IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SALVATORE CHIMENTI, et al.,	:	
	:	
Plaintiff,	:	
	:	**Civil No. 15-CV-3333**
vs.	:	
	:	
PENNSYLVANIA DEPARTMENT OF CORRECTIONS, et al.	:	**Judge John R. Padova**
	:	
	:	
Defendants.		

SETTLEMENT AGREEMENT AND GENERAL RELEASE

This SETTLEMENT AGREEMENT ("Settlement Agreement" or "Agreement") sets forth the terms of the settlement by and between the individual and class Plaintiffs and Defendants Pennsylvania Department of Corrections ("DOC"), Secretary John Wetzel, and Dr. Paul Noel (collectively, the "DOC" defendants), on Plaintiffs' claims for injunctive relief.

INTRODUCTION

WHEREAS, Plaintiffs filed this lawsuit, on behalf of themselves and other similarly situated inmates who are in the custody of the DOC, alleging that the DOC, under its Hepatitis C Protocol and related practices, fails to provide necessary medical care to all inmates with Chronic Hepatitis C, in violation of the Eighth Amendment of the United States Constitution.

WHEREAS, Plaintiffs and the DOC, without conceding any infirmity in their claims or defenses, have engaged in settlement negotiations to resolve the claims raised in this litigation and recognize that it is in their mutual best interest to fully resolve and finally settle any and all past, existing, and/or potential injunctive and equitable claims between the Plaintiffs and the DOC defendants relating to the Hepatitis C treatment.

WHEREAS, the DOC is entering into this Settlement Agreement for the purpose of settlement and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law or regulation, or of any other matter of fact or law, or of any liability or wrongdoing (including allegations of the Amended Complaint), all of which the DOC expressly denies. The DOC does not admit to any violation of law and does not admit to any wrongdoing that was or could have been alleged by the Plaintiffs. No part of this Agreement, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by the DOC or the DOC defendants.

WHEREAS, this Agreement is made without trial or adjudication of any issue of fact or law or finding of wrongdoing or liability of any kind. It is the intent of the parties that this Agreement shall not create a private cause of action or confer any right to any third party for violation of any federal or state statute.

NOW, THEREFORE, IT IS HEREBY AGREED by and between the parties, as follows:

DEFINITIONS

As used in this Agreement, the following terms have the following meanings:

1. The "Hepatitis C Protocol" refers to the current 2018 DOC Hepatitis C Protocol, and any superseding Protocol(s) promulgated by the DOC. *See* Exhibit A.
2. The "Preliminary Approval Date" is the date on which the U.S. District Court gives preliminary approval to this Agreement.
3. The "Effective Date" means the date upon which the District Court gives final approval to this Settlement Agreement.
4. "Class members" refers to all current and future inmates in the DOC with Chronic Hepatitis C, but only for the duration of the Agreement.
5. "DAA" refers to the class of medications known as FDA-approved Direct-Acting Antivirals used to treat Hepatitis C.
6. "Eligible Inmates" shall include all inmates with Chronic Hepatitis C who do not affirmatively reject DAA treatment, have at least one year's life expectancy, have a release date from the DOC at least twenty (20) weeks in the future, and for whom DAA treatment is not contraindicated under the terms of the Hepatitis C Protocol.

AGREEMENT

In consideration of the mutual terms, covenants, conditions and releases of this Settlement Agreement, the parties agree as follows:

1. <u>Replacement of the Hepatitis C Protocol</u>

No later than sixty (60) days after the Effective Date, the DOC shall replace the current Hepatitis C Protocol with a new Hepatitis C Protocol that incorporates and reflects the terms of

this Settlement Agreement. The DOC shall be responsible for informing its staff, correctional health care providers, and outside medical providers of the new Hepatitis C Protocol.

2. Medical Evaluation and Treatment for Identified Affected Inmates

Pursuant to this Settlement Agreement and the Hepatitis C Protocol, the DOC shall provide DAA to inmates with Chronic Hepatitis C on the following schedule:

a. Upon the Preliminary Approval of this Agreement, all eligible inmates with a Metavir Fibrosis Score of F-2, F-3, or F-4, as determined by the testing standards set forth in the Hepatitis C Protocol, including consideration of APRI scores and Fibrosure tests, and named Plaintiff Daniel Leyva, shall be treated with DAA no later than six months following the DOC determination of their F-2, F-3 or F-4 Fibrosis Score, as more fully defined, para. 3, infra.

b. Starting July 1, 2019, and for each of the following two years to June 30, 2021, the DOC shall treat no fewer than 1500 eligible inmates each year with DAA, based on the priority provisions of the DOC Hepatitis C Protocol. For the year, July 1, 2021 to June 30, 2022, the DOC shall treat 2000 eligible inmates with DAA, based on the priority provisions of the DOC Hepatitis C Protocol. These requirements shall be suspended if and when the DAA treatments exhaust the entire pool of eligible inmates.

c. The DOC shall implement the priority treatment provisions of this Agreement and the DOC Hepatitis C Protocol based on the APRI and Fibrosure scores set forth in section 3, infra, and absent exigent circumstances, shall treat eligible inmates with the higher scores first, without regard to their release dates.

d. In the period from May 1 to July 1, 2022, the parties shall confer on a schedule for treating the eligible inmates not yet provided with DAA treatment, and to discuss termination of this Agreement. The parties agree that if the number of eligible inmates as of January 1, 2022 does not exceed 500, that none of these inmates have a Metavir Fibrosis Score of more than F-0, as defined in this Agreement, and that none of the eligible inmates have been awaiting DAA treatment for more than six months following documentation of their Chronic Hepatitis C status under the DOC Protocol, the Agreement shall be terminated as of June 30, 2022.

e. If these conditions are not satisfied, the parties shall negotiate a continuing treatment schedule and termination date. If the parties are unable to reach an Agreement, the Court, after hearing, may intervene to determine the schedule for DAA treatments going forward, and shall determine the termination date for the Agreement and for the Court's jurisdiction over this case.

3. Hepatitis C Metavir Fibrosis Score Testing

The DOC shall determine the Metavir Fibrosis Score referenced in this Settlement Agreement and the Hepatitis C Protocol using the following tests:

a. Initially, the Fibrosis Score shall be determined by the APRI test score, with the following designations: APRI score of 2.0 or above, F-4; APRI score of more than 1.5-2.0, F-3; APRI score of more than 0.7-1.5, F-2; APRI score of more than 0.5-0.7, F-1; APRI score of less than 0.5, F-0; all subject to the provisions of 3(c) and (d).

b. Where Fibrosure is used to determine the Metavir Fibrosis Score ("Score"), the following designations shall be made: Less than 0.21, Score of F-0; 0.21-0.27, Score, F-0-F-1; 0.27-0.31, Score, F-1; 0.31-0.48, Score F-1-F-2; 0.48-0.58, Score F-2; 0.58-0.72, Score F-3; 0.72-0.74, Score F-3-F-4; greater than 0.74, Score F-4.

c. If the APRI and Fibrosure tests result in different Metavir Fibrosis Scores, the Fibrosure Score shall control.

d. Fibrosis Score evaluations of class members at F-0 to F-2 shall be made every six months, as set forth in the Hepatitis C Protocol.

4. Preventive Health and Patient Education

The class members shall be evaluated to assess the need for preventive health interventions such as vaccines and screenings for other conditions, as well as counseled with information on Hepatitis C infection. All inmates who are positive for the Hepatitis C virus shall be evaluated to assess the need for the preventive health interventions in accordance with DOC policies on preventive health visits, including:

- Hepatitis B vaccine: Indicated for susceptible class members with Chronic Hepatitis C infection. The DOC shall consider blood test prescreening for Hepatitis B immunity prior to vaccination.

- Class members with evidence of liver disease shall be priority candidates for a Hepatitis B vaccination.

- Hepatitis A vaccine: Indicated for susceptible class members with Chronic Hepatitis C infection. The DOC shall consider blood test prescreening for Hepatitis A immunity prior to vaccination.

- Influenza vaccine: Offer to all class members annually.

- Class members with cirrhosis shall be high priority for an influenza vaccine.

Class members shall be counseled by a health care provider regarding the natural history of the infection, potential treatment options, and specific measures to prevent transmitting Hepatitis C infection to others (both during incarceration and upon release), consistent with DOC policies on preventive health visits and other policies. Class members have the right to refuse DAA treatment, but they shall be counseled by a health care provider regarding the risks of refusing treatment and the benefits of DAA treatment. These class members shall continue to be monitored under the terms of the Hepatitis C Protocol and may request DAA treatment at any time during the course or their incarceration. Upon such a request, the class member shall be provided DAA treatment under the terms of paras. 2 and 3, *supra*.

The DOC shall provide all class members who do not receive DAA treatment, before their release from custody, with pertinent information about their Hepatitis C condition and access to DAA treatment upon release through Medicaid or other state or local programs, including information provided by counsel for the Plaintiff Class.

5. Class Definition

The definition of the class that was certified by the Court on May 24, 2018 shall be amended to include inmates with Chronic Hepatitis C who enter the DOC after the date of class certification. The class shall be defined as follows:

> All persons who are currently incarcerated in a Pennsylvania Department of Corrections ("DOC") facility, or who are incarcerated in the DOC in the future, with a diagnosis of Chronic Hepatitis C, who have a release date from the DOC that is at least twenty (20) weeks in the future, who have a life expectancy of over one year, and for whom DAA treatment is not contraindicated under the terms of the Hepatitis C Protocol.

The class shall be entitled to the benefits of this Agreement only for the duration of the Agreement.

6. Notice to Inmates

The DOC shall provide notice to all class members of this Settlement Agreement by:

- Making regular audio and video announcements at each DOC facility equipped with a CCTV system and/or prison-wide intercom system for a fourteen (14) day period beginning within thirty (30) days of the Effective Date;
- If a DOC facility has neither a prison-wide intercom nor a CCTV system, DOC shall provide each class member with a written version of the announcement;
- Posting a copy of this Agreement in each medical facility accessible to inmates for a period of at least two (2) years;
- Posting a copy of this Agreement in each library accessible to class members for the period of this Agreement; and
- Providing class members with a letter from Plaintiffs' counsel explaining the Agreement and access to DAA treatment.

7. Monitoring Period

For a period that begins with the Effective Date of this Agreement and ending with the termination of the Agreement, the DOC shall on a quarterly basis provide Plaintiffs' counsel with reports to permit monitoring of the implementation of the Agreement. These reports shall include the data currently maintained on the DOC Hepatitis C Spreadsheets regarding testing, diagnosis, evaluation, and treatment of all class members diagnosed with Chronic Hepatitis C in the DOC, and the class members' Metavir Fibrosis Scores by date determined, and scheduled dates for DAA treatment. The Spreadsheets, or other documentation, shall also include (a) information regarding all inmates with Chronic Hepatitis C who, because of any exclusionary policy or reason, is not being provided DAA; (b) the specific reason(s) for non-treatment with

DAA; and (c) the dates of entry into and release from the DOC of eligible inmates not provided with DAA treatment during their incarceration.

8. Notice and Comment to Future Changes to the Hepatitis C Protocol

During the period of this agreement (pre-termination), the DOC shall provide Plaintiffs' counsel with a copy of any proposed revisions or changes to the Hepatitis C Protocol. Such proposed revisions or changes shall not be placed into effect without Plaintiffs' counsel being given an opportunity to provide comments on the changes and, if invoked, until the conclusion of the Dispute Resolution procedure identified below.

9. Dispute Resolution

If Plaintiffs' counsel believe that the DOC has improperly denied a class member medically necessary DAA, failed to comply with the terms of this Settlement Agreement, or proposed revisions or changes to the Hepatitis C Protocol that are inconsistent with the Settlement Agreement, Plaintiffs' counsel will provide the DOC with a notice of potential non-compliance. This notice will identify, with particularity, the basis of the claim that the DOC is not in compliance and the specific material provision of the Settlement Agreement or Hepatitis C Protocol that is implicated.

Within thirty (30) days of receipt of the notification, the DOC shall provide a good-faith written response to the Plaintiffs' notification with a full factual explanation as to why the DOC believes it is in compliance with the specified material provisions, or an explanation of the DOC's plans to achieve full compliance with the specified material provisions.

It is understood between the parties that certain unforeseeable events or conditions, for example, long-term lockdowns in the DOC, changes adopted by the AASLD/IDSA regarding medical treatment for persons with Chronic Hepatitis C, or changes in FDA regulations, may

prevent compliance with this Agreement. If so, the DOC shall notify Plaintiffs' counsel of the event or condition and the parties shall enter into good-faith discussions to resolve the issues.

If the parties are unable to resolve the dispute within thirty (30) days of DOC's response, Plaintiffs' counsel may seek intervention from the Court by filing a motion for specific performance of the material provision identified through the aforementioned Dispute Resolution procedure. The Court may order specific performance of the material provision upon a showing that the DOC is in substantial non-compliance with the material provision specified in the notice. The Court may not entertain a motion for contempt and the Court may not grant any remedial relief in the nature of a contempt of court finding against the Department. However, if the Department does not comply with an order for specific performance, the Court may order additional equitable relief, including extending the term of this Agreement in one (1) year increments. In no event, may the Court extend the term of this Agreement beyond five (5) years from the Effective Date of this Agreement.

10. Preliminary Approval

As soon as practicable following execution of this Agreement, the parties shall apply to the Court for a preliminary order:

a. Granting Preliminary Approval of this Agreement for purposes of disseminating notice to current DOC prisoners who are Class Members;

b. Approving the form, contents, and dissemination of the Notice of this Agreement to current DOC prisoners who are Class Members; and

c. Scheduling a Fairness Hearing to review comments and/or objections regarding this Agreement, consider the fairness, reasonableness, and adequacy of this Agreement, and consider whether the Court should order Final Approval of this Agreement and grant Class Counsel's requested Fee Award.

11. Final Approval

This Agreement shall be subject to the Final Approval of the Court. The parties shall

cooperate in presenting this Agreement to the Court for Final Approval and/or at any hearing under Rule 23(e) of the Federal Rules of Civil Procedure. If the Court does not grant Final Approval, this Agreement shall be null and void and of no force and effect, and nothing herein shall be deemed to prejudice the position of any party with respect to the Action or otherwise, and neither the existence of this Agreement, nor any of its terms or provisions, nor any of the negotiations or proceedings connected with it, shall be admissible in evidence, referred to for any purpose in the Action or in any other litigation or proceeding, or construed as an admission, presumption, or concession by any Defendant of any liability or the truth of any of the allegations in the Action.

12. Dismissal

The parties understand and agree that the Court will maintain jurisdiction of this civil action throughout the duration of the Agreement to enforce the provisions of the Agreement and that the Plaintiffs may seek to enforce the Agreement, pursuant to paragraph 9, *supra*. The parties also agree that, upon termination of the Agreement, they will sign and submit a joint stipulation of dismissal with prejudice pursuant to F. R. Civ. P. 4l (a), thereby ending the Court's jurisdiction over this case.

13. No Admission of Liability

Neither this Settlement Agreement nor anything in this Settlement Agreement shall be deemed an admission or concession of liability or evidence respecting any liability on the part of the DOC Defendants or an admission that any of Plaintiffs' claims lack merit.

Neither this Agreement nor any policies or procedures referenced herein shall define any state or federal constitutional rights.

14. Notices

All notices required under the Agreement will be sent overnight mail or overnight courier to the following:

To Plaintiffs:

David Rudovsky
Kairys, Rudovsky, Messing, Feinberg & Lin, LLP
718 Arch Street, Suite 501S
Philadelphia, PA 19106

and

Su Ming Yeh
Pennsylvania Institutional Law Project
The Cast Iron Building
718 Arch Street, Suite 304 South
Philadelphia, PA 19106

To Defendants:

Vincent R. Mazeski
Department of Corrections
Office of Chief Counsel
1920 Technology Parkway
Mechanicsburg, PA 17050

Either party may substitute the individual designated to receive notice by advising the other side in a writing sent by overnight mail or overnight courier.

15. Payment of Attorneys' Fees and Costs

The DOC agrees to pay Plaintiffs' attorneys $195,000 in Attorneys' Fees and Costs within sixty (60) days of the Effective Date of this Agreement. Plaintiffs' counsel agree to monitor the enforcement of this Agreement without payment of counsel fees; provided, however, that if the Plaintiffs prevail on a motion to enforce the Agreement pursuant to para. 9, *supra*, Plaintiffs' counsel may seek attorneys' fees and costs for reasonable time spent on the enforcement of this Agreement.

16. Release

In consideration of the terms and conditions called for herein, Plaintiffs release and completely and forever discharge the DOC, their agents, attorneys, servants, representatives, and employees, past and present, and their past, present, and future agents, attorneys, servants, representatives, and employees, and all other persons with whom any of the former have been, are now, or may hereinafter be affiliated, of and from any and all past or present claims, demands, obligations, actions, causes of action, rights, damages, costs, expenses, and any claims for relief or punitive or other damages of any type which have accrued as of the Effective Date of this Agreement, and which relate to the subject matter of this civil action.

17. Non-Waiver of Claims and Defenses as to Non-Parties

The parties agree that by entering into this Settlement Agreement, Plaintiffs do not waive other rights to continue to pursue claims against any non-party to this Settlement Agreement. Furthermore, this Settlement Agreement does not waive any rights of other inmates in the custody of the DOC.

18. Integration Clause

The terms of this Settlement Agreement and its exhibits as written are the entire agreement and there are no other terms relied upon by the parties, verbal or otherwise.

19. Counterparts

This Settlement Agreement may be signed in multiple counterparts by fax or email and interchangeably executed. Such execution shall be valid and binding upon the parties and all counterparts when so executed and shall together be deemed one final original instrument. The parties may rely on fax or email copies as if they were originals and such copies shall be equally admissible in evidence.

20. Captions

The captions and headings used throughout this Settlement Agreement are for convenience only and shall not be deemed to modify the meaning of any provisions of this Settlement Agreement.

21. Written Modification

As permitted by law, this Settlement Agreement may be modified only by a written instrument signed by both the parties.

22. Severability

If, for any reason, any provision of this Settlement Agreement is determined to be invalid or unenforceable, the remaining provisions of this Settlement Agreement shall be construed, performed, or enforced as if the invalidated or unenforceable provision had not been included in the text of the Agreement.

23. Governing Laws

This Settlement Agreement shall be governed by the laws of the Commonwealth of Pennsylvania.

24. Binding Effect

Except as provided elsewhere herein, this Settlement Agreement is binding upon the parties and their respective agents, officers, directors, employees, executors, administrators, heirs, assigns, and successors-in-interest regarding this action.

25. Advice of Counsel

The parties acknowledge that each has carefully read the entire Settlement Agreement, has been given the opportunity to consult with and be advised by their attorney, and knows and understands the contents of this Settlement Agreement.

26. Ambiguities

This Settlement Agreement has been reviewed by the parties and their respective attorneys, and the parties have had a full opportunity to negotiate the contents of this Settlement Agreement. The parties waive any common law or statutory rule of construction that ambiguities should be construed against the drafter(s) of this Settlement Agreement, and agree that the language in all parts of this Settlement Agreement shall be in all cases construed as a whole, according to its fair and reasonable meaning.

27. Jurisdiction: Dispute Resolution

The parties hereby consent to personal jurisdiction and venue in the United States District Court for the Eastern District of Pennsylvania to resolve any dispute relating to the terms of the Settlement Agreement or the obligations of the parties under this Settlement Agreement. The Court shall retain jurisdiction of this matter for the purposes of the enforcement of this Settlement Agreement.

Dated: November 19, 2018

IT IS SO AGREED:

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Counsel for Defendants

Pennsylvania Department of Corrections

EXHIBIT A

Section 20 – Hepatitis C Protocol

A. Introduction

1. This Hepatitis C Protocol for the Pennsylvania Department of Corrections (PA DOC) provides clinical guidelines for the diagnosis, management, and treatment of inmate patients with chronic Hepatitis C Virus (HCV).[1] HCV is a slowly progressive disease, usually requiring ***decades*** to progress to cirrhosis; however, the natural history of HCV is variable and not all patients with chronic HCV will develop cirrhosis during their lifetime. ***Of every 100 persons infected with HCV, approximately: 15-25 will clear the virus from their body and be naturally cured with no risk of future liver disease; 75-85 will develop chronic infection; 60-70 with chronic infection will develop chronic liver disease; 5-20 with chronic infection will develop cirrhosis of the liver over a period of 20-30 years; and 1-5 will die from the consequences of chronic infection, such as end-stage cirrhosis or liver cancer*** (for content references, please see **Subsection *K*.1. below**).

2. The goal of Hepatitis C anti-viral treatment is to achieve a sustained virological response (SVR), defined as undetectable HCV virus in the blood, 12 or more weeks after completing anti-viral treatment.

B. Screening

1. All new intakes will be screened at their home institutions utilizing the Hepatitis C Antibody test.[2] Anyone may refuse testing by signing a **DC-462, Release from Responsibility for Medical Treatment Form.**

2. The Infection Control Nurse (ICN) will review positive antibody results with all inmates, whether it be at intake or later during incarceration. The Medical Director/designee will order a confirmatory Hepatitis C Ribonucleic Acid (RNA) Quantitative Polymerase Chain Reaction (PCR) test (viral load).[3] Recommended immunizations, counseling, and literature will be provided during that encounter.

3. Inmate patients with documented (+) Hepatitis C Antibody test should not be retested, but entered into tracking.

4. Inmate patients who have a documented undetectable Hepatitis C Quantitative PCR may become re-infected while out on parole. If they return to the PA DOC, the Medical Director/designee shall order a repeat viral load on intake.

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[2] 4-4359
[3] 4-4359

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Effective: 5/16/2018

C. Tracking

For all patients with a positive HCV antibody test, the ICN will maintain a current **Hepatitis C Tracking Spreadsheet (Attachment 20-*A*)** in Excel format. This spreadsheet will be forwarded to the Bureau of Health Care Services (BHCS) Infection Control Coordinator (ICC) on a monthly basis.

D. Diagnosing Cirrhosis (for content reference, please see Subsection *K*.2. below)

1. 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:

   a. Symptoms and signs that support the diagnosis of cirrhosis may include: Low albumin or platelets, elevated bilirubin or International Normalized Ratio (INR), ascites, esophageal varices, and hepatic encephalopathy. However, isolated lab abnormalities may require additional diagnostic evaluation to determine the etiology.

   b. The AST (Aspartate Aminotransferase) to Platelet Ratio Index (APRI) score is the DOC-preferred initial method for non-invasive assessment of hepatic fibrosis and cirrhosis:

      (1) 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.

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

      (3) 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.

      (4) A single APRI score should not be used in isolation. There are multiple medications and conditions that can result in a transient elevation of AST.

      (5) The APRI score may be invalidated in cases of splenectomy.

2. Liver biopsy is no longer required unless otherwise clinically indicated. However, the presence of cirrhosis on a prior liver biopsy may be used to meet the DOC criteria for HCV treatment.

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3. Abdominal imaging studies such as ultrasound or computerized tomography (CT) scan may identify findings consistent with or suggestive of the following: cirrhosis (nodular contour of the liver), portal hypertension (ascites, splenomegaly, varices), or hepatocellular carcinoma (HCC).

E. Assessing Hepatic Compensation (for content reference, please see Subsection *K.2.* below)[4]

1. Assessing hepatic compensation is important for determining the most appropriate HCV treatment regimen to be used. The recommended HCV treatment regimen may differ depending on whether the cirrhosis is compensated or decompensated.

2. The CTP (Child-Turcotte-Pugh) score is a useful tool to help determine the severity of cirrhosis and is used by the American Association for the Study of Liver Diseases (AASLD) to distinguish between compensated and decompensated liver disease in patients with known or suspected cirrhosis.

   a. CTP calculator ***is*** available in the Resource Section of the electronic health record.

   b. 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	

   c. A CTP score of 5 or 6 is considered to be compensated cirrhosis, while a score of 7 or greater is considered decompensated.

      (1) Warfarin anticoagulation will invalidate CTP calculations if the INR is 1.7 or higher.

      (2) 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 Direct Acting Antivirals (DAA) medications are not well-established with significant hepatic impairment.

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F. Additional Interventions for Inmates with Cirrhosis: (for content reference, please see Subsection *K.2.* below)[5]

1. Pneumococcal vaccine: Offer to all HCV-infected inmates with cirrhosis who are 19 through 64 years of age.

2. HCC screening: Liver ultrasound is recommended every six months for patients with cirrhosis ***(F4) or advanced fibrosis (F3)***.

3. Esophageal varices screening: Screening for esophageal and gastric varices with esophagogastroduodenoscopy (EGD) is recommended for patients diagnosed with cirrhosis.

4. Other healthcare interventions recommended for patients with cirrhosis may include:

   a. non-selective beta blockers for prevention of variceal bleeding in patients with esophageal varices;

   b. antibiotic prophylaxis if risk factors are present for spontaneous bacterial peritonitis;

   c. optimized diuretic therapy for ascites; and

   d. lactulose and rifaximin therapy for encephalopathy.

5. In general, Non-Steroidal Anti-Inflammatory Drugs (NSAID) 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.

G. Chronic Care Clinic[6]

1. All patients who have chronic Hepatitis C (confirmed by a detectable viral load) will be entered into the Liver Disease Chronic Care Clinic. The ICN will confer with the Site Medical Director to determine if the patient's diagnosis is:

   a. F0-F2 (no fibrosis, mild fibrosis, or moderate fibrosis). All cases not documented F3 or F4.

   b. F3 (advanced fibrosis). Documented by liver biopsy, elastography, ***or Fibrosure.***

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[6] 4-4350, 4-4359

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c. F4 (cirrhosis). See **Subsection D. above.**

2. Patients who are antibody positive only (confirmed by an undetectable viral load) do not have chronic Hepatitis C and will be followed in Chronic Care Clinic at the discretion of the Site Medical Director, if the patient exhibits signs or symptoms of liver disease. Patients who have been treated with medication will continue to be followed in Chronic Care Clinic, whether or not they achieved a SVR.

3. At a minimum, the following will be documented in a Progress Note[7] during the Chronic Care Clinic encounter:

   a. Subjective:

      (1) symptoms of cirrhosis or liver failure;

      (2) history of ascites, encephalopathy, or esophageal varices (bleeding or not);

      (3) estimated date of contracting the disease; and

      (4) any recent admissions to the Infirmary, emergency room (ER), or hospital.

   b. Objective:

      (1) vital signs, weight, and Body Mass Index (BMI);

      (2) examination of the sclera for jaundice;

      (3) examination of the abdomen, including both ascites and the size and character of either hepatomegaly or splenomegaly;

      (4) examination of the skin for changes suggestive of cirrhosis (jaundice, spider angiomata/telangiectasia, palmar erythema, and caput medusae);

      (5) examination of the neurological system for the presence of asterixis ("liver flap");

      (6) fibrosis stage, if known, and method used to determine the fibrosis stage (e.g. liver biopsy or elastography);

      (7) calculation of the APRI, using the calculator located in the Resource Section of the electronic health record;

      (8) calculation of the Model of End Stage Liver Disease (MELD) score and the CTP score for patients with cirrhosis, using the calculator located in the Resource Section of the electronic health record;

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(9) review of any results of the EGD, elastography, or abdominal ultrasound; and

(10) examination of pertinent laboratory results.

c. Assessment:

(1) F0-F2 (no fibrosis, mild fibrosis, or moderate fibrosis);

(2) F3 (advanced fibrosis); or

(3) F4 (cirrhosis).

d. Plan of Treatment:[8]

(1) schedule the follow-up Clinic appointment according to the assessment:

(a) F0-F2 (six months);

(b) F3 (three months); or

(c) F4 (one month).

(2) diagnostics ordered will include the following:

(a) initial Chronic Care Clinic for all patients: Comprehensive Metabolic Profile (CMP), Complete Blood Count (CBC), Chronic Hepatitis Panel, and Prothrombin Time (PT)/INR;

(b) yearly labs for all patients: CMP, CBC, and PT/INR. ***Quantitative PCR (viral load) for those who have completed treatment***;

(c) every six month labs for patients with cirrhosis (F4): CMP, CBC, PT/INR, and abdominal ultrasound to evaluate for HCC;

(d) every six month labs for patients without cirrhosis (F0-F3): Liver Function Tests (LFTs) and CBC; and

(e) monthly visits for patients with cirrhosis (F4): No labs required.

4. If the APRI > ***1.0***, notify the ICN.

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H. Evaluation for Treatment with Anti-Viral Medication[9]

1. The PA DOC will utilize the Federal Bureau of Prisons (FBOP) Priority Criteria as listed in the "Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection Clinical Practice Guidelines, ***October*** 2016." (please refer to **Subsection *K*.2. below**)

2. Determining whether PA DOC priority criteria for treatment are met is an important part of the initial evaluation and ongoing management of inmates with chronic HCV infection. Although all patients with chronic HCV infection may benefit from treatment, certain cases are at higher risk for complications or disease progression and require more urgent consideration for treatment.

3. The PA DOC will use ***Fibrosure*** to determine fibrosis scoring for patients without a diagnosis of cirrhosis who have an APRI > ***1.0*** or select patients as clinically indicated.

4. The DOC has established priority criteria to ensure that those with the greatest need are identified and treated first (for content reference, please see **Subsection *K*.2. below**). The DOC Chief of Clinical Services will provide periodic guidance on specific strategies for implementing these priority levels:

    a. Priority Level 1 – High Priority for Treatment

        (1) ***Advanced hepatic fibrosis***:

            (a) ***APRI > 2.0;***

            (b) ***Metavir or Batts/Ludwig stage 3 or 4 on liver biopsy, Elastography, or Fibrosure; or***

            (c) ***known or suspected cirrhosis.***

        (2) Liver Transplant Recipients

        (3) Hepatocellular Carcinoma (HCC)

        (4) Comorbid Medical Conditions Associated with HCV, including:

            (a) Cryoglobulinemia with renal disease or vasculitis;

            (b) certain types of lymphomas or hematologic malignancies; ***and/or***

            (c) ***Porphyria cutanea tarda.***

        (5) Immunosuppressant Medication for a Comorbid Medical Condition

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For example, certain chemotherapy agents and tumor necrosis factor inhibitors. Such cases will be considered for ***prioritized*** treatment on an individual basis.

(6) Continuity of Care for those already started on treatment, including inmates who are newly incarcerated in the ***PA*** DOC.

b. Priority Level 2 – ***Intermediate*** Priority for Treatment

(1) ***Evidence of progressive fibrosis***.

(a) ***APRI > 0.7***.

(b) ***Stage 2 fibrosis on liver biopsy, Elastography, or Fibrosure***.

(2) ***Comorbid medical conditions associated with more rapid progression of fibrosis***.

(a) ***Coinfection with Hepatitis B Virus (HBV) or Human Immunodeficiency Virus (HIV)***.

(b) Comorbid liver disease (e.g., autoimmune hepatitis, hemochromatosis, steatohepatitis).

(c) ***Diabetes Mellitus***.

(3) Chronic Kidney Disease (CKD) with Glomerular Filtration Rate (GFR) < 59 mL/min per 1.73 m ***squared***.

c. Priority Level 3 – ***Low*** Priority for Treatment

(1) Stage ***0 to stage 1*** fibrosis on liver biopsy, ***Elastography, or Fibrosure***.

(2) APRI < ***0.7***.

(3) ***All other cases of HCV infection meeting criteria for treatment, as noted below under Other Criteria for Treatment***.

5. Other Criteria for Treatment: In addition to meeting the above criteria for Priority 1–***3***, inmates being considered for treatment of HCV infection should:

a. ***have no significant or unstable medical conditions, to include, but not limited to, cardiopulmonary, cancer, and diabetes***;

b. have no contraindications to, or significant drug interactions with, any component of the treatment regimen;

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c. not be pregnant, especially for any regimen that would require ribavirin or interferon;

d. ***have been in the DOC at least six months and have at least six months until expected release. Inmates with Priority Level 1 criteria who are outside these parameters may be considered on an individual basis***;

e. have a life expectancy > 18 months;

f. demonstrate a willingness and an ability to adhere to a ***rigorous*** treatment regimen. ***Inmates with a history of non-compliance may be offered a one month trial of taking a multi-vitamin daily under direct observation. If successful, they may be considered for treatment on an individual basis***; ***and***

g. ***demonstrate a willingness and an ability to abstain from high-risk activities while incarcerated. Inmates with evidence for ongoing high-risk behavior, e.g. misconducts for illicit drug use or tattoos, will be considered for treatment on an individual basis. Referral for evaluation and treatment of substance abuse is required***.

6. The first level of screening patients for treatment with anti-viral medications will occur at the patient's home site. Patients with ***an APRI > 1.0*** will have an initial review of their medical chart only. The review will be conducted utilizing the **Hepatitis C Treatment Referral Form (Attachment 20-*B*)** and will be conducted by the Corrections Health Care Administrator (CHCA), ICN, and Site Medical Director, who will look for the presence of any exclusionary indications listed ***above***.

7. If the CHCA determines that there are no exclusionary indications to anti-viral treatment, ***a Fibrosure test needs to be ordered. If the Fibrosure test indicates F-2, F-3, or F-4,*** the **Hepatitis C Treatment Referral Form** shall be forwarded to the BHCS ICC for further evaluation, possible recommendations for further testing, and initial determination.

I. *Bureau of Health Care Services Review*[10]

1. The PA DOC has determined that there is no single method of prioritizing patients for treatment with anti-viral medications. ***The Hepatitis C Treatment Referral Form shall be forwarded to the BHCS for final review and approval by the Chief of Clinical Services, who may consult with a HCV specialist as deemed necessary***.

2. The ***Chief of Clinical Services*** will utilize the pertinent information available to determine if continued progression through the evaluation process is indicated. The review may include, but will not be limited to, laboratory test trending (INR, AST, albumin, platelet count, bilirubin, etc.), Fibrosure, previous shear wave elastography, liver biopsy, previous treatment results, APRI score, MELD score, and the CTP score. The ***Chief of Clinical***

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Services will also review the stability of any chronic medical and mental health conditions.

3. ***The BHCS will use the Fibrosure score as its main determinant of fibrosis to be used within the FBOP prioritization levels*** as outlined in **Subsection H.4. above**.

   a. Fibrosis Stage 0-***1***

      (1) Repeat ***Fibrosure*** in ***one*** year.

      (2) Follow in Chronic Care Clinic every six months.

   b. ***Fibrosis Stage 2***

      (1) ***Refer to Temple University for final review and the ordering of DAA medications unless there are contraindications***.

      (2) ***Follow in Chronic Care Clinic every six months***.

   c. Fibrosis Stage 3

      (1) Refer to ***Temple University*** for final review and the ordering of DAA medications unless there are contraindications.

      (2) ***Order full ultrasound screening for HCC every six months***.

      (3) Follow in Chronic Care Clinic every three months.

   d. Fibrosis Stage 4

      (1) ***Order*** full ultrasound screening for HCC every six months.

      (2) ***Order baseline*** EGD for esophageal varices surveillance.

      (3) Refer to ***Temple University*** for final review and the ordering of DAA medications unless there are contraindications.

      (4) Follow in Chronic Care Clinic every month.

4. The ***Chief of Clinical Services*** will render ***a*** decision and forward the determination, along with follow-up recommendations for those not meeting current priority criteria for greatest need of treatment with anti-viral medications, to the ICN and Site Medical Director, who will then discuss the results with the patient and document the encounter in the **DC-472, Progress Notes**.[11]

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5. If the ***Chief of Clinical Services*** recommends treatment with anti-viral medication, the Site Medical Director will refer the patient to ***Temple University*** who will direct the anti-viral treatment. The referral will be made utilizing a **Hepatitis C Treatment Referral Form**, to include the following updated laboratory results:

   a. genotype, ***no time limit if completed during this incarceration; otherwise, one year***;

   b. viral load (within ***three months***);

   c. HIV (within one year);

   d. CMP (within one month);

   e. CBC (within one month);

   f. abdominal sonogram for patients with cirrhosis (within six months); and

   g. the treatment of HCV with anti-viral medications is rapidly evolving. New medications are being approved by the Federal Drug Administration (FDA) frequently. The regimens currently approved by PA DOC will be included in the Diamond Pharmacy Services Formulary for this contract. The Formulary will include all necessary prescribing information and will be updated quarterly via the PA DOC Pharmacy and Therapeutics Committee.

J. *American Correctional Association (ACA) Accreditation*

As part of the audit for ACA accreditation, each site is required to submit data representing Outcome Measures. This information is available on the Hepatitis C Tracking Spreadsheet and includes all inmates who are diagnosed with chronic Hepatitis C infection at a given point in time. ACA recommends selecting June as the midpoint of a calendar year.

1. ***Include all inmates within the facility with a current laboratory test indicative of Hepatitis C viral infection whether or not they have received antiviral treatment.***

2. ***Exclude inmates diagnosed with chronic Hepatitis C infection, but housed in another correctional system, community-based facility, or home detention.***

3. ***Exclude inmates with suspected acute Hepatitis C viral infection who are currently under evaluation for clearance of their infections (in other words, viremia).***

K. References

1. ***Centers for Disease Control and Prevention. "Hepatitis C FAQs for health professionals," accessed August 2017 at www.cdc.gov/hepatitis/hcv/hcvfaq.htm.***

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2. Federal Bureau of Prisons, ***January 2018***, "Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection," accessed ***March 7, 2018***, at https://www.bop.gov/resources/pdfs/012018_hcv_infection.pdf.

3. AASLD and IDSA, "Recommendations for Testing, Managing, and Treating Hepatitis C," accessed ***August 2017*** at http://www.hcvguidelines.org.