UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JEFFREY FOWLER, PAUL WHOOTEN, MICHAEL TURNER, and MICHAEL FITZPATRICK on behalf of themselves and all others similarly situated, Plaintiffs, v. THOMAS TURCO, Commissioner of Massachusetts Department of Correction, in his official capacity, and MASSACHUSETTS PARTNERSHIP FOR CORRECTIONAL HEALTHCARE, INC., Defendants.	C.A. NO. 1:15CV12298-NMG

JOINT MOTION TO APPROVE SETTLEMENT

Plaintiffs and Defendant Thomas Turco, pursuant to Fed. R. Civ. P. 23(e), move this Court to approve the Settlement Agreement attached hereto, including the issuance of preliminary approval, approval of a notice to class members concerning the Agreement and an opportunity for them to comment, and the issuance of final approval after a hearing and finding that it is fair, reasonable, and adequate. In support of their motion, Plaintiffs and Defendant Turco state as follows:

1. Plaintiffs filed the Complaint in this case on June 10, 2015, challenging the adequacy of Hepatitis C treatment in the Massachusetts Department of Correction ("DOC"). Plaintiffs contend that the DOC and its contracted medical provider, Defendant Massachusetts Partnership for Correctional Healthcare, LLC ("MPCH"), were not treating prisoners with new,

highly effective direct acting antiviral ("DAA") medications, in violation of the Eighth Amendment to the United States Constitution. Defendants deny the allegations.

2. On July 25, 2016, this Court certified a Plaintiff class of all current and future DOC prisoners who have or will have Hepatitis C.

3. On February 9, 2018, the parties reported that they had reached agreement on the terms of a proposed settlement.

4. Under the terms of the Settlement Agreement (attached hereto at Exhibit 1), the DOC will arrange for its contracted medical provider - currently MPCH - to implement a new protocol to govern the testing, evaluation, and treatment of Hepatitis C. This new Clinical Guidance is attached to the Settlement Agreement (as Exhibit A thereto).

5. All class members will be assigned to a Priority Level (1 through 3), pursuant to agreed-upon criteria including the degree of liver fibrosis and the presence of certain other complications. Current Priority Level 1 patients will be treated with DAA medications within 12 months of preliminary approval. Current Priority Level 2 patients will be treated with DAA medications within 18 months of preliminary approval of the settlement.

6. During the 18 months after preliminary approval, prisoners entering DOC custody who are assigned to Priority Level 1 or 2, or those in custody who progress into one of those two levels, will be treated with DAA medications within 9 months (for Priority Level 1) or 12 months (for Priority Level 2).

7. After the 18-month period following preliminary approval, prisoners who are assigned to Priority Level 1 will be treated with DAA medications within 3 months, those

assigned to Priority Level 2a or 2b will be treated within 6 months, and those assigned to Priority Level 2c will be treated within 12 months.

8. The Settlement Agreement also calls for Priority Level 3 prisoners to receive updated lab tests every 6 months, to determine if their disease has progressed and whether they should be reassigned to Priority Level 1 or 2. New prisoners will be offered testing to determine whether they have Hepatitis C.

9. The Clinical Guidance incorporated into the Settlement Agreement also limits the circumstances in which a patient who otherwise qualifies for treatment may be denied treatment. For example, a patient who receives a disciplinary report is no longer disqualified from treatment.

10. Under the Settlement Agreement, the DOC will hire a third party to monitor the progress of MPCH (or any other medical provider with whom DOC contracts) in implementing the Clinical Guidance. The third party will conduct some ongoing reviews, as well as periodic chart reviews, and its findings will be shared with counsel for Plaintiffs.

11. The Settlement Agreement calls for written notice to be issued to class members, which the parties intend to provide by first-class mail to class members in DOC custody and by posting the notice in a common area in DOC facilities. The form of the notice is attached to the Settlement Agreement as Exhibit B thereto.

12. Plaintiffs and Defendant Turco are parties to the Settlement Agreement; the agreement calls for Plaintiffs to dismiss MPCH from this action once this Court issues final approval of the settlement.

13. Plaintiffs and Defendant Turco agree that this Court should retain jurisdiction over this action during the settlement term (30 months) and should be the sole forum for enforcement of the settlement's terms, as described in the Settlement Agreement.

14. Plaintiffs and Defendant Turco believe that this settlement is fair, reasonable, and adequate. It was reached after extensive arms-length negotiations between counsel, and it came after most document production had taken place and the parties had conducted preliminary expert work.

WHEREFORE, Plaintiffs and Defendant Turco respectfully request that this Court:

(1) Preliminarily approve the settlement, as set forth in the Settlement Agreement (Exhibit 1);

(2) Approve the proposed notice (Exhibit B to the Settlement Agreement), which will be posted and mailed immediately after preliminary approval, and a deadline of **April 19, 2018** for class members to submit comments about or objections to the proposed settlement;

(3) Schedule a fairness hearing for a date during the **week of April 23, 2018**; and

(4) Issue final approval of the settlement set forth in the Settlement Agreement and exhibits thereto.

Respectfully submitted,

PLAINTIFFS JEFFREY FOWLER, PAUL WHOOTEN, MICHAEL TURNER, AND MICHAEL FITZPATRICK on behalf of themselves and all others similarly situated, By their attorneys,

/s/ Joel H. Thompson
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DEFENDANT THOMAS TURCO,
As Commissioner of the Massachusetts Department of Correction, in his official capacity,

By his Attorneys,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent

electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on March 9, 2018.

/s/ Joel H. Thompson

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JEFFREY FOWLER, PAUL WHOOTEN, MICHAEL TURNER, and MICHAEL FITZPATRICK on behalf of themselves and all others similarly situated, Plaintiffs, v. THOMAS TURCO, Commissioner of Massachusetts Department of Correction, in his official capacity, and MASSACHUSETTS PARTNERSHIP FOR CORRECTIONAL HEALTHCARE, INC., Defendants.	C.A. NO. 1:15CV12298-NMG

SETTLEMENT AGREEMENT

I. PARTIES AND DEFINITIONS

1. The Parties to this Settlement Agreement ("Agreement") are plaintiffs Jeffrey Fowler, Paul Whooten, and Michael Turner[1]; the Class Members; and defendant Thomas Turco, in his official capacity as Commissioner of the Massachusetts Department of Correction. Defendant Massachusetts Partnership for Correctional Healthcare is not a party to this Agreement.

2. "Action" shall refer to the above-captioned action.

3. "Amended Complaint" shall refer to the Amended Complaint filed in the Action on or about July 29, 2016.

4. "Class Counsel" shall refer to Joel Thompson of Prisoners' Legal Services and

[1] Michael Fitzpatrick, identified in the case as a class representative, is no longer in the custody of the Department of Correction and thus is not a member of the class. Counsel will file an appropriate motion removing him as a class representative.

Jonathan Shapiro and David Kelston of Shapiro, Weissberg & Garin.

5. "Class Members" shall refer to all current and future DOC prisoners who have or will have Hepatitis C, as defined by the Court in its order allowing class certification.

6. "Contractor" shall refer to the entity providing correctional healthcare to DOC prisoners.

7. "DAA" shall refer to the class of medications known as Direct-Acting Antivirals, used to treat the Hepatitis C virus.

8. "DOC" shall refer to the Massachusetts Department of Correction, as established by G.L. c. 27.

9. "DOC Commissioner" shall refer to the Commissioner of the Massachusetts Department of Correction, as defined in G.L. c. 27, § 1.

10. "Fairness Hearing" shall refer to the hearing before the Court where the Parties will request that this Agreement be entered as an Order of the Court, as fair, reasonable, and adequate, and approve the Fee Award.

11. "Fee Award" shall refer to the amount of attorneys' fees and reimbursement of expenses and costs awarded by the Court to Class Counsel.

12. "Final Approval" shall refer to this Court's entry of this Agreement as an Order of the Court following the Fairness Hearing.

13. "Monitor" shall refer to the consultant(s) hired by DOC to ensure compliance with the Protocol, including any subsequent consultant(s), which DOC selects.

14. "MPCH" shall refer to the Massachusetts Partnership for Correctional Healthcare, one of the defendants in the Action.

15. "Notice" shall refer to the notice to the Class Members of this Agreement.

16. "Patient" shall refer to any prisoner in the custody of DOC who has Hepatitis C.

17. "Plaintiffs" shall refer to the individuals named as plaintiffs in the Action, and Class Members.

18. "Preliminary Court Approval" shall refer to the Court's preliminary approval of this Agreement and the Notice.

19. "Prisoner" shall refer to a committed offender and such other person as is placed in custody in a state correctional facility in accordance with law, as defined in G.L. c. 125, § 1(m), or an Inmate as defined in G.L. c. 125, § 1(i).

20. "Protocol" shall refer to the document titled "Clinical Guidance: Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection," as amended from time to time in accordance with the provisions of this Agreement. A current version of the Protocol, dated February 2018, is appended hereto as Exhibit A, the provisions of which are incorporated herein by reference.

II. FOCUS OF THIS AGREEMENT

21. The Parties acknowledge and agree that this Agreement is intended to address the medical treatment of Prisoners who have Hepatitis C.

III. IMPLEMENTATION OF HEPATITIS C TREATMENT PROTOCOL

22. Immediately following execution of this Agreement and Preliminary Approval by the Court and for the term of this Agreement, DOC shall cause the Contractor to implement the Protocol.

23. As of the date of Preliminary Approval of this Agreement by the Court, DOC shall cause the Contractor to produce a list of all Patients, and DOC shall produce a copy of the list to Class Counsel.

24. As detailed at pages 12-14 of the Protocol, DOC shall cause the Contractor to assign all Patients a Priority Level of 1, 2a, 2b, 2c, or 3, based on the criteria stated therein, and in

accordance with the screening and testing procedures set forth in the Protocol.

25. Within 12 months of the date of Preliminary Approval of this Agreement by the Court, DOC shall cause the Contractor to treat all Priority Level 1 Patients identified pursuant to paragraph 24 of this Agreement with DAAs, in accordance with the terms of the Protocol, regardless of how long it takes for the Contractor to assign them to this Priority Level.

26. Within 18 months of the date of Preliminary Approval of this Agreement by the Court, DOC shall cause the Contractor to treat all Priority Level 2a, 2b, and 2c Patients identified pursuant to paragraph 24 of this Agreement with DAAs, in accordance with the terms of the Protocol, regardless of how long it takes for the Contractor to assign them to this Priority Level.

27. During the 18 months following the date of Preliminary Approval of this Agreement by the Court, DOC shall cause the Contractor to treat any newly-admitted Prisoner who has the Hepatitis C virus and who is assigned a Priority Level of 1, 2a, 2b, or 2c, with DAAs, in accordance with the terms of the Protocol and in the following timeframes:

- Level 1 within 9 months of being assigned to Level 1; and,
- Levels 2a, 2b, and 2c within 12 months of being assigned to Level 2a, 2b, or 2c.

28. Within 18 months of the date of Preliminary Approval of this Agreement by the Court, DOC shall cause the Contractor to treat any existing Patient who had been assigned a Priority Level of 3, but who subsequently is re-assigned a Priority Level of 1, 2a, 2b, or 2c, with DAAs, in accordance with the terms of the Protocol and in the following timeframes:

- Level 1 within 9 months of being assigned to Level 1; and,
- Levels 2a, 2b, and 2c within 12 months of being assigned to Level 2a, 2b, or 2c.

29. Notwithstanding any other provision in this Agreement, after the initial 18-month period following Preliminary Approval of this Agreement by the Court, DOC shall cause the Contractor to treat any Prisoner who has the Hepatitis C virus and who is assigned a Priority Level of 1 with DAAs, in accordance with the terms of the Protocol, within 3 months of being assigned

or reassigned to Level 1.

30. Notwithstanding any other provision in this Agreement, after the initial 18-month period following Preliminary Approval of this Agreement by the Court, DOC shall cause the Contractor to treat any Prisoner who has the Hepatitis C virus and who is assigned a Priority Level of 2a or 2b with DAAs, in accordance with the terms of the Protocol, within 6 months of being assigned or reassigned to Level 2a or 2b.

31. Notwithstanding any other provision in this Agreement, after the initial 18-month period following Preliminary Approval of this Agreement by the Court, DOC shall cause the Contractor to treat any Prisoner who has the Hepatitis C virus and who is assigned a Priority Level of 2c with DAAs, in accordance with the terms of the Protocol, within 12 months of being assigned or reassigned to Level 2c.

32. The schedule laid out above is based on the review and analysis of current Patient information provided by DOC's Contractor and on national benchmarking data. DOC estimates that approximately 280 Patients in the current Prisoner population fall into Priority Levels 1, 2a, 2b, or 2c. If actual clinical experience demonstrates a 30% higher number of patients categorized as Priority Level 1, 2a, 2b or 2c than expected, the schedule shall be subject to revision. In this event, DOC shall notify Class Counsel in writing of the higher than expected Patient identification numbers and Class Counsel and DOC shall negotiate in good faith on a revised schedule. In any event:

- the schedule laid out in paragraph 25 shall not extend beyond 12 months from the date of Preliminary Approval of this Agreement by the Court;
- the schedule laid out in paragraph 26 shall not extend beyond 30 months from the date of Preliminary Approval of this Agreement by the Court.

33. In the event that changes in medical practice or the operational needs of DOC and/or the Contractor require revisions to the Protocol, DOC agrees to provide written notice of the

proposed changes to Class Counsel. Class Counsel shall have 30 days to comment on the proposed changes, which DOC shall consider in good faith, and any disputes between DOC and Class Counsel shall be resolved pursuant to Section VII of this Agreement. Any changes to the Protocol shall not extend the schedule for treatment outlined above or materially reduce the treatment provided.

IV. MONITORING FOR COMPLIANCE WITH THE PROTOCOL AND AGREEMENT

34. Within 60 days of Final Approval, DOC shall enter into an agreement with a Monitor, who shall not be DOC's medical contractor or any person employed by DOC, and who shall be reasonably acceptable to Class Counsel, whose role will be to ensure proper adoption and implementation of the Protocol. DOC shall provide a copy of the agreement with the Monitor to Class Counsel.

35. The Monitor shall conduct a concurrent review of a random selection of 100 identified Patients within the first 180 days of implementation of the Protocol, as set forth in paragraph 23 of this Agreement, from the screening and testing phase through the treatment and post-treatment monitoring, for such period of time as the Patient remains in DOC custody.

36. In addition to its concurrent review, the Monitor shall, at 6-month intervals starting upon DOC's entering into an agreement with the Monitor as set forth in paragraph 34 of this Agreement, conduct a retrospective review of Protocol adherence, from patient screening and baseline testing through post-treatment monitoring. The retrospective review shall include an audit of at least 10% of all Patient medical records, to ensure appropriate testing and staging in accordance with the Protocol.

37. The Monitor shall provide 6-month reports to the Parties on the results of its reviews. The Monitor, Class Counsel, Plaintiffs, and the Contractor shall use these reports only in connection with this litigation and for no purpose other than determining adherence to the Agreement and the agreed-upon Protocol. These reports shall not be disseminated other than to

Class Counsel, DOC, and the Contractor and cannot be introduced in any proceeding other than in this Action and then only for the purpose of demonstrating material compliance or material non-compliance with the adoption and implementation of the Protocol .

38. The Monitor's monitoring functions under this Agreement shall continue for a period of 30 months from the date of Final Approval of this Agreement by the Court.

39. The Monitor shall have access to all Prisoner medical records for the limited purpose of conducting its concurrent and retrospective reviews as detailed above. DOC shall cause the Contractor to cooperate with the Monitor and to provide access to all needed Prisoner medical records. All Parties shall comply with all applicable state and federal laws and requirements governing confidentiality of medical records, and shall negotiate in good faith to enter into any agreements required to protect said confidentiality of Prisoner medical records.

40. DOC's agreement with the Monitor shall provide that if the Monitor believes that there has been material non-compliance with the adoption and implementation of the Protocol, the Monitor shall raise that issue promptly with DOC and with Class Counsel and shall identify, in writing, the specific provision for which the Monitor believes there has been material non-compliance. The purpose of doing so will be to give the Parties a reasonable opportunity to review, discuss and correct any such material non-compliance. DOC shall provide the Monitor and Class Counsel with a written response within thirty (30) days. Any further dispute resolution required in response to findings by the Monitor shall be subject to the Dispute Resolution provisions of Section VII of this Agreement.

41. In addition to the Monitor's review for compliance with the Protocol, DOC shall, at 3-month intervals, generate and provide to Class Counsel reports sufficient to determine compliance with the treatment schedule set forth in paragraphs 25 to 31 of this Agreement. Such reports shall include, at a minimum, a list of all Patients, along with each Patient's assigned Priority Level, the date each Patient was assigned that Priority Level, the date each Patient entered DOC custody, and

the date each Patient began treatment with DAAs, if at all. If Class Counsel believes there has been material non-compliance with the treatment schedule set forth in paragraphs 25 to 31 of this Agreement, Class Counsel shall notify DOC in writing of the specific provision for which the Monitor believes there has been material non-compliance. DOC shall provide Class Counsel with a written response within thirty (30) days. Any further dispute resolution shall be subject to the Dispute Resolution provisions of Section VII of this Agreement.

V. PRELIMINARY APPROVAL

42. As soon as practicable following execution of this Agreement, DOC shall provide Class Counsel with the names and addresses of all Class Members, in the form of the "HCV Summary" provided by MPCH, and 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 in the form and pursuant to the method attached hereto as Exhibit B;

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.

VI. THE FEE AWARD

43. Class Counsel may file an application with the Court for payment by DOC of the Fee Award, to include (i) their reasonable attorneys' fees in an amount not to exceed $270,000.00, and (ii) their costs and expenses incurred in prosecution of this Action not to exceed $1,500.00. DOC agrees not to object to, and DOC agrees to pay such Fee Award if limited to those amounts. Notwithstanding anything herein, the Parties agree that the Court's failure to approve, in whole or

in part, the Fee Award sought by Class Counsel shall not prevent this Agreement from becoming effective nor be grounds for termination of this Agreement. Class counsel reserve all rights to seek reasonable attorneys' fees and costs for successful enforcement of this Agreement after Final Approval, and DOC reserves all rights to oppose any such petition for fees and costs.

VII. FINAL APPROVAL, DISPUTE RESOLUTION, AND ENFORCEMENT

44. All Parties agree that this Agreement represents a full and fair resolution of the claims for relief alleged in the Amended Complaint concerning the medical treatment of Prisoners who have Hepatitis C.

45. For purposes of this Agreement and its Final Approval by the Court, the Parties agree that this Action shall be maintained as a class action under FED. R. CIV. P. 23 with the class defined as all current and future DOC prisoners who have or will have Hepatitis C. The Parties also agree that the named plaintiffs, with the exception of Michael Fitzpatrick, or any person substituted for a named plaintiff by the Parties, shall be the class representatives for the Class Members.

46. 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 FED. R. CIV. P. 23(e). If the Court grants Final Approval, the Parties stipulate that this Agreement shall not be construed as a consent decree. 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.

47. This Agreement may be enforced only by the Parties hereto. Nothing contained in this Agreement is intended or shall be construed to evidence an intention to confer any rights or

remedies upon any person other than the Parties hereto.

48. If Plaintiffs believe that there has been material non-compliance with any provision of this Agreement by DOC, Plaintiffs, through Class Counsel, shall provide counsel of record for DOC, in writing, the specific reasons and grounds for such belief, including an identification of the specific provision with which such Plaintiff or Class Member believes there was material non-compliance. DOC shall have 30 days to respond to Plaintiffs' written statement. The Parties agree that any minor, incidental, or isolated breach or delay in implementation of a provision of this Agreement shall not constitute material non-compliance.

49. If the alleged material non-compliance is not resolved by or in connection with DOC's response to Plaintiffs' written statement, Plaintiffs, through Class Counsel, and DOC may jointly or individually seek relief from the Court to effect material compliance with this Agreement.

50. If the Court determines that there has been material non-compliance by DOC with a provision of this Agreement at any time during the period of the Agreement, the Court may enter an order consistent with equitable principles that is designed to achieve material compliance with such provision(s) of this Agreement, but not through a petition for contempt.

51. If Plaintiffs, through Class Counsel, contend that DOC has not complied with an order entered by the Court under the preceding paragraph, Plaintiffs may, after reasonable notice to DOC, move for further relief from the Court to obtain compliance with the Court's prior order. In ruling on such motion, the Court may apply equitable principles and may use any appropriate equitable or remedial power available to it.

52. The term of this Agreement shall commence upon the date of Final Approval by the Court and shall extend for 30 months from said date of Final Approval. The Court's jurisdiction shall terminate at the end of the 30-month period with respect to any provision of this Agreement for which there is no pending claim that DOC is in material non-compliance. If the Court

determines that there has been material non-compliance by DOC with a provision of this Agreement at any time during the 30-month period of this Agreement, or if there is a pending claim at the end of the 30-month period, the Court's jurisdiction with respect to such provision or provisions relating thereto shall continue until such time as DOC is found by the Court to be in compliance with this Agreement.

53. The Court shall be the sole forum for the enforcement of this Agreement. The Parties agree not to seek termination of or otherwise challenge this Agreement or any order approving this Agreement during the period of time that the Court retains jurisdiction. Nothing in this paragraph shall limit the Parties' rights to challenge or appeal any finding or any order entered by the Court.

54. Subject to the provisions set forth in this Section, this Agreement shall expire at the end of 30 months from the date of Final Approval by the Court and the Action shall be dismissed with prejudice.

VIII. DISMISSAL OF MPCH FROM ACTION

55. Plaintiffs agree to dismiss MPCH from this Action, with prejudice, upon Final Approval of this Agreement.

IX. APPROPRIATIONS AND RECEIPT OF FUNDING

56. The Parties acknowledge that DOC's ability to fulfill its obligations under this Agreement is subject to appropriations by the Legislature.

57. In order to implement and comply with this Agreement, the DOC shall submit budget requests as needed and will, consistent with Article 63 of the Massachusetts Constitution, make its best efforts to obtain the funding necessary to implement and comply with this Agreement. In the event that DOC alleges that it is unable to fulfill its obligations under this Agreement because of no or inadequate appropriations by the Legislature, Class Counsel reserve all rights to seek additional relief from the Court, including orders to the Commonwealth's executive or

legislative branch and DOC reserves all rights to respond and/or oppose any such requested additional relief.

X. NO ADMISSION OF LIABILITY

58. Nothing in this Agreement shall be construed in any way as an admission by DOC of any liability or wrongdoing whatsoever. DOC specifically disclaims any liability or wrongdoing whatsoever on the part of itself, its agents, and employees.

XI. MISCELLANEOUS

59. This Agreement sets forth the entire agreement between the Parties hereto, and fully supersedes any and all prior agreements or understandings between the Parties hereto pertaining to the subject matter hereof.

60. This Agreement shall be deemed to be made and entered into in the Commonwealth of Massachusetts and shall in all respects be interpreted, enforced, and governed under the laws of said Commonwealth and the laws of the United States.

61. This Agreement may not be relied upon as precedent in any future claim and shall not in any way be construed as an admission, presumption, or concession by any Defendant of any liability or wrongdoing whatsoever.

62. Each Party represents and acknowledges that each Party is and has been represented by its own counsel. Each Party further represents and acknowledges that, in executing this Agreement, no Party relies or has relied upon any representations or statements made by any other Party or its counsel other than the promises and representations set forth in this Agreement.

63. Should any part, term, or provision of this Agreement be declared or be determined by any Court to be illegal or invalid, the validity of the remaining parts, terms, or provisions shall not be affected thereby and said illegal or invalid part, term, or provision shall be deemed not to be a part of this Agreement, unless the Court declines to approve this Agreement.

64. Except as otherwise stated, this Agreement shall only be amended, revoked,

changed, or modified through a written agreement executed by all the Parties and approved by the Court. No waiver of any provision of this Agreement will be valid unless it is in writing and signed by the Party against whom such waiver is charged and approved by the Court.

65. This Agreement is the result of an arm's-length negotiation. Since all Parties contributed substantially, materially, and cooperatively in drafting this Agreement, it shall not be more strictly construed against one Party than any other.

66. This Agreement may be executed in a number of identical counterparts, all of which shall together constitute one Agreement, and such execution may be evidenced by signatures delivered by facsimile transmission or other electronic means.

JEFFREY FOWLER, PAUL WHOOTEN, AND MICHAEL TURNER on behalf of themselves and all others similarly situated,

Plaintiffs,
By their attorneys,

2/15/18
Date

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THOMAS TURCO, III, Commissioner of the Massachusetts Department of Correction,

Defendant

Signature

2/14/18
Date

Counsel for Thomas Turco, III

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Exhibit A

Clinical Guidance

Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection

MA Department of Correction

February 2018

This Clinical Guidance Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection is based largely on the May 2017 Federal Bureau of Prisons Clinical Guidance: Evaluation and Management of Chronic Hepatitis C Virus (HCV) (https://www.bop.gov/resources/pdfs/hcv_201707.pdf), with adjustments and tailoring to the Massachusetts Department of Correction (DOC) and its contracted medical vendor.

Proper medical practice necessitates that each case is evaluated on an individual basis and that treatment decisions, the exclusive province of the DOC's contracted medical vendor and its clinicians, are patient-specific.

Table of Contents

1. Purpose and Overview

The Massachusetts Department of Correction (DOC) Clinical Guidance on *Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection* provides recommendations for the treatment of chronic HCV infection in the state inmate population. **Guidance for Hepatitis C treatment in adults is changing constantly with the advent of new therapies and other developments.** The national hepatology and infectious diseases subspecialty organizations: the *American Association for the Study of Liver Diseases (AASLD)* and the *Infectious Diseases Society of America (IDSA)*, respectively, provide updated treatment recommendations for Hepatitis C on the website, www.HCVguidelines.org. The DOC Health Services Division and its contracted medical vendor will regularly monitor this website to stay abreast of revised treatment recommendations.

Although nearly all patients with chronic HCV infection are candidates for direct-acting antivirals (DAAs) therapies, there is more urgency to treat certain patients first. A prioritization approach is particularly important in correctional settings that have an extremely large number of patients available for treatment.

The recommended approach to evaluation and management of HCV includes six basic steps.

STEP 1: Screening and Testing for HCV infection

- All inmates (as outlined in Section: **Screening Criteria; page 5-6**) are tested (with an opt-out allowance)
- Evaluation of other clinical conditions
- Upon inmate request

STEP 2: Perform a Baseline evaluation of Inmates

- Targeted history and physical exam
- Laboratory Tests (as outlined in Section: **Baseline Examination; page 6**)

STEP 3: Assess for Hepatic Cirrhosis and Decompensation

- Assess for hepatic cirrhosis/compensation
- Calculation of APRI and FIB-4 scores if no obvious cirrhosis
- Calculation of CTP scores if cirrhosis is known or suspected

STEP 4: Priority criteria for treatment, if HCV RNA is detectable.

- Assess for priority criteria for treatment of HCV (as outlined in Section: **Priority Criteria for HCV Treatment; page 11**)

STEP 5: Refer Patient to Treatment with DAAs

- Treatment, for purposes of this Clinical Guidance, means the prescribed course of DAA medication administration, and does not include pre-treatment assessments or evaluations or ongoing monitoring of patients determined not to meet the criteria for treatment with DAAs.
- Determine the most appropriate DAA regimen(s) based on pretreatment labs
- DAA regimen selection is based on genotype, cirrhosis, compensation, and drug interactions
- Refer to AASLD HCV guidelines, DHHS antiretroviral guidelines, and manufacturers' prescribing information for specific drug interactions

STEP 6: Hepatitis C Treatment Monitoring

- Testing for HCV infection will be logged and tracked
- All diagnosed with HCV infection; including labs, will be entered into a patient registry by the contracted medical vendor.

2. Inmate History and Patient Education

All inmates should be provided with educational information regarding HCV infection, which must include information concerning prevention and transmission, risk factors, testing, and medical management of HCV infection.

a. Screening for Chronic HCV Infection

The incarcerated population is reported to have higher prevalence rates of HCV than the general population. Incarceration has been identified by the AASLD and United States Preventive Services Task Force (USPSTF) as a risk factor for which screening is recommended.

Medical staff should develop a complete health history for all newly incarcerated DOC inmates in accordance with Department of Public Health, DOC, and medical vendor policies: *105 CMR 205.000 - MINIMUM STANDARDS GOVERNING MEDICAL RECORDS AND THE CONDUCT OF PHYSICAL EXAMINATIONS IN CORRECTIONAL FACILITIES; § 205.200 - CONTENT OF PHYSICAL EXAMINATION; 103 DOC 630.06 - MEDICAL ENTRANCE SCREEN*; MPCH *32.00 - RECEIVING SCREENING;* AND *MPCH 34.00 - INITIAL HEALTH ASSESSMENT*.

Testing for HCV infection is recommended and will be offered for **(a)** all newly incarcerated inmates within 14 days of admission, as part of their intake physical examination pursuant to 103 DOC 630.09(1), **(b)** all inmates with certain clinical conditions and risk factors, and **(c)** all inmates who request testing.

Testing for HCV infection at the prevention baseline visit will be offered and recommended for all inmates with an "opt-out."

- An "opt out" approach involves an informed refusal of testing, rather than informed consent (or "opt in") for testing. After informing a patient of the indications and plan for testing, the particular test is ordered and performed—unless the patient declines it. Testing is considered voluntary in that it is good clinical practice, but is not required by policy or Massachusetts law.

- Inmates who initially opt out of testing will be approached at a later time in their incarceration consistent with DOC policy: *103 DOC 630.09 - INTAKE PHYSICAL EXAMINATION*.

- A tracking system to be implemented by the medical vendor will document inmate acceptance rate for OPT OUT voluntary testing for HCV infection.

b. Clinical Conditions and Risk Factors

HCV testing is recommended for all inmates with the following clinical conditions:

- Chronic hemodialysis – screen alanine aminotransferase (ALT) monthly and anti-HCV

semiannually
- Signs or symptoms of HCV infection
- Elevated ALT levels of unknown etiology
- Evidence of extrahepatic manifestations of HCV – mixed cryoglobulinemia, membranoproliferative glomerulonephritis, porphyria cutanea tarda, vasculitis

As described by the USPSTF and the Centers for Disease Control and Prevention (CDC), risk factors should be assessed when educating inmates about HCV screening. Major risk factors include:

- 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
- Experienced percutaneous exposure to blood
- Received hemodialysis
- Born to a mother who had HCV infection at the time of delivery
- Born between 1945 and 1965

3. Baseline Evaluation of Anti-HCV Positive Inmates

The preferred testing for HCV infection is an immunoassay that measures the presence of antibodies to HCV antigens, referred to as *HCV Ab* or *anti-HCV*. The presence of these antibodies only indicates a history of exposure to the HCV virus, but does not distinguish between active and resolved infection.

Baseline evaluation of anti-HCV positive inmates includes: (a) Baseline Clinical Evaluation, (b) Assessment of Liver Fibrosis, (c) Assessment for Hepatic Cirrhosis, (d) Assessing Hepatic Compensation, and (e) Additional Evaluations for Inmates with Advanced Fibrosis or Cirrhosis.

THE BASELINE CLINICAL EVALUATION SHOULD BE CONDUCTED **WITHIN TWO MONTHS** FROM THE DATE OF THE HCV TEST, AS SET FORTH ABOVE. PATIENTS WITH GREATER RISK FACTORS OR ADVANCED CLINICAL CONDITIONS SHOULD BE PRIORITIZED FOR BASELINE CLINICAL EVALUATIONS.

a. Baseline Clinical Evaluation

A baseline clinical evaluation should be conducted for all inmates who are found to be anti-HCV positive within two months of test. At a minimum, this evaluation should include the following elements:

i. Targeted History Review and Physical Examination

- Evaluate for signs and symptoms of liver disease, quantify prior alcohol consumption, and determine risk behaviors for acquiring HCV infection (see the section on risk factors under Screening Criteria above).

- Attempt to estimate the earliest possible date of infection, including when risk factors for exposures started and stopped (e.g., the time period in which the inmate engaged in injection drug use).

- Evaluate for other possible causes of liver disease, especially alcoholism, nonalcoholic steatohepatitis (NASH), iron overload, and autoimmune hepatitis.

- Inquire about prior treatment for HCV infection, specific medications used, dosages, and duration of treatment, and outcomes, if known.

ii. Laboratory Tests

Recommended baseline laboratory tests are listed in Appendix I and include the following:

- 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).

- Unexplained abnormalities should prompt additional diagnostic evaluations, as clinically indicated, to determine the underlying cause, e.g., low hemoglobin/platelet count or GFR.

- Hepatitis B serologies (HBsAg, anti-HBs, and anti-HBc) and HIV antibody (anti-HIV or HIV Ab).

- Quantitative HCV RNA viral load testing, sensitive to ≤ 25 IU/ml, with reflex testing for HCV genotype, to determine if the inmate has active HCV infection and identify the HCV genotype. Undetectable levels of HCV RNA indicate resolved infection or a false positive HCV Ab test.

- 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.

b. Assessment of Liver Fibrosis

The APRI and FIB-4 scores are the preferred approach for assessing the degree of liver fibrosis.

- If a person is known to have cirrhosis, calculating the APRI or FIB-4 is irrelevant and unnecessary. For all other identified inmates, an APRI and FIB-4 score shall be calculated.

- Previous staging tests of any kind shall be obtained (reasonable effort shall be made to obtain pre-DOC records) and their results shall be considered alongside current testing, with the priority level based on the highest test result under consideration.

- The APRI score is a calculation based on results from two blood tests—the AST (aspartate aminotransferase) and the platelet count. A calculator is available at: http://www.hepatitisc.uw.edu/page/clinical-calculators/apri.

- An APRI score of > 2 is associated with cirrhosis (Stage 4). An APRI score of > 1.5 is associated with advanced fibrosis (Stage 3).

- The FIB-4 is a calculation using the patient's age and the following blood test results: aspartate

aminotransferase (AST); alanine aminotransferase (ALT); and platelet count. A calculator is available at http://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4.

- A FIB-4 score of > 3.25 is associated with advanced fibrosis (Stages 3 or 4). A FIB-4 score of < 1.45 has a very high negative predictive value for cirrhosis.

- Certain inmates, e.g., those with mid-range APRI and FIB-4 scores or otherwise uncertain diagnostic studies, can be assessed for advanced fibrosis or cirrhosis using other staging tests, for example, elastography, to be determined on a case-by-case basis. Said inmates shall be assigned to a priority level, pursuant to Section 6 below, based on their APRI and FIB-4 scores while the results of other staging tests are pending, and they shall be reassigned if needed once those results are available.

- Liver biopsies are not usually required to assess liver disease unless there are unusual clinical indications. The results of a prior biopsy shall be considered in assigning a priority level.

- All inmates diagnosed with HCV infection will be entered into a patient registry created and maintained by the medical vendor to be updated within 30 days of Baseline Evaluation, which will include - at a minimum - age, ALT, AST, APRI score, FIB-4 score, results of other staging tests (if any), platelet count, and CTP and MELD scores if cirrhotic.

- In situations where the APRI and FIB-4 Score result in differing liver fibrosis assessment results, the higher score shall generally be applied (i.e., the higher score representing a higher degree of liver fibrosis), unless there is a clinical reason, unrelated to Hepatitis C, for the discordantly higher assessment result.

c. Assessment for Hepatic Cirrhosis

Assessing for cirrhosis is important for prioritizing inmates for treatment of HCV infection and for determining the need for additional health care interventions. Cirrhosis can be diagnosed in several ways:

- Inmates may present with symptoms and signs that support the diagnosis of cirrhosis that may include: Low albumin, low platelets, elevated bilirubin, elevated INR, ascites, esophageal varices, and hepatic encephalopathy.

- Isolated laboratory abnormalities may require additional diagnostic evaluations to determine their etiology.

- Abdominal imaging studies such as an ultrasound or CT scan may identify findings consistent with advanced liver disease such as: (a) cirrhosis, as evidenced by a nodular contour of the liver; (b) portal hypertension, as evidenced by ascites or splenomegaly; or (c) hepatocellular carcinoma (HCC).

- Inmates without clinical or radiographic evidence of cirrhosis can be assessed for liver fibrosis or cirrhosis through non-invasive assessments. The APRI and FIB-4 scores are the preferred methods for assessing liver disease related to HCV infection.

- The Child-Turcotte-Pugh (CTP) score is a useful tool in determining the severity of cirrhosis and in

distinguishing between compensated and decompensated liver disease. See the discussion below under Assessing Hepatic Compensation.

d. Assessing Hepatic Compensation

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.

The CTP SCORE is a useful tool to help determine the severity of cirrhosis and is used by the AASLD to distinguish between compensated and decompensated liver disease in patients with known or suspected cirrhosis.

- CTP calculators are readily available on the Internet and are not reproduced in these guidelines: http://www.hepatitisc.uw.edu/page/clinical-calculators/ctp .

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 and notes below:

CTP SCORE	CTP CLASS	HEPATIC COMPENSATION
5–6	Class A	Compensated cirrhosis
7–9	Class B	Decompensated cirrhosis
≥ 10	Class C	Decompensated cirrhosis

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

- Warfarin anticoagulation will invalidate CTP calculations if the INR is 1.7 or higher.

- 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.

e. Additional Evaluations for Inmates with Advanced Fibrosis or Cirrhosis

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

- **Hepatocellular carcinoma (HCC) screening:** Liver ultrasound is recommended every 6 months for patients with advanced fibrosis (Stage 3) or cirrhosis and chronic HCV infection. HCC surveillance should continue in patients who have been successfully treated for HCV infection.

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

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 the Clinical Guidelines. Other resources should be consulted for more specific recommendations related to this condition.

4. Preventive Health and Patient Education

The inmate should also 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 HCV infection. All inmates who are anti-HCV positive should be evaluated to assess the need for the preventive health interventions in accordance with policies on preventive health visits (as outlined in *DOC Policy: 103 DOC 630 - MEDICAL SERVICES* and *MPCH 34.00 - INITIAL HEALTH ASSESSMENT*), 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 a Hepatitis B vaccination.

- Hepatitis A vaccine: Indicated for susceptible inmates with chronic HCV. 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 an influenza vaccine.

Inmates diagnosed with chronic HCV infection should be counseled by a health care provider regarding the natural history of the infection, potential treatment options, and specific measures to prevent transmitting HCV infection to others (both during incarceration and upon release) consistent with DOC policies on preventive health visits and other policies (as outlined in *105 CMR 205.000 - MINIMUM STANDARDS GOVERNING MEDICAL RECORDS AND THE CONDUCT OF PHYSICAL EXAMINATIONS IN CORRECTIONAL FACILITIES; § 205.104 - RESULTS OF EXAMINATION TO BE DISCUSSED WITH INMATE, 103 DOC 630.09 - INTAKE PHYSICAL EXAMINATION; MPCH 34.00 - INITIAL HEALTH ASSESSMENT; MPCH 46.00 - HEALTH PROMOTION AND DISEASE PREVENTION;* AND *MPCH 51.00 - SPECIAL NEEDS, CHRONIC, AND CONVALESCENT CARE)*.

5. Priority Criteria for HCV Treatment

An important part of the initial evaluation and ongoing management of inmates with chronic HCV

infection is determining if the priority criteria for treatment are met. Although nearly all patients with chronic HCV infection are candidates for DAA therapies, there is more urgency to treat certain patients first. A prioritization approach is particularly important in correctional settings that have an extremely large number of patients available for treatment.

The medical vendor will apply the criteria below for prioritizing inmates for treatment with direct-acting antivirals (DAAs).

In situations where the APRI and FIB-4 Score result in differing liver fibrosis assessment results, the higher score shall generally be applied (i.e., the higher score representing a higher degree of liver fibrosis), unless there is a clinical reason, unrelated to Hepatitis C, for the discordantly higher assessment result. Likewise, in cases where there are one or more other liver fibrosis staging test results, the higher result shall generally be applied, unless there is a clinical reason, unrelated to Hepatitis C, for the higher result.

Note: The priority categories do not provide a comprehensive review and are not all inclusive of all possible patient conditions or clinical scenarios. Prioritization and treatment decisions are patient-specific.

a. Priority Level 1 - High Priority for Treatment

- Clinical evidence of cirrhosis or

- Subclinical advanced fibrosis or cirrhosis of the liver (F3, F4 stages) as diagnosed by:

    - Liver biopsy or
    - AST-platelet ratio index (APRI) ≥ 2.0[5] or FIB-4 score > 3.25 or
    - Other staging tests (e.g., Fibrosure, Fibroscan) may also be considered.

or

- Liver transplant recipients or

- Hepatocellular carcinoma (HCC) or

- Comorbid conditions associated with HCV infection:
    - Certain lymphomas/hematologic malignancies or
    - Cryoglobulinemia with renal disease or vasculitis.

or

- Continuity of care for those entering custody already on treatment

b. Priority Level 2a - Intermediate Priority for Treatment

- APRI ≥ 1.5 and < 2.0

    - In situations where the APRI and FIB-4 Score result in differing liver fibrosis assessment results, the higher score shall be applied (i.e., the higher score representing a higher

degree of liver fibrosis).
- Other staging tests (e.g., Fibrosure, Fibroscan) may also be considered. In situations where the results of such tests result in differing liver fibrosis assessment results, the higher score shall be applied (i.e., the higher score representing a higher degree of liver fibrosis).

c. Priority Level 2b - Intermediate Priority for Treatment

- Co-infection with HIV or HBV or
- Chronic kidney disease with GFR ≤ 59 mL/min per 1.73m^2

d. Priority Level 2c - Intermediate Priority for Treatment

- F2 fibrosis stage on liver biopsy or
- APRI ≥ 1.0 and < 1.5

  - In situations where the APRI and FIB-4 Score result in differing liver fibrosis assessment results, the higher score shall be applied (i.e., the higher score representing a higher degree of liver fibrosis).
  - Other staging tests (e.g., Fibrosure, Fibroscan) may also be considered. In situations where the results of such tests result in differing liver fibrosis assessment results, the higher score shall be applied (i.e., the higher score representing a higher degree of liver fibrosis).

or

- Diabetes mellitus or
- Comorbid liver diseases, e.g. steatohepatitis
  - *A higher category of prioritization may be clinically indicated, depending on the type and severity of concurring liver disease*

e. Priority Level 3 – Low Priority for Treatment

- F0/F1 fibrosis stage on liver biopsy or
- APRI < 1 or FIB-4 < 1.45

  - In situations where the APRI and FIB-4 Score result in differing liver fibrosis assessment results, the higher score shall be applied (i.e., the higher score representing a higher degree of liver fibrosis).
  - Other staging tests (e.g., Fibrosure, Fibroscan) may also be considered. In situations where the results of such tests result in differing liver fibrosis assessment results, the higher score shall be applied (i.e., the higher score representing a higher degree of liver fibrosis).

* EXCEPTIONS to the above criteria for PRIORITY LEVELS 1–3 will be made on an individual basis and will be determined primarily by a compelling or urgent need for treatment, such as evidence for rapid progression of fibrosis, or deteriorating health status from other comorbidities.

f. Other Criteria for Treatment

In addition to meeting the above criteria for PRIORITY LEVELS 1–3, inmates being considered for treatment of HCV infection should be evaluated for the following criteria:

- Have no contraindications with a component of the DAA treatment regimen or drug interactions which cannot be mitigated (i.e., temporary cessation, dose adjustment or use of alternatives).

- Not be pregnant.

- Lacking sufficient time remaining on their sentence in the DOC to complete a course of treatment (that is, the prescribed course of DAA treatment, which is typically 8-12 weeks but could be longer) shall not be an automatic exclusion from treatment. If time remaining on their sentence is an issue, Pre-Treatment Assessment (Section 7.a., below) must be expedited and a continuity of care plan should be implemented prior to the prisoner being released during the treatment.

- Have a life expectancy > 18 months (for any condition or aliment, not specific to HCV infection).

- Have a willingness and an ability to adhere to a DAA treatment regimen.

- Evidence of current IV drug use shall not be an automatic exclusion from treatment. Patients with current IV drug use will be evaluated on a case-by-case basis for DAA therapy and referred for evaluation and treatment of chronic substance use disorder.

6. Treatment of HCV Infection

ALL INMATES WHO RECEIVED A BASELINE CLINICAL EVALUATION SHALL BE ASSIGNED A PRIORITY LEVEL (1, 2A, 2B, 2C, OR 3) ACCORDING TO THE FOLLOWING PRIORITY CRITERIA FOR HCV TREATMENT **WITHIN ONE MONTH** FROM INITIAL BASELINE EVALUATION. THEY SHALL BE REASSIGNED, IF NEEDED, UPON RECEIPT OF RESULTS FROM ANY OTHER STAGING TESTS THAT PRECEDED OR FOLLOWED THE BASELINE CLINICAL EVALUATION.

Curative medications are now available for most patients with chronic HCV infection. These medications are called direct-acting antivirals (DAAs) since they directly attack the replicating Hepatitis C virus. There are three major classes of DAAs: polymerase inhibitors ending in “buvir”; protease inhibitors ending in “previr”; and NS5A replication complex inhibitors ending in “asvir.”

- Major factors that determine the most appropriate DAAs include HCV genotype, history of prior HCV treatment, presence of compensated or decompensated cirrhosis, and the potential for significant drug interactions.

- Patients with HCV infection complicated by chronic kidney disease, solid organ transplantation, pregnancy, or decompensated cirrhosis require special considerations in determining DAA treatment options.

- Once an inmate is engaged in a treatment regimen, the filing of any disciplinary action (e.g., D Report) against the inmate shall not be a reason for discontinuing the regimen. Only clinical concerns identified through Monitoring Parameters for Inmates with Ongoing (Active) HCV Infection, shall be cause for mid-treatment suspension.

a. Preferred Treatment Regimens

The preferred treatment options for HCV infection are consistent with the DAA regimens currently recommended by the AASLD and IDSA subspecialty organizations as updated on their website, www.hcvguidelines.org.

- The general preferred treatment regimens non-specific to any particular inmate will be determined through a centralized review process co-led by the DOC's Health Services Division and the DOC's contracted medical vendor.

- Prior to selecting a specific DAA treatment, potential drug interactions must be carefully reviewed.

- Mixed genotypes or unclear genotypes should be treated with a pan-genotypic regimen, in accordance with the AASLD/IDSA guidelines

- Adjustments of the inmate's current medications may be needed prior to the initiation of HCV treatment. Useful resources for potential drug interactions include the AASLD/IDSA guidelines, the individual manufacturer's prescribing information, and the DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents.

Please refer to the AASLD/IDSA/IAS-USA website (www.hcvguidelines.org) for any updates since September 16, 2016.

Please refer to this resource that is regularly updated, http://hep-druginteractions.org, for potential drug interactions which must be reviewed before choosing a DAA regimen.

7. Monitoring

a. Pre-Treatment Assessment

Pre-treatment assessment should be accomplished within 3 months of the projected start of treatment, and should include the following:

- Laboratory tests including CBC, PT/INR, liver panel, serum creatinine, calculated GFR.

- Calculation of the APRI and FIB-4 scores from the pre-treatment labs. The scores are not needed if there is confirmed cirrhosis.

- Quantitative HCV RNA viral load and HCV genotype if the most recent results are more than one year old or if not previously performed.
- Calculation of current CTP scores for inmates with known or suspected cirrhosis.
- Assessment for significant drug-drug interactions.
- Assessment for current/prior medication adherence.

Prior to starting treatment for HCV infection, patient education is required. Patient education should include instruction on how to take the medication, the importance of adherence, monitoring, and follow up, and potential medication side effects. When ribavirin is used, specific counseling about the risks and recommendations related to pregnancy should be provided.

b. Treatment Monitoring

Comprehensive monitoring parameters for inmates receiving DAA therapies are outlined in Appendix I - *Hepatitis C Treatment Monitoring Schedule*.

i. On-treatment monitoring should include the following:

- **Clinic visits at 2 weeks and at 4 weeks** after starting therapy and monthly thereafter; more frequently as clinically indicated.
- **Labs drawn at 4 weeks** after the start of therapy should include CBC, creatinine, calculated GFR, liver panel, and quantitative HCV viral load sensitive to ≤ 25 IU/ml; others as clinically indicated.

ii. More Frequent Monitoring of Asymptomatic ALT

- Increases in the ALT should prompt more frequent monitoring or early discontinuation. Asymptomatic ALT increases of less than tenfold should be monitored approximately every 2 weeks. Early discontinuation of HCV treatment is recommended if ALT increases by tenfold—or if less than tenfold, but accompanied by *symptoms* such as weakness, anorexia, nausea, vomiting, or change in stool color, or *signs* including elevations in conjugated bilirubin, alkaline phosphatase, and INR, related to hepatic dysfunction.
- If the quantitative HCV viral load is detectable after 4 weeks of treatment, the test 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.
- 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.
- Pregnancy testing is required prior to treatment, and then periodically during and after treatment—usually monthly during treatment and for 6 months after completion of treatment.

- Monitoring parameters for inmates receiving DAA therapies are outlined in Appendix I - *Hepatitis C Treatment Monitoring Schedule.*

- Testing for HCV drug-resistant mutations is not routinely recommended at this time.

c. 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 patient no longer requires periodic follow-up if s/he does not have advanced fibrosis or cirrhosis. Patients with advanced fibrosis and cirrhosis who have been successfully treated for HCV infection should be monitored with a clinical assessment and an ultrasound every 6 months to screen for hepatocellular carcinoma.

- 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.

d. Monitoring Parameters for Inmates with Ongoing (Active) HCV Infection

Periodic monitoring is required for all inmates with ongoing HCV 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: the evaluation should include a focused review of systems and patient education relevant to HCV; vital signs and a focused physical examination; laboratory monitoring (CDC, PT/INR, liver panel, serum creatinine, calculated GFR; and calculation of APRI and FIB-4 scores). Patients should generally be periodically evaluated with the following frequency:

    - APRI < 1 and FIB-4 < 1.45 or other staging test (F0-F1) – minimum of 6-month evaluations

    - APRI 1.0 to 1.5 and FIB-4 ≥ 1.45 and ≤3.25 or other staging test (F2) – minimum of 6-month evaluations

- Patients with advanced fibrosis (F3), cirrhosis (F4) or significant comorbidities should have ongoing monitoring at least every 3 months or more frequently as clinically indicated. Evaluations should include an ultrasound every 6 months to screen for hepatocellular carcinoma.

- In cases of acute HCV infection, monitoring for spontaneous clearance of the infection with ALT and quantitative HCV RNA levels every 4 to 8 weeks, for 6 to 12 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.

8. HCV and Coinfection and/or Comorbidities

a. Hepatitis B Coinfection (HBV)

- In patients coinfected with HBV and HCV, HBV reactivation may occur during or after treatment with HCV DAAs. Testing for HBV infection—including HBsAg, anti-HBs, and anti-HBc, as well as HBV DNA levels in those with positive HBsAg or anti-HBc serologies prior to treatment with DAAs is recommended for all patients being considered for treatment of HCV infection.
    - **IF CRITERIA FOR TREATMENT OF HBV ARE MET**, it is recommended that HBV treatment be started prior to or at the same time as HCV treatment, and monitored according to HBV treatment standards.
    - **IF CRITERIA FOR TREATMENT OF HBV INFECTION ARE NOT MET**, monitoring of HBV DNA every 4 weeks during HCV treatment is recommended.

A patient coinfected with HBV and HCV should be seen by a clinician with experience and training in both clinical areas.

b. HIV Coinfection

In general, HCV medication regimens are the same for HIV coinfected patients as for HIV-negative patients. Existing guidelines for currently recommended HCV regimens are equally effective for HCV mono-infection and coinfection with HIV. However, an alternative HCV regimen or an alternative antiretroviral medication regimen may be necessary due to potential drug interactions between the HCV DAAs and certain antiretrovirals.

A patient coinfected with HIV and HCV should be seen by a clinician with experience and training in both clinical areas.

c. Decompensated Cirrhosis

HCV treatment recommendations for patients with decompensated cirrhosis apply regardless of eligibility for a liver transplant or the presence of hepatocellular carcinoma. Such cases should be managed in consultation with an experienced clinician/specialist, with treatment requests considered on a case-by-case basis.

d. Pregnancy

Data is limited on the reproductive and fetal effects of HCV DAAs in humans. The FDA lists the current HCV DAAs as Pregnancy Category B (i.e., no evidence of risk), based on studies using animal reproduction models. Current guidelines do not address the use of DAAs for treatment of HCV in pregnancy.

- Women of childbearing potential who are being considered for an HCV regimen that includes

ribavirin should be counseled on the adverse fetal effects of ribavirin. They should be advised not to become pregnant during treatment with ribavirin *and* for 6 months after the treatment has ended. They should also be advised that the same risks apply if a male sex partner is being treated with ribavirin.

- A negative pregnancy test should be documented prior to starting treatment with ribavirin, monthly during treatment, and for 6 months after treatment.

- Men being treated with ribavirin should also be counseled on the adverse fetal effects of ribavirin. They should be advised not to cause pregnancy in their female sex partners during treatment with ribavirin *and* for 6 months after the treatment has ended.

APPENDIX I. HEPATITIS C TREATMENT MONITORING SCHEDULE

Evaluation[1]	Baseline (anti-HCV positive)	Pretreatment (Within 90 days of Tx)	On-Treatment Monitoring (by week of treatment)[2]							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[3], HBsAb, Anti-HAV (IgG)	X										
Prothrombin Time / INR	X	X									
CBC	X	X	X	X							
Serum creatinine + eGFR	X	X		X						X	X
ALT, AST, bilirubin, alkaline phosphatase, albumin	X			X	As clinically indicated[4]						
APRI, FIB-4 score & CTP score[5]	X	X									
HCV RNA, quantitative[6]	X	X		X						X	X
HCV genotype	X										
Assess for drug-drug interactions & adherence		X	At each clinician evaluation during treatment.								
Urine pregnancy test (if childbearing potential)		X		X	X	X	X	X	X	monthly x 6 mos	

1 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.

2 More frequent monitoring may be required if clinically indicated.

3 Recommended baseline testing for hepatitis B status includes HBsAg, anti-HBc, and anti-HBs. If either HBsAg or anti-HBc is positive, obtain an HBV DNA viral load. If criteria for HBV treatment are met, initiating antiviral therapy for HBV is recommended prior to or at the same time as HCV treatment. If criteria for treatment of chronic HBV infection are not met, monthly HBV DNA viral loads are recommended during treatment for HCV.

4 More frequent monitoring of ALT is necessary in certain situations: 1) Regimens containing elbasvir/grazoprevir: An ALT should be drawn at 4 weeks and again at 8 weeks, and as clinically indicated. For 16-week regimens, an ALT should also be drawn at 12 weeks; 2) Patients with compensated cirrhosis who are treated with paritaprevir/ritonavir/ ombitasvir, with or without dasabuvir, require more frequent monitoring of ALT; 3) Increases in the ALT should prompt more frequent monitoring or early discontinuation. Asymptomatic ALT increases of less than tenfold should be monitored approximately every 2 weeks. Early discontinuation of HCV treatment is recommended if ALT increases by tenfold—or if less than tenfold , but accompanied by *symptoms* such as weakness, anorexia, nausea, vomiting, or change in stool color, or *signs* including elevations in conjugated bilirubin, alkaline phosphatase, and INR, related to hepatic dysfunction.

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

6 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.

IBAVIRIN-CONTAINING REGIMENS: **A pretreatment ECG is recommended for inmates with preexisting coronary heart disease. A CBC should be obtained 2 and 4 weeks after starting treatment, every 4 weeks while on treatment, and more frequently as clinically indicated.**

Exhibit B

NOTICE CONCERNING HEPATITIS C TREATMENT IN THE DOC
Proposed Class Action Settlement
***Fowler, et al. v. Turco, et al.*, U.S.D.C. Mass., No. 1:15-cv-12298-NMG**

If you have or may have Hepatitis C, please be aware that a settlement has been proposed to the federal court in the case of *Fowler v. Turco*, a class action brought on behalf of all DOC prisoners with Hepatitis C, challenging the adequacy of Hepatitis C evaluation and treatment. The proposed settlement contains several terms, including the following:

- All Hepatitis C patients who now have advanced liver fibrosis or cirrhosis (stage F3 or F4), or other serious complications, will be treated within 12 months, with direct acting antiviral (DAA) medications;
- All Hepatitis C patients who now have moderate liver fibrosis (stage F2) will be treated within 18 months;
- Those who do not have liver fibrosis at or above stage F2 will be reevaluated every 6 months;
- Any prisoners who in the future develop advanced liver fibrosis or cirrhosis (stage F3 or F4), or other serious complications, will be treated in no longer than 9 months and, after the first 18 months of the settlement, will be treated within 3 months;
- Any prisoners who in the future develop moderate liver fibrosis (stage F2) will be treated within 12 months;
- Exclusion from treatment based on disciplinary reports will be eliminated, and exclusions from treatment based on alleged substance use or time remaining in custody, will be narrowed;
- All new prisoners will be offered testing to see if they have Hepatitis C, and testing will be given to any prisoners already in custody who request it.

The U.S. District Court will review the proposed settlement, and any objections from class members (DOC prisoners with Hepatitis C), before deciding whether to approve it. If you would like more information about the proposed settlement or a copy of the settlement agreement, please contact the attorneys for the plaintiff class, care of:

Joel Thompson
Prisoners' Legal Services
10 Winthrop Square, 3rd Flr.
Boston, MA 02110
Phone (from a DOC facility): *9004#

If you are a class member and want to object to the proposed settlement, please send your objection in writing, by no later than **April 19**, **2018**, to the Court (include in your letter the title of the case and the docket number, as shown at the top of this notice):

Clerk, United States District Court
One Courthouse Way, Suite 2300
Boston, MA 02210