 19 at 3–4.) The FDA began approving DAAs in 2011 and designated them as "breakthrough therapies," a classification given to "drugs that have proved to provide substantial improvement over available therapies for patients with serious or life-threatening diseases." (*Id.* at 4.) Harvoni, a DAA treatment, was FDA-approved on October 10, 2014 and has a success rate of achieving "sustained virological response [] of nearly 100%, with little to no side effects. (*Id.*)

Plaintiffs bring a claim under 42 U.S.C. § 1983, alleging violation of Title XIX of the Social Security Act (also known as the "Medicaid Act") against the Washington State Health Care Authority ("WHCA") and seek declaratory and injunctive relief pursuant to 28 U.S.C. §§ 2201 and 2202. (Dkt. No. 1 at 13–15.) On March 18, 2016, Plaintiffs moved to certify their class and also moved for a preliminary injunction. (Dkt. Nos. 17 and 18.) Plaintiffs, on behalf of the proposed class, request that the Court "enjoin [the] WHCA from continuing to apply its February 25, 2015 HCV treatment policy, including its exclusion of all treatment based on fibrosis score, and to require WHCA to return to providing coverage for prescription medications to treat Hepatitis C virus ("HCV") without regard to fibrosis score, consistent with existing state and federal Medicaid requirements." (Dkt. No. 18 at 10.) In this Order, the Court addresses Plaintiffs' request for injunctive relief but does not yet reach the class certification question.

At the center of this dispute is the WHCA's HCV treatment policy, which excludes Plaintiffs from receiving these breakthrough therapies, DAAs. On February 25, 2015, the WHCA

implemented a Hepatitis C Treatment Policy ("Policy") restricting DAA coverage based on enrollees fibrosis score and other health conditions. (Dkt. No. 1-1.) Plaintiffs contend that the Policy categorically excludes "all monoinfected patients—patients without another diagnosis, such as HIV—who have a fibrosis score of F0 through F2." (Dkt. No. 18 at 13.) Many insurers in Washington State have voluntarily removed similar restrictions on the availability of HCV treatment, including Premera BlueCross, Aetna, United Healthcare, Medicare, and the VA. (*See* Dkt. No. 18 at 8) (linking to policies). Other insurers, Bridgespan, Regency BlueShield, and Group Health Cooperative, changed their policies within weeks after lawsuits were filed against them on similar grounds to those brought in the above-captioned matter. (Dkt. No. 24 at 4.)

II. PRELIMINARY INJUNCTION

A. Legal Standard

Under Fed. R. Civ. P. 65(a), the Court may issue a preliminary injunction if a plaintiff establishes that she "[1] is likely to succeed on the merits, [2] that [s]he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in [her] favor, and [4] that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Mandatory preliminary injunctions, the kind requested here, are generally disfavored in the law as they seek relief beyond maintaining the status quo, and will only be ordered when the law and facts clearly favor the moving party. *Stanley v. Univ. of S. Cal.*, 13 F.3d 1313, 1319–20 (9th Cir. 1994).

B. Success on the Merits

Plaintiffs assert claims under 42 U.S.C. § 1983, alleging that the WHCA failed to provide medically necessary treatment as required by the Medicaid Act. Plaintiffs claim that the WHCA's HCV policy violates three distinct provisions of federal Medicaid law: (1) excluding qualified Medicaid recipients from "medically necessary" treatment as required by 42 U.S.C. § 1396a(a)(10(A); (2) discriminating among similarly situated Medicaid recipients in violation of 42 U.S.C. § 1396a(a)(10)(B)(i); and (3) failing to provide medically necessary treatment with

"reasonable promptness" as required by 42 U.S.C. § 1396a(a)(8). The Court first considers the likelihood of Plaintiffs' success on the merits of these claims.

a. Medically Necessary Treatment

The Court first considers the likelihood that Plaintiffs will prevail on their claim that the WHCA failed to provide "medically necessary" DAAs for enrollees in violation of 42 U.S.C. § 1396a(a)(10(A). WHCA participates in Medicaid, receiving federal matching funds, and therefore is required to provide payment for FDA-approved, covered prescription drugs to all Medicaid enrollees when the treatment is "medically necessary." *Alvarez v. Betlach*, 572 F. App'x 519, 520–21 (9th Cir. 2014); *see also Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378, 1382 (2015) ("Medicaid offers the States a bargain: Congress provides federal funds in exchange for the State's agreement to spend them in accordance with congressionally imposed conditions.").

i. State and Federal Legal Structure

The federal Medicaid Act and Washington Administrative Code set forth the legal structure that guides the Court's analysis. The crux of this claim is whether the WHCA's Policy excludes DAAs that are "medically necessary." Plaintiffs have provided strong evidence that DAAs are, in fact, "medically necessary," as defined by law, for all enrollees with HCV, regardless of fibrosis score. They submitted a plethora of exhibits showing that providing DAAs to all HCV-infected enrollees is the standard espoused by national liver disease organizations and experts, leading medical officers of major Washington providers and the federal agency responsible for administering Medicaid. These facts "clearly favor" Plaintiffs' claim that the WHCA's Policy excluding monoinfected enrollees with a Fibrosis score of F0-F2 violates Federal law. *Stanley* at 1319–20.

The WHCA is the sole state agency responsible for implementing the Medicaid program. (Dkt. No. 18 at 13.) As the agency has opted to provide prescription drug coverage, the Medicaid program must adhere to the Medicaid Act's specific limits regarding prescription drugs. (*Id.*)

(Citing RCW §§ 74.04.055; 74.08.090); *see also* 42 U.S.C. § 1396a(a)(54). Under § 1396a(a)(10)(A), the Medicaid Act "prohibits states from denying coverage of 'medically necessary' services that fall under a category covered in their Medicaid plans." *Alvarez v. Betlach*, 572 F. App'x 519, 521 (9th Cir. 2014) (quoting *Beal v. Doe*, 432 U.S. 438, 444 (1977)). The Washington Administrative Code provides the definition of "[m]edically necessary":

> [A] term for describing requested service which is reasonably calculated to prevent, diagnose, correct, cure, alleviate or prevent worsening of conditions in the client that endanger life, or cause suffering or pain, or result in an illness or infirmity, or threaten to cause or aggravate a handicap, or cause physical deformity or malfunction. There is no other equally effective, more conservative or substantially less costly course of treatment available or suitable for the client requesting the service. For the purposes of this section, "course of treatment" may include mere observation or, where appropriate, no medical treatment at all.

Wash. Admin. Code 182-500-0070.

The WHCA's procedure for determining whether a requested service is "medically necessary" is established in Wash. Admin. Code 182-501-0165(6). First, the agency rates the evidence of the service's effectiveness and safety on a scale from A to D, with A being the highest level. Wash. Admin. Code 182-501-0165(6). If the requested service has an evidence level of A or B, then it must be approved so long as it does not expose the enrollee "to a greater risk of mortality or morbidity" and "is not more costly" when compared to an equally effective treatment. Wash. Admin. Code 182-501-0165(6)(c)(i).

ii. Plaintiffs' Evidence

It is undisputed that DAAs such as Harvoni have been rated at an "A" evidence level. (Dkt. No. 19 at 10.) Defendants concede that there is no equally effective alternative medication. (Dkt. No. 16 at 4.) Despite this rating, the current WHCA Policy mandates rejecting DAA requests from enrollees who have an F0-F2 fibrosis score, absent other concerning health factors, and instead offering "monitoring" as the "equally effective treatment" in lieu of DAAs. (*See* Dkt. No. 1-1.) Plaintiffs argue that mere "monitoring" is not an equally effective treatment

because "waiting until a Medicaid enrollee's liver is damaged before providing treatment is harmful to his/her health and significantly increases the risk of both morbidity and mortality." (Dkt. No. 18 at 19–20.) Plaintiffs provide a plethora of evidence to support this assertion.

Plaintiffs provide a letter from liver specialists, physicians, and the medical officers of nearly every major health care provider in the State of Washington, urging the Washington Insurance Commissioner to remove restrictions on the availability of life-saving HCV treatment. (Dkt. No. 19-1 at 32–35.) The letter states in part, "The cost of these drugs cannot compare to the human toll on our patients and their families and the eventual cost and expense we would pay as a society by postponing treatment." (Dkt. No. 19-1 at 33.)

Plaintiffs attach an internal meeting transcript in which Donna L. Sullivan, M.S., Pharm.D., the WHCA's Chief Pharmacy Officer, stated with respect to patients with HCV: "I can guarantee you that all of us agree that everyone should be treated whether they are at stage 2, stage 3, stage 4." (Dkt. No. 24-1 at 10.) Ms. Sullivan identified fiscal concerns as the sole basis for the WHCA's exclusionary policy, adding, "we have received funding only based on the criteria that we gave for F3 . . . It's out of our hands. None of us would argue that we should not expand it, that it's not the right thing to do, but we live in a political environment as a state that I have to operate within the resources and the rules around those resources that have been given to us." (*Id.*)

Furthermore, the Centers for Medicare and Medicaid Services ("CMS"), the federal agency responsible for the administration of Medicaid, has specifically rejected the WHCA's current policy. On November 5, 2015, CMS issued a Notice entitled, "Assuring Medicaid Beneficiaries Access to Hepatitis C Drugs." (Dkt. No. 24-1 at 27–30.) In the Notice, CMS explicitly states: "CMS is concerned that some states are restricting access to DAA HCV drugs contrary to the statutory requirements . . . by imposing conditions for coverage that may unreasonably restrict access to these drugs. For example, several state Medicaid programs are limiting treatment to those beneficiaries whose extend of liver damages has progressed to [a]

fibrosis score [of] F3 . . ." (*Id.* at 28.) This interpretation of the Medicaid Act is entitled to deference. *Katie A. v. L.A. Cnty.*, 481 F.3d 1150, 1155, n. 11 (9th Cir. 2007).

Finally, the use of DAAs such as Harvoni is considered the "standard of care" by the American Association for the Study of Liver Disease ("AASLD") and the Infectious Diseases Society of America ("IDSA"). (Dkt. No. 19 at 4.)

Despite these facts, the WHCA argues that the Policy is in line with the "medically necessary" definition because monitoring is suitable for people who have HCV but show either mild or no symptoms. (Dkt. No. 29 at 16.) The WHCA does not address the liver damage that enrollees could suffer during this "monitoring" period and, instead, argues that by refusing to provide the DAA drugs, the Policy "ensures these people are not unnecessarily exposed to the currently ill-defined risks of these new medications." (*Id.*) This assertion of "ill-defined risks" is not supported by any clinical evidence and is contradicted by the WHCA's own documents.

In fact, when the WHCA was making a budget request to cover DAAs like Harvoni, it presented a completely opposite argument. The WHCA's 2016 Supplemental Budget Request Adjustment states that DAAs like Harvoni are "highly effective," "safe," and even "cost-effective." (Dkt. No. 24-1 at 2–3.) The Budget Request refutes the argument now presented by the WHCA that there are "ill-defined risks" associated with DAAs, stating instead that "because the new therapies are so effective, there is the potential to completely eradicate [HCV]." (Dkt. No. 24-1 at 15.) The extensive evidence provided by the Plaintiffs and the lack of substantial counter-evidence from the WHCA establishes that there is a consensus among medical experts and providers that the life-saving DAAs are "medically necessary" for all HCV-infected persons, regardless of Fibrosis score. Plaintiffs have adequately demonstrated that they are likely to prevail on their claim.

The WHCA argues that its interpretation of what is "medically necessary" is entitled to deference. (Dkt. No. 19 at 10–11.) This Court has previously considered a similar argument in *A.H.R. v. Washington State Health Care Authority*, 2016 WL 98513, at *14 (W.D. Wash. Jan. 7,

2016) (Robart, J.). In *A.H.R.*, the Court declined to defer to the WHCA because there was no indication that CMS was aware of the WHCA's practices. *Id.* In this case, unlike in *A.H.R.*, CMS has explicitly stated that policies like the WHCA's contravene the Medicaid Act. (*See* Dkt. No. 24-1 at 27–30.) In other words, the agency to defer to under *Chevron*, CMS, has clearly stated that the WHCA's HCV policy defies the relevant statutory requirements.

The WHCA does not address whether its Policy is in line with the procedure enumerated in Wash. Admin. Code 182-501-0165(6). Instead, the WHCA asserts that the "Policy is the agency's best attempt at making reasonable medical necessity determinations." (Dkt. No. 29 at 15.) However, whether the WHCA made its "best" attempt is not the pertinent standard. The appropriate legal test is whether Plaintiffs will likely establish that the current WHCA Hepatitis C Treatment Policy deprives Medicaid enrollees from access to a life-saving drug in situations where it is "medically necessary." And this turns on whether there is an equally effective alternative treatment that does not expose the enrollee to "a greater risk of mortality or morbidity." WAC 182-501-0165(6)(c)(i)(A). The Court is satisfied that Plaintiffs' evidence will likely establish that the WHCA is failing to follow its own definition of medical necessity by refusing to provide DAAs to monoinfected enrollees with a F0-F2 score and offering only "monitoring" in lieu of this breakthrough treatment.

b. Medicaid Comparability & Reasonable Promptness

The Court finds that Plaintiffs are likely to succeed on the merits of their first claim. Plaintiffs' latter two claims similarly turn on whether DAAs are "medically necessary" because if they are given that designation, then the Medicaid Act requires the WHCA to provide that treatment with "reasonable promptness" in a non-discriminatory manner. For the same reasons discussed above, the Court concludes that Plaintiffs are likely to succeed on the merits with respect to their second and third claims.

C. Likelihood of Irreparable Harm

Next, the Court considers whether Plaintiffs are likely to suffer irreparable harm in the

absence of this preliminary injunction. *Winter*, 555 U.S. at 20.

It is well-established that denying necessary Medicaid services causes irreparable harm. *Rodde v. Bonta*, 357 F.3d 988, 999 (9th Cir. 2004) (finding that while the injunction would cause the county financial hardship, the plaintiffs met their burden by showing delayed or lack of necessary treatment, increased pain, and medical complications); *Beltran v. Myers*, 677 F.2d 1317, 1322 (holding that plaintiffs' showing of risk of irreparable injury as a result of denying needed medical care was sufficient to meet this factor for a preliminary injunction).

Plaintiffs argue, persuasively, that without an injunction "they are at imminent risk of deteriorating health, liver damage and even death." (Dkt. No. 18 at 25.) Plaintiffs maintain that denying "necessary medical benefits directly impacts an individual's health, creating '(1) substantial risk to plaintiffs' health; (2) severe financial hardship; (3) the inability to purchase life's necessities; and (4) anxiety associated with uncertainty.'" (*Id.*) (quoting *LaForest v. Former Clean Air Holding Co., Inc.*, 376 F.3d 48, 55 (2nd Cir. 2004)).) The WHCA argues that this claim of imminent risk is "completely speculative." (Dkt. No. 29 at 20.)

An experience endured by a Medicaid enrollee provides a clear example of the substantial risk of deteriorating health and death presented by the Policy. L.B., a Washington Medicaid enrollee, was prescribed Solvaldi, a DAA, in July 2014. (Dkt. No. 23 at 1–2.) His request was denied. (*Id.* at 2.) The WHCA's letter on August 21, 2014 states that because L.B. did not have a fibrosis score of "F3 or greater," the treatment was not "medically necessary." (Dkt. No. 23-1 at 5.) Soon after, in October 2014, Harvoni was approved by the FDA and L.B.'s provider submitted his prescription to WHCA. (Dkt. No. 23 at 2.) His provider noted that his "cirrhosis and renal function [were] worsening. [He n]eeds HCV treatment ASAP" and that [w]ithout it, [he will] likely die." (*Id.*) Again, his request was denied.[1] (*Id*). While he awaited a

[1] The WHCA notes that L.B.'s request for Harvoni was denied because "his provider did not provide requested documentation" and asserts that if documentation of Hepatitis C induced renal disease would have been sent the Harvoni request would have been approved. (Dkt. No. 29 at 21, n. 9.) However, under the proposed injunction, L.B.'s provider would not need to submit additional documentation because the

hearing on his Medicaid administrative appeal, "his kidneys deteriorated so significantly that his provider could no longer recommend Harvoni." (*Id.* at 2–3.) In other words, the window of L.B.'s ability to seek a cure for his HCV has likely closed. This is not speculative harm. It is concrete evidence that under the Policy, an enrollee suffered such severe liver damage that DAA treatment may no longer be an available option.

In arguing that Plaintiffs will not suffer irreparable harm, the WHCA again contradicts its own pronouncements. The WHCA argues in its response brief that a HCV diagnosis alone, "without further complicating factors, does not warrant authorization" of DAAs like Harvoni. (Dkt. No. 29 at 20.) And in a budget request, the WHCA noted that only treating "people with more severe disease[,] those patients who by definition have cirrhosis, liver cancer or are in need of a liver transplant[,] . . . would be objectionable from a medical ethical standpoint." (Dkt. No. 24-1 at 16.)

Plaintiffs have introduced compelling evidence that they will suffer irreparable harm if the preliminary injunction is denied. This factor weighs strongly in favor of a preliminary injunction.

D. Balance of Equities and Public Interest

Next, the Court assesses whether the balance of equities tips in Plaintiffs' favor and the injunction is in the public interest. *Winter*, 555 U.S. at 20. These factors may be considered together. *A.H.R. v. Wash. State Health Care Auth.*, 2016 WL 98513, at *17 (W.D. Wash. Jan. 7, 2016). As discussed above, Plaintiffs' evidence establishes they will suffer severe hardship if the WHCA continues to follow the Policy. The Ninth Circuit holds that "the balance of hardship favors beneficiaries of public assistance who may be forced to do without needed medical

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request would have been approved on the basis of his HCV diagnosis alone. He suffered irreparable damage to his liver because the WHCA's policy required proof of other concerning health factors with an F2 fibrosis score. Moreover, his initial request for DAA treatment in July 2014 was denied because WHCA determined it was not "medically necessary." (Dkt. No. 23 at 2.) The WHCA does not address this determination.

services over a state concerned with conserving scarce resources." *M.R. v. Dreyfus*, 697 F.3d 706, 737–38 (9th Cir. 2012). The Ninth Circuit also noted the strong public interest in protecting access to health care for Medicaid enrollees, those deemed by Congress as "the most needy in the country." *Id.* (quoting *Schweiker v. Hogan*, 457 U.S. 569, 590 (1982)).

Plaintiffs argue that the injunction is in the public interest because it seeks to bar a public agency from violating "existing law." (Dkt. No. 18 at 27.) The Court agrees. "[H]aving government officials act in accordance with law . . . invokes a public interest of the highest order." *Seattle Audubon Soc. v. Evans*, 771 F. Supp. 1081, 1096 (W.D. Wash. 1991). Furthermore, as Plaintiffs emphasize, an injunction is an important matter for the public because it deals with the treatment and management of a communicable disease. (Dkt. No. 18 at 27.)

The WHCA argues that the injunction would double the State's Medicaid outpatient Pharmacy budget and cause them to reduce Medicaid enrollments, benefits, or provider rates to compensate for the increased expenditure in HCV treatment. (Dkt. No. 29 at 22.) The Ninth Circuit has also addressed the question of balancing the risk of irreparable harm with the risk of financial hardship for the enjoined institution. Posed with this question, the Ninth Circuit held that when "[f]aced with such a conflict between financial concerns and human suffering, we have little difficulty concluding that the balance of hardships tips decidedly in plaintiffs' favor." *Lopez v. Heckler*, 713 F.2d 1432, 1437 (9th Cir. 1983).

In conclusion, the Court finds that the Plaintiffs have satisfied all factors necessary to warrant granting a preliminary injunction.

E. Scope of Injunction

The WHCA is hereby ENJOINED from continuing to apply its February 25, 2015 HCV treatment policy, including its exclusion of all treatment based on fibrosis score, and is required to return to providing coverage for prescription medications to treat Hepatitis C virus ("HCV") without regard to fibrosis score, consistent with existing state and federal Medicaid requirements. The parties are hereby ORDERED to submit a joint status report to the Court sixty (60) days

after the date of this order with an update as to the implementation of these changes.

F. Pending Class Certification Motion

The Court's review of Plaintiffs' motion for class certification (Dkt. No. 17) remains pending.

III. CONCLUSION

For the foregoing reasons, Plaintiffs' motion for a preliminary injunction (Dkt. No. 18) is GRANTED.

DATED this 27th day of May 2016.

John C. Coughenour
UNITED STATES DISTRICT JUDGE

`DESCRIPTION of the

TDOC ADVISORY COMMITTEE ON HIV AND VIRAL HEPATITIS

PREVENTION AND TREATMENT

Authority

The Tennessee Department of Corrections (TDOC) Advisory Committee on HIV, Viral Hepatitis Prevention and Treatment (TACHH) will be established in early 2014. The committee is has been granted authority to assist in recommending treatments for communicable infectious illnesses as directed by the TDOC Medical Director.

Objective and Scope of Activities

The Medical Director, Tennessee Department of Corrections (TDOC), and by delegation, the Medical Director of Centurion Healthcare, and their designees, known as advisory board members, are authorized to: (1) conduct, encourage, cooperate with, and assist TDOC as it relates to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases, and other impairments related to communicable infectious disease namely HIV/AIDS/Hepatitis; (2) assist in preventing and suppressing communicable diseases and other preventable conditions and in promoting health and well-being; and (3) assist developing public and non-profit partnerships that can assist in preventing and controlling hepatitis and HIV, including Acquired Immunodeficiency Syndrome (AIDS) and assist the affected in reentry in society upon sentence expiration.

Description of Duties

Consistent with the scope of activities described above, the TACHH is authorized to perform the following tasks:

1. Undertake such information gathering activities as necessary to define issues for consideration by the TACHH, develop positions on those issues, and communicate the board member's position to the TDOC Medical Director, Chair and Centurion Medical Director, Co-chair.
2. Provide TDOC with ongoing medical expertise to shape decisions about the health and wellness of inmates living with HIV/AIDS and viral Hepatitis.
3. Advise TDOC on the development of uniform hepatitis treatment standards.
4. Provide advice and recommendations for the treatment regimens for HIV/AIDS and viral Hepatitis for individuals with HIV/AIDS and viral Hepatitis.
5. The TDOC Advisory Committee on HIV and Viral Hepatitis Prevention and Treatment shall advise the TDOC and its vendor partners: Centurion, CCA, and Corizon regarding objectives, strategies, policies, and priorities for HIV and Viral Hepatitis prevention and treatment efforts including selection of appropriate pharmaceutical treatment regimens, improving surveillance of HIV infection, AIDS, Viral Hepatitis, and related behaviors; identification of policy issues related to HIV/ Hepatitis professional education, patient healthcare delivery, and prevention services; departmental policies about prevention of HIV/AIDS, Viral Hepatitis, treatment, healthcare delivery, and training; strategic issues influencing the ability of TDOC and its vendor partners to

fulfill their missions of providing prevention and treatment services; programmatic efforts to prevent and treat HIV and Viral Hepatitis; and support to the department in their development of responses to emerging health needs related to HIV, and Viral Hepatitis.

6. To assist TDOC and its vendor partners in carrying out their responsibilities, the TDOC Advisory Committee on HIV and Viral Hepatitis Prevention and Treatment will assess TDOC's activities related to the Human Immunodeficiency Virus (HIV), AIDS, and Viral Hepatitis, and make recommendations for the future directions of TDOC's programs to prevent, control, and treat HIV/AIDS, and Viral Hepatitis. TACHH will advise TDOC and vendor partners on activities related to the prevention and control of HIV/AIDS, and Viral Hepatitis, the support of healthcare services to persons living with HIV/AIDS, and the education of health professionals and the public about HIV/AIDS, and Viral Hepatitis. The committee will support the departments' process of identifying and responding to the prevention and health service delivery needs of affected prison sites across Tennessee, and the needs of individuals living with or at risk for HIV, and Viral Hepatitis.

Official to Whom the Committee Reports

The committee reports to the TDOC Medical Director and/ or the Centurion Healthcare Medical Director.

Support

Management and support services shall be provided by TDOC and its vendor partners.

Designated Board Chair (DBC)

TDOC Medical Director or Centurion Medical Director will be present to preside as Chair of the committee. At least one Medical Director will attend each committee meeting and ensure that all procedures are within applicable policies. The DBCs will approve and prepare all meeting policies and agendas, call all of the committee, adjourn any meeting when the DBCs deems adjournment to be in the public interest, and chair meetings. The DBCs or their designee(s) shall be present at all meetings of the full committee.

Meetings

Meetings shall be held at least four a year at the call of the DBCs, in consultation with the co-chairs. An emergency meeting may be arranged as necessary with at least one month's notice. The DBCs shall also approve the agenda and shall be present at all meetings. Meetings shall be open to TDOC medical personnel except as determined otherwise by the TDOC Medical Director to whom the authority has been delegated.

Termination Date

Unless renewed by appropriate action prior to its expiration, the TACHH will terminate three years from the date this charter is filed.

Membership and Designation

The committee shall consist of at least three physician members, in addition to the TDOC Medical Director, Chair, and the Centurion Medical Director, Co-Chair. TDOC and Centurion shall recommend nominees for committee membership. Members shall be selected by the TDOC Medical Directors and Centurion Medical Director, or his/her designee, from authorities knowledgeable in the fields of infectious disease; hepatology; preventive, family and internal medicine; public health; immunology; drug abuse; behavioral science; pharmacy; and healthcare financing.

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