

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

MICHAEL RAY STAFFORD,
CHARLES SMITH and DOUGLAS SMITH,
individually, and on behalf of those
similarly situated,

Plaintiffs,

v.

ROBERT E. CARTER, JR., et al.,

Defendants.

Case No. 1:17-cv-289-JMS-MJD

Third Stipulation to Enter into Settlement Agreement
Pursuant to 18 U.S. Code § 3626(c)(2)
Following Notice to the Class and Fairness Hearing

The parties, in person and by their counsel, stipulate and agree as follows:

I. History of the case.

1. Hepatitis C is an infectious disease that affects the liver and other parts of the body. It is generally transmitted through blood. There are two stages of HCV: acute and chronic. Approximately 80% of people with acute HCV will develop chronic HCV after six months, and the other 20% will self-resolve. Once a person develops chronic HCV, it will not self-resolve, and the person will be infected for life without treatment. This lawsuit deals with those who have chronic HCV.
2. In 2017, several prisoners of Indiana Department of Correction (“IDOC”) facilities who suffer from chronic Hepatitis C infection (“HCV”) filed the operative complaint in this action. (ECF 39.) Plaintiffs sought damages and declaratory and injunctive relief from Wexford of Indiana, LLC, Corizon

Health, Inc., Corizon, LLC¹, treating physicians at Pendleton Correctional Facility², and three IDOC officials: IDOC's Commissioner Robert E. Carter, Jr., IDOC's Chief Medical Officer Dr. Kristen Dauss³, and IDOC's Director of Health Care Services, Monica Gipson, R.N.⁴ (ECF 39.)

3. Plaintiffs' suit alleged that the medical treatment that Plaintiffs received for their HCV while incarcerated violated the Eighth Amendment to the United States Constitution, the Americans with Disabilities Act, and the Rehabilitation Act. (ECF 39.) Plaintiffs' suit specified that the medical standard of care required that HCV-infected prisoners be treated with certain Direct-Acting Antiviral oral medications ("DAAs") approved by the U.S. Food and Drug Administration. (ECF 39.)
4. At all times, State Defendants have denied, and continue to deny, Plaintiffs' allegations. (ECF 74; ECF 79.)
5. On March 2, 2018, the Court certified this case as a class action, and at that time defined the class as:

¹ Corizon Health, Inc. and Corizon, LLC were removed from this class action for declaratory and injunctive relief because those Defendants are no longer the medical contractor with the IDOC. (ECF 111.) These Defendants were subsequently dismissed from the suit with prejudice through a joint stipulation of dismissal. (ECF 157.)

² The treating physicians were subsequently dismissed from the suit with prejudice through a joint stipulation of dismissal. (ECF 157.)

³ Dr. Dauss has been substituted as a Defendant in place of former Chief Medical Officer Dr. VanNess, who was substituted as a Defendant in place of former Chief Medical Officer Dr. Michael Mitcheff.

⁴ Ms. Gipson was dismissed from this case by the Court in its order of September 13, 2018. (ECF 186)

“All current and future prisoners in IDOC custody who have been diagnosed, or will be diagnosed, with chronic HCV.” (ECF 154.)

6. The class is represented by three inmates: Michael Ray Stafford, Charles Smith, and Douglas Smith. (ECF 154.)
7. On April 13, 2018, Plaintiffs moved for summary judgment on their Eighth Amendment claim, and Defendants moved for cross-summary judgment on all claims. (ECF 167; ECF 173).
8. On September 13, 2018, the Court granted Plaintiffs’ motion for summary judgment as to Defendants’ liability on the Eighth Amendment claim. (ECF 186.) The Court specifically found that IDOC’s failure to provide DAAs to all offenders with HCV constituted a violation of the Eighth Amendment. (ECF 186.) The Court modified the class definition to: “all current and future prisoners in IDOC custody who have been diagnosed, or will be diagnosed, with chronic HCV, and for whom treatment with DAA medication is not medically contraindicated” and decertified the class as to the ADA and Rehabilitation Act claims only. (ECF 186.) Finally, the Court denied Defendants’ cross-motion for summary judgment. (ECF 186.)
9. Subsequent to settlement negotiations between the parties, the Court granted Plaintiffs’ motion to convert the trial set in this matter to a remedy hearing and ordered briefing on the remedy issue. (ECF 205.) The parties stipulated that the following issues would be resolved at a remedy hearing:
 - i. Whether the Court should issue an injunction;

- ii. If the Court does issue an injunction, whether it should mandate treatment with DAAs for class members with HCV;
- iii. If the Court does mandate treatment with DAAs for class members with HCV, should treatment be universal or should treatment be cut off at a certain level of disease progression; and if the latter, where the cutoff should be; and
- iv. If the Court does mandate treatment with DAAs, what is a realistic timeline for implementation of such a mandate? (ECF 214.)

10. On March 26, 2019, Plaintiffs filed a motion for a permanent injunction, which would require Defendants to provide all class members access to DAAs. (ECF 218.) Prior to State Defendants filing their response to Plaintiffs' motion for permanent injunction, the parties stipulated to the dismissal of Wexford of Indiana, LLC, from the suit. (ECF 222.) On April 9, 2019, State Defendants filed their pre-hearing brief and response to Plaintiff's motion for a permanent injunction. (ECF 224.)

11. A remedy hearing was scheduled for April 29, 2019; however, prior to the hearing, the parties filed a joint motion for continuance and for the matter to be referred to a magistrate for a settlement conference. (ECF 230.)

12. Since the Court's Entry on September 13, 2018 the parties, as set out in more detail below, have been working to address concerns expressed by the Court and to modify the conditions of confinement for the class.

13. Because Plaintiffs have sought relief under 42 U.S.C. § 1983 for violations of the United States Constitution and federal law, parts of this litigation are subject to the Prison Litigation Reform Act, 18 U.S.C. § 3626, et seq. This Act imposes certain requirements on judicially sanctioned agreements made in litigation such as this, but provides that the parties may enter into private agreements, which are exempted from the requirements of the Act. 18 U.S.C. § 3626(c). However, such agreements are not subject to enforcement under federal law other than through potential reinstatement of the proceedings, although they are enforceable under state law as breaches of contract. *Id.*

14. Because this case is a certified class action the Court must determine, pursuant to Rule 23(e) of the Federal Rules of Civil Procedure, that this Private Settlement Agreement (“Agreement”) is a fair, reasonable, and adequate resolution of this matter. The Court cannot ascertain this until after reasonable notice is given to the class. Accordingly, even though this Private Settlement Agreement has been agreed to by State Defendants and all named Plaintiffs, it will not be effective until after notice is given to the class and the Court conducts the hearing required by Rule 23(e). State Defendants and the named Plaintiffs specifically agree that their approval of this Agreement is contingent on the Court finding that the Agreement is fair, reasonable, and adequate, and in the event that the Court does not find that the Agreement is fair, reasonable, and adequate, this Agreement

will immediately be deemed null and void. Plaintiffs will file, along with this Agreement, a motion seeking approval of the form and manner of notice to the class of this Agreement.

15. The Indiana Department of Correction continues to deny that it has at any time violated the Eighth Amendment rights of the class and denies the various claims made by plaintiffs to support their Eighth Amendment argument. However, the parties are desirous of attempting to reach a settlement of this matter and therefore they enter into this Stipulation. Defendants' entry into this Agreement is not an admission of any kind and imposes no liability on defendant or any of its agents, employees, officers or other persons for any violation of law, constitutional or otherwise.

16. Accordingly, to the extent that the parties agree to the terms and conditions as set forth below, this is deemed to be a "private settlement agreement" as defined under the Prison Litigation Reform Act, 18 U.S. Code § 3626(c)(2).

17. This Agreement is supported by good and valuable consideration. This includes, but is not limited to, the following: Plaintiffs agree that they will not seek a final judgment in this cause, unless this case is reinstated as set forth below. State Defendants agree that they will not seek to appeal this Court's Entry of September 13, 2018 (ECF 186), whether as an interlocutory matter or after final judgment, and will not challenge any of the Court's other rulings in this cause, unless this case is reinstated as set forth below.

II. Definitions.

1. “Agreement” shall mean this private settlement agreement between the parties, as set forth below.
2. “Effective Date” shall mean the date upon which the Court approves this private settlement agreement as a fair, reasonable, and adequate resolution of this matter following notice to the class and a hearing conducted under Federal Rule of Civil Procedure 23(e).
3. “HCSD” shall mean Indiana Department of Correction Health Care Services Directive 3.09a, as written in Exhibit A to this Agreement, which contains the policy and procedures for the treatment of prisoners infected with chronic hepatitis C.
4. “HCV” shall mean chronic Hepatitis C viral infection.
5. “IDOC” shall mean the Indiana Department of Correction.
6. “State Defendants” shall mean the Commissioner of the Indiana Department of Correction and the Chief Medical Officer of the Indiana Department of Correction, both in their official capacity.

III. Class Definition and Size.

1. In the Court’s summary judgment order of September 13, 2018, (ECF 186), the Court enumerated the class definition as follows:

All current and future prisoners in IDOC custody who have been diagnosed, or will be diagnosed, with chronic HCV, and for whom treatment with DAA medication is not medically contraindicated.

2. As of July 2019, it is estimated that approximately 3350 prisoners⁵ in IDOC custody have HCV and are not medically contraindicated for treatment with DAA medication.

IV. Substantive Agreement.

Health Care Services Directive 3.09a.

1. In response to the Court's and the plaintiffs' concerns, and to expand the scope of treatment to the offender population chronic HCV, the IDOC's revised Health Care Service Directive 3.09a ("HCSD") outlines the treatment of offenders with HCV. The parties agree that the HCSD will be modified as set forth in Exhibit A within 14 days of the effective date of this Agreement. State Defendants agree that the HCSD will bind all medical contractors and subcontractors responsible for the medical treatment of class members.
2. Following the implementation of the HCSD as written in Exhibit A, modification of the HCSD by IDOC in the future will be permitted so long as the modification does not operate to reduce the medical treatment of class members below the standard prescribed in the HCSD in Exhibit A.

⁵ The total number of prisoners in IDOC that have tested positive for the hepatitis C virus antibody is 4,188 as of June 2019. Of those, approximately 20% will spontaneously clear the hepatitis C virus, leaving 3,350 as the estimated class size that is currently incarcerated.

3. State Defendants agree to pay for and implement universal treatment with DAAs for class members as set forth in the HCSD, subject to the terms otherwise prescribed by this Agreement.
4. Treatment exceptions will be limited to the counter-indications identified in the AASLD/IDSA HCV Guidance (i.e., short life expectancy that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy), or the informed refusal of treatment;

Treatment of Current Class.

5. The IDOC shall abide by the following schedule of DAA treatment for class members incarcerated in the IDOC on the effective date of this agreement:
 - i. Class members at $APRI \geq 1.5$: all such class members must start receiving medication immediately;
 - ii. Class members at $APRI \geq 0.7$ but < 1.5 : must start receiving medication by July 1, 2020;
 - iii. Class members at $APRI < 0.7$ but ≥ 0.4 : must begin receiving medication by July 1, 2022, subject to an appropriation of the Indiana General Assembly;
 - iv. Class members at $APRI < 0.4$: must begin receiving medication by July 1, 2023, subject to an appropriation of the Indiana General Assembly;
 - v. Named Plaintiffs, to the extent they have not already begun treatment and who are otherwise eligible for treatment, are to begin

treatment immediately following the effective date of this Agreement.

Treatment of future class members.

6. The IDOC shall abide by the following schedule of DAA treatment for class members newly incarcerated and/or re-infected after the effective date of this Agreement:

- i. Class members at $APRI \geq 1.5$: all such class members will receive DAA medication immediately;
- ii. Class members at $APRI \geq 0.7$: all such class members must start receiving DAA medication by July 1, 2021, or immediately if incarcerated or re-infected after that date;
- iii. Class members at $APRI < 0.7$ but ≥ 0.4 : must begin receiving medication by July 1, 2022, or immediately if incarcerated or re-infected after that date.
- iv. Class members at $APRI < 0.4$: all such class members must start receiving DAA medication by July 1, 2023, or immediately if incarcerated or re-infected after that date.

7. The IDOC shall request an appropriation in the 2021 Legislation Session for the treatment of HCV. Such request shall be for an amount at least equal to the number of class members currently incarcerated multiplied by the cost of a standard course of DAA medication as those numbers exist on December 1, 2020.

Other Facets of Treatment.

8. If a class member doesn't currently qualify for DAAs during the phase-in period as described in section IV(5), then the patient will be re-evaluated and/or re-staged every 90 days, as set forth in the HCSD;
9. A class member's disciplinary record does not affect eligibility for treatment.
10. With the exception of class members who have less than four (4) months remaining on their sentence after the development of a class member's HCV Individualized Treatment Plan, a class member's release date does not automatically exclude him or her from treatment;
11. Noninvasive methods, such as APRI scores or transient elastography, can be used as indicators of HCV status and progression. A class member with an established transient elastography score shall be used instead of an APRI score. A class member who has multiple APRI scores following diagnosis with HCV shall be classified using the highest APRI score, except that any APRI score generated during the first 30 days of a class member's incarceration shall not be used.
12. For purposes of determining the schedule that applies to class members as specified in sections IV(5) and IV(6), the following APRI to transient elastography conversions shall be used:
 - i. Fibrosis Level F4 or F3 \rightarrow APRI score ≥ 1.5
 - ii. Fibrosis Level F2 \rightarrow APRI score ≥ 0.7

iii. Fibrosis Level F1 \rightarrow APRI score ≥ 0.4

iv. Fibrosis Level F0 \rightarrow APRI score < 0.4

13. HCV testing will be universal but class members have the right to opt-out;

14. The State Defendants agree to provide transient elastography as clinically indicated.

Monitoring and Review by Plaintiffs' Counsel.

15. The IDOC recognizes that during the time that this Agreement is actively in effect, as set forth below, Plaintiffs' counsel shall have a continuing right to information and review of the treatment of class members as follows:

- i. The IDOC will transmit any substantive revision to the HCSD within 30 days of the effective date of any change to the HCSD.
- ii. Every 90 days, the IDOC or its agents will provide status updates to Plaintiffs' counsel, including, but not limited to, the name, IDOC number, incarceration date, estimated release date, date that HCV infection was determined, APRI score(s), transient elastography scores (if available), and estimated date when DAA medication will be administered to all class members in IDOC custody.
- iii. If Plaintiffs' counsel has questions regarding specific class members, counsel or any experts retained by counsel may review the medical records of those class members upon request. The Stipulated Protective Order filed May 15, 2018, ECF 175, shall govern the review of all such records.

- iv. Requests under sections IV(15)(ii) and (iii) must be submitted in writing via certified mail or electronically via email to the Chief Legal Officer of the IDOC. Such records will be produced to Plaintiffs' counsel within 10 days of receipt of such request.

V. Further Proceedings.

1. State Defendants will not be required to be in full compliance with the terms of this Agreement until 90 days have passed from the effective date of this Agreement.
2. The parties will seek the administrative closure of Case No. 1:17-cv-00289-JMS-MJD after the effective date of this Agreement.
3. In the event that:
 - i. The IDOC does not request an appropriation from the Indiana General Assembly for the treatment of HCV in the 2021 legislative session in an amount at least equal to the amount required by the formula contained in section IV(7), supra;
 - ii. The Indiana General Assembly fails to grant an appropriation in the 2021 legislative session for the treatment of HCV in an amount at least equal to the amount required by the formula contained in section IV(7), supra; or
 - iii. The IDOC does not revise the HCSD as required by this Agreement;the remedy shall be to seek to have this litigation re-opened on the merits, including, specifically, the pending motion for injunctive relief, and State

Defendants will not object based on mootness stemming from the treatment of all named Plaintiffs, nor will State Defendants object to the substitution of new named Plaintiffs. To facilitate the substitution of plaintiffs, the IDOC will provide notice to the inmate population that any untreated inmate with HCV may contact Plaintiffs' counsel of record for purposes of becoming a named plaintiff, and State Defendants will waive the affirmative defense of failure to exhaust administrative remedies as to any substituted named plaintiff.

4. In the event of any asserted failure to comply with any term of the settlement other than the terms described in section V(3), the IDOC shall be provided with written notice of the alleged failure. The IDOC shall have an opportunity to cure the failure within 30 days of the written notice. Such notice shall be provided to the IDOC by sending a certified letter to the chief legal counsel of the IDOC. In the event the parties are not able to informally resolve the alleged failure within the 30-day time period, the parties shall submit the asserted failure to the magistrate assigned to this case for potential resolution between the parties. If no resolution is reached within 60 days following submission to the magistrate, Plaintiffs may take action as described in section V(5).
5. In the event of a failure to comply with any term of the settlement other than those described in section V(3), the remedy shall be a motion to enforce

the settlement. The parties stipulate that the Southern District of Indiana shall maintain jurisdiction to enforce the settlement.

6. The pending Americans with Disabilities Act and Rehabilitation Act claims made by each of the class representatives, Charles Smith, Michael Ray Stafford, and Douglas Smith, shall be permanently stayed until (1) this case is dismissed under Section VII(1) of this Agreement, at which time these claims shall be dismissed automatically; or (2) this case is reopened on the merits under Section V(3).

VI. Conflict Resolution.

1. The parties agree that in the event that a term of this Agreement is in conflict with the HCSD during the active period of this Agreement, a term specified in this Agreement shall supersede a conflicting term in the HCSD.

VII. Termination of this Agreement.

1. It is the parties' intent that this Agreement will remain actively in effect until July 1, 2025. Absent written agreement or order of the Court, the case will automatically be dismissed without prejudice at that time. The period that this Agreement is actively in effect may be extended by written agreement of the parties or by order of the Court after a motion by either party. In the event of any extension, the case will be automatically dismissed without prejudice at the end of the extended period.

VIII. Attorneys' Fees.

1. State Defendants shall pay to plaintiffs' counsel the amounts of \$307,359 in full satisfaction of any claims in this lawsuit for all attorneys' fees, and \$4,974.00 in costs, owing as of the date of this Agreement. The payment shall be made within 60 days of: (1) the Court finding that this Settlement Agreement is fair, reasonable, and adequate pursuant to Rule 23(e) of the Federal Rules of Civil Procedure; and (2) the Court granting a motion for fees and costs under Federal Rule of Civil Procedure 23(h).
2. As noted above, Plaintiffs' counsel anticipates that they will continue to monitor this Agreement during the time that it remains in effect. Absent a final judgment or other order that allows fees to be sought pursuant to 42 U.S.C. § 1988, Plaintiffs' counsel will not seek attorneys' fees or costs for their monitoring efforts.
3. If, however, Plaintiffs' counsel assert failures to comply with this Agreement under Sections V(3) or (5), then associated fees and costs shall be by negotiated resolution of the claim or upon proper fee petition submitted to the Court by Plaintiffs.


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Legal References (includes but is not limited to)	Related Policies/Procedures (includes but is not limited to)	Other References (includes but is not limited to)
Indiana Code: 11-8-2-5 11-8-5-2 11-10-1-2 11-10-2-4 11-10-3-1 11-10-8-2 11-10-8-5 11-10-9-2 11-10-10-2 11-11-5-4 11-11-6-2	01-02-101	ACA Health Care Standards

I. PURPOSE:

The purpose of this Health Care Services Directive (HCS D) is to provide information and guidelines concerning the management of Hepatitis C Virus (HCV) infections.

II. GUIDELINES:

A. General Information

HCV is the most common chronic bloodborne viral infection in the United States and correctional facilities have a disproportionate number of infected individuals. Within the Department, approximately 15-20% off arriving offenders at Intake are HCV-Antibody positive.

HCV is spread primarily by contact wih infected blood and blood products from a person infected with HCV. Blood transfusions and shared drug paraphernalia have been identified as the main routes of the spread of HCV in the United States. Other common risk factors include receiving a blood transfusion prior June 1992, receiving clotting factor concentrates before 1987, hemodialysis, birth to an HCV-infected mother, tattooing and suffering a needle-stick accident from a person with HCV. There is a slightly increased risk of transmission of HCV through sexual contact. However, some individuals who acquire HCV have no known risk factors.

Hepatitis C Virus can be acute or chronic.

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Acute HCV can present clinically with a discrete onset of fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and/or abdominal pain;
AND

(a) jaundice, OR

(b) a peak elevated serum alanine aminotransferase (ALT) level >200 IU/L during the period of acute illness.

Laboratory Criteria for Acute HCV Diagnosis includes a positive test for antibodies to hepatitis C virus (anti-HCV). Hepatitis C virus detection tests could also be utilized e.g Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative or genotype testing).

In April 2019, the Center for Disease Control reported approximately 15-25% of patients, who initially test positive for antibodies to hepatitis C virus, will clear the virus spontaneously. In at least two-thirds of patients who spontaneously clear acute HCV infection, this occurs within 6 months of the estimated time of infection. Only 11% of those who remain viremic at 6 months will spontaneously clear the infection at a later time. Thus, detectable HCV RNA at 6 months after the time of infection may signify chronic HCV. Once established the chronic infection rarely resolves spontaneously. The clinical course of HCV varies greatly; some individuals have no signs or symptoms and normal levels of serum enzymes, some have mild to moderate elevations in liver enzymes with an uncertain prognosis, and some have severe disease with symptoms, high viral load, and elevated serum enzymes.

Chronic HCV treatment can be accomplished with antiviral medications (interferon, pefinterferon, ribavirin or any HCV direct-acting antiviral agents). Antiviral medication regimen choice should be determined based on patient-specific data, including drug-drug interactions. Patients receiving antiviral therapy require careful pretreatment assessment for comorbidities that may influence treatment response. All patients require careful monitoring during treatment.

Another component of treatment for patients with HCV is substance use treatment. In accordance with HCSO 4.03, "Addiction Recovery Services", offenders newly diagnosed with Hepatitis C (that is, the diagnosis was made after the offender was committed to the Department) or being treated for Hepatitis C shall be referred for substance abuse assessment by Unit Team personnel in **all** cases.

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B. Screening for HCV Infection

In accordance with the provisions of Health Care Services Directive 2.03, “Reception Screening”, after an offender arrives at an intake site, the offender must complete the 2 page Offender health History, State Form 45999. This is a directed screening history designed to identify serious health conditions, and to provide staff with information that will be useful in managing and anticipating serious health conditions. The health history should be completed after the Point of Entry screening and prior to or during the Arrival Health Screening completed with medical staff.

All incoming and returning offenders shall have mandatory Hepatitis C antibody testing completed in accordance with State statute.

Initial testing with an HCV RNA test is recommended for cases with a known prior positive HCV Ab if they are at risk for reinfection or suspected of reinfection, and if they previously cleared the HCV spontaneously or achieved a sustained virologic response with treatment.

Offenders who decline testing at the baseline visit, should be counseled about and offered HCV testing during periodic preventive health visits. A treatment refusal form must be completed for every testing and treatment refusal.

C. Baseline Evaluation

Initial evaluation of anti-HCV positive offenders shall include, but is not limited to the following:

- (a) a baseline history and physical examination within the first 90 days with emphasis on evaluation for other possible causes of liver disease and inquiry regarding prior treatment for HCV infection
- (b) baseline lab tests within the first 90 days
- (c) assessed regarding the need for preventive health interventions such as vaccines and screenings for other conditions
- (d) counseled with information on HCV infection
- (e) enrollment in chronic care clinic
- (f) attempt to estimate the earliest possible date of infection, including when risk factors for exposures started and stopped

New HCV diagnoses will be reported to authorities at Indiana State Department of Health.

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D. Management of HCV

All infected patients, regardless of liver inflammation, shall be counseled regarding HCV disease. This counseling shall include information on HCV infection, transmissin, avoiding transmission, the nature of the HCV disease and its long-term sequelae, and the pros and cons of the treatment for HCV disease.

All patients with HCV disease shall be offered vaccination against Hepatitis B and Hepatitis A, unless previous infection or vaccination has been documented, or the attending physician believes that vaccination is unnecessary or contraindicated. All patients with HCV disease shall be offered vaccination against pneumococcus once, and against influenza annually.

Informed consent for treatment must be obtained prior to initiating treatment in accordance with Health Care Services Directive 1.30, "Consent and Refusal."

1. Acute Hepatitis C Treatment

This section provides guidance on the diagnosis and medical management of acute HCV infection, which is defined as presenting within 6 months of the exposure.

- Counseling is recommended for patients with acute HCV infection to avoid hepatotoxic insults, including hepatotoxic drugs (eg, acetaminophen) and alcohol consumption, and to reduce the risk of HCV transmission to others.
- A referral to addictions recovery services shall be completed.
- Regular clinical monitoring, including routine laboratory testing, is recommended in the setting of acute HCV infection for 6 months to determine spontaneous clearance versus persistence of HCV infection.
 - Laboratory monitoring should continue until the ALT level normalizes and HCV RNA becomes repeatedly undetectable, suggesting spontaneous resolution. If this does not occur, frequency of laboratory monitoring for patients with persistently detectable HCV RNA and elevated ALT levels should follow recommendations for monitoring patients with chronic HCV infection, as outlined below.

2. Chronic Hepatitis C Treatment

All sentenced offenders with chronic HCV infection are eligible for consideration of antiviral treatment. Certain cases are at higher risk for complications or disease progression and may require more urgent consideration for treatment. The IDOC has

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established a framework to ensure that offenders with the greatest need are identified and treated.

Treatment Group One:

Patients in group are considered the most clinically ill and require urgent consideration for treatment, including antiviral medications. Patients in group one would have at least one or more of the following:

- Advanced Hepatic Fibrosis
 - APRI ≥ 1.5 , or
 - Metavir or Batts/Ludwig stage 3 or 4 on liver biopsy or as indicated by transient elastography, or
 - Known or suspected cirrhosis
- Liver Transplant Recipients
- Hepatocellular Carcinoma (HCC)
- Comorbid Medical Conditions Associated with HCV, including:
 - Cryoglobulinemia with renal disease or vasculitis
 - Certain types of lymphomas or hematologic malignancies
 - Porphyria cutanea tarda
- Immunosuppressant Medication for a Comorbid Medical Condition
 - Some immunosuppressant medications (e.g., certain chemotherapy agents and tumor necrosis factor inhibitors) may be needed to treat a comorbid medical condition, but are not recommended for use when infection is present. Although data are insufficient and current guidelines are inconsistent regarding treatment of HCV infection in this setting, such cases will be considered for prioritized treatment of HCV on an individual basis.
- Continuity of care for those already started on antiviral treatment, including offenders who are newly incarcerated in the IDOC.

Recommended treatment for patients in group one includes antiviral medications to treat chronic HCV and an addictions recovery services referral. Patients in group one shall be seen at minimum every 30 days in chronic care clinic, unless otherwise clinically determined. A targeted history and physical examination to evaluate for signs and symptoms of liver disease shall be completed each visit. Labs will be obtained at least every 30 days for monitoring purposes.

Treatment Group Two

Offenders in group two have been identified as being at increased risk for liver disease, yet stable. This group requires prompt consideration for treatment, including antiviral medications. Offenders in group two would have one or more of the following, yet not have any of the clinical indicators listed in group one:

- Evidence for Progressive Fibrosis:
 - APRI score ≥ 0.7

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- Stage 2 fibrosis on liver biopsy or as indicated by transient elastography
- Comorbid medical conditions associated with more rapid progression of fibrosis:
 - Coinfection with HBV or HIV
 - Comorbid liver diseases (e.g., autoimmune hepatitis, hemochromatosis, fatty infiltration of the liver, steatohepatitis)
 - Diabetes mellitus
- Chronic Kidney Disease (CKD) with $\text{GFR} \leq 59 \text{ mL/min per } 1.73 \text{ m}^2$
- Birth Cohort 1945–1965

Recommended treatment for patients in group two includes antiviral medications to treat chronic HCV and an addictions recovery services referral. Patients in group two shall be seen at minimum every 90 days in chronic care clinic, unless otherwise clinically determined. A targeted history and physical examination to evaluate for signs and symptoms of liver disease shall be completed each visit. Labs will be obtained at least every 90 days for monitoring purposes.

Treatment Group Three

Offenders in group three have been identified as being at a lower risk for liver disease. This group requires consideration for treatment, including antiviral medications. Offenders in group three would have one or more of the following, yet not have any of the clinical indicators listed in groups one or two:

- Stage 0 to stage 1 fibrosis on liver biopsy or as indicated by transient elastography
- $\text{APRI} < 0.7$
- All other cases of HCV infection meeting the eligibility criteria for treatment, as noted below under *Other Criteria for Treatment*

Recommended treatment for patients in group three includes consideration for antiviral medications to treat chronic HCV and an addictions recovery services referral. Patients in group three shall be seen at minimum every 90 days in chronic care clinic, unless otherwise clinically determined. A targeted history and physical examination to evaluate for signs and symptoms of liver disease shall be completed each visit. Labs will be obtained at least every 90 days for monitoring purposes.

Other Criteria for Treatment

In addition to the above groups, HCV infected offenders being considered for treatment with antiviral medications should:

- Have no contraindications to, or significant drug interactions with, any component of the treatment regimen.
- Not be pregnant, especially for any regimen that would require ribavirin or interferon.

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Number 3.09	Effective Date DRAFT	Page 7	Total Pages 7
Title MANAGEMENT OF HEPATITIS C			

- Have sufficient time remaining on their sentence in the IDOC to complete a course of treatment.
 - Offenders in group one, but insufficient time remaining in IDOC custody, may be considered for treatment if they will have access to antiviral medications and health care providers for continuity of care at the time of release.
- Have a life expectancy > 18 months.
- Demonstrate a willingness and an ability to adhere to a rigorous treatment regimen and to abstain from high-risk activities while incarcerated.
- Offenders with evidence for ongoing high-risk behaviors, e.g., injection drug use, are considered for HCV treatment on an individual basis. Referral for evaluation and treatment of addiction recovery services will be completed.

Treatment of HCV will be based on clinical indication. At anytime an offender can be moved up from one group based on the attending physicians individualized treatment plan for the offender.

Upon release of an offender from IDOC custody, the Medicaid Processing Unit as part of the Re-Entry division, will process electronic Medicaid applications prior to release from the department. The Medicaid provider will be responsible for connecting releasing offenders with community based resources to include offenders with HCV.

E. End Stage Liver Disease

Offenders in end stage liver disease secondary to HCV shall be provided with off-site consultation with a hepatologist or GI specialist for recommendations. If a liver transplant is recommended, the offender shall be referred to the appropriate off-site provider.

III. APPLICABILITY:

This HCSD is applicable to all facilities providing Health Services to adult offenders.

Chief Medical Officer

Date

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

MICHAEL RAY STAFFORD,
CHARLES SMITH and DOUGLAS SMITH,
individually, and on behalf of those
similarly situated,

Plaintiffs,

v.

ROBERT E. CARTER, JR., et al.,

Defendants.

Case No. 1:17-cv-289-JMS-MJD

**ORDER FINDING SETTLEMENT AGREEMENT TO BE FAIR,
REASONABLE AND ADEQUATE PURSUANT TO RULE 23(e) OF THE
FEDERAL RULES OF CIVIL PROCEDURE**

This matter comes before the Court after the filing of the Third Stipulation to Enter into Settlement Agreement Pursuant to 18 U.S.C. § 3626(c)(2) Following Notice to the Class and Fairness Hearing (hereinafter referred to as “Stipulation”). [Filing No. 268.] On October 15, 2019, this Court held a fairness hearing pursuant to Rule 23(e) of the Federal Rules of Civil Procedure, to determine whether the proposed settlement is a fair, reasonable, and adequate resolution of this matter. The parties appeared by counsel at the hearing. The parties addressed the Court concerning the history of the litigation and the process and content of the proposed settlement.

Having considered the Stipulation, the reports of class counsel, and the arguments of counsel at the fairness hearing and the record in this matter,

IT IS HEREBY FOUND that:

1. This action was filed on January 27, 2017, by three inmates incarcerated in the Indiana Department of Correction (“IDOC”), who alleged that Defendants failed to provide medical treatment for chronic Hepatitis C (“HCV”) that met the recognized

standard of care in the United States and that this failure violated the Eighth Amendment to the United State Constitution, Title II of the Americans with Disabilities Act, as amended, 42 U.S.C. § 12131 et seq. (the “ADA”), and the Rehabilitation Act of 1973, as amended, 29 U.S.C. § 791 et seq. (the “Rehabilitation Act”). [Filing Nos. 1, 39.]

2. On September 15, 2017, Plaintiffs moved for class certification pursuant to Fed. R. Civ. P. 23(b)(2), seeking only injunctive and declaratory relief for the class [Filing No. 99 at 2; Filing No. 100 at 1-2.]

3. On February 21, 2018, this Court certified this case as a class action with respect to the Eighth Amendment, ADA, and Rehabilitation Act claims. [Filing No. 148.] The Court later amended the class to be comprised of: “all current and future prisoners in IDOC custody who have been diagnosed, or will be diagnosed, with chronic HCV, and for whom treatment with DAA medication is not medically contraindicated.” [Filing No. 186 at 43.] The Court also decertified the class with respect to the ADA and Rehabilitation Act claims. [*Id.*]

4. On September 13, 2018, this Court issued its Order on cross-motions for summary judgment, granting, inter alia, “Plaintiffs’ Motion for Summary Judgment as to liability on the Eighth Amendment claim.” [*Id.* at 44.]

5. On March 26, 2019, Plaintiffs moved for a permanent injunction. [Filing No. 218.] This motion is fully briefed. [Filing Nos. 219, 224, 225, 226, 227 and 229.] Before a hearing or ruling on this motion, the Parties filed the Stipulation.

6. No final judgment has been entered in this case.

7. Settlement conferences have been held on January 18, 2018; November 13 and 19, 2018; and May 21, 2019. [Filing Nos. 142, 201, 202 and 236.]

8. The Stipulation is designed to settle all pending matters in this litigation.

9. This Court has jurisdiction over the subject matter of this action and over all the parties, including the members of the certified class.

10. The class has been given proper and adequate notice of the proposed resolution of this case through the Stipulation. This notice was given as required by the Court's order of August 13, 2019. [Filing No. 257.] The notice invited class members to notify class counsel as to any objections to, or comments on, the proposed Stipulation. Additional notice was given pursuant to the Court's order regarding attorney fees and costs. These notices provided valid, due, and sufficient notification of these proceedings and of the proposed settlement, and it included information regarding the procedures for making comments to the Stipulation.

11. The notice to the class fully satisfies the requirements of Rule 23 of the Federal Rules of Civil Procedure and the requirements of due process.

12. On October 4, 2019, class counsel filed their Report to the Court Following Notice to Class with comments from class members who replied to the notice. [Filing No. 263.] Class counsel filed an additional report following the second notice regarding attorneys' fees and costs. The Court has reviewed the comments.

13. Following the standards established by Fed. R. Civ. P. 23 and *Synfuel Technologies, Inc. v. DHL Express, Inc.*, 463 F.3d 646, 653 (7th Cir. 2006), the Court finds that the Stipulation, the administrative closure and the ultimate dismissal of this action as contemplated by the Stipulation, to be fair, reasonable, and adequate for the following reasons:

a. The purpose of this litigation was to obtain medical treatment for chronic HCV that meets the recognized standard of care in the United States.

The Stipulation provides that all class members will receive such treatment, which

will be phased in by July 1, 2023. Those inmates with higher-stage progression and fibrosis, as measured by APRI or Fibroscan scores, will be treated first. The DAA treatment will be phased in based on the individual class member's HCV progression and fibrosis score, which will be re-evaluated every 90 days. The Stipulation is fair and reasonable because it ensures treatment for all class members while maximizing the IDOC's ability to timely treat the class members. Class members with less than four months left on their sentence will not be guaranteed treatment because of the time it takes to treat them with DAA drugs—12 weeks—and the time it takes to prepare them for treatment. However, these members will be eligible for treatment under Medicaid (if they are otherwise eligible for Medicaid) upon their release, and the IDOC will apply for Medicaid on their behalf. The Stipulation is contingent upon the Indiana General Assembly providing adequate funding to treat class members with an APRI score of less than 0.7: if it does not, this case will be re-opened and proceed on the merits. The Stipulation provides necessary flexibility to meet the future needs of class members by allowing for the case to be re-opened and to proceed on the merits should the IDOC not request an appropriation, should the IDOC not obtain an appropriation, or should the HCSD not be revised. Thus, it appears to the Court that the proposed Stipulation accomplishes the litigation goals of the Plaintiffs. Given the current status of the case, the Court finds that the comparison of the strength of Plaintiffs' case balanced against the Stipulation, renders the proposed settlement fair, reasonable, and adequate.

b. The complexity, length, and expense of continued litigation weigh in favor of finding that the Stipulation is fair, reasonable, and adequate. Given the

provisions of the Stipulation, and the significant changes already made by the IDOC and its medical vendor since the inception of this case, continued litigation would require a hearing on the motion for permanent injunction, implementation of any potential injunction ordered by this Court, and a potential appeal, and it is unclear to the Court that a better result than that presented in the Stipulation could be attained by Plaintiffs even if they were to be victorious on appeal. Additionally, protracted litigation may impede the speed with which class members obtain treatment due to the availability of funding. The Stipulation allows Plaintiffs to re-open this action if the General Assembly does not provide the necessary funding, if the Defendants do not request the appropriate funding, or if they fail to revise their policies; and it allows Plaintiffs to move to enforce the settlement for any other failure to comply with the Stipulation. [Filing No. 268 at 13-15.] Further, Defendants will provide Plaintiffs' counsel with updated records concerning the treatment status of class members every 90 days: Plaintiffs' counsel will monitor those records and will bring questions and concerns to the attention of Defendants, the IDOC, and its medical vendor. These additional safeguards further demonstrate, in the Court's opinion, that the Stipulation is fair, reasonable, and adequate.

c. As indicated, the Court has reviewed the report filed by Plaintiffs' counsel concerning the comments of inmates who have responded to the notice of the proposed Stipulation and has reviewed the comments that have been filed. The Court notes that few prisoners actually object to the settlement itself, and that many want the appropriate treatment, but they want it as quickly as possible. The Court is confident that Plaintiffs' counsel will monitor the implementation of this

agreement and will bring to defense counsel's and the medical provider's attention the cases of inmates who believe they should receive treatment more expeditiously. In short, the Court does not find the level of opposition to the Stipulation to be sufficient for the Court to question that it is a fair, reasonable, and adequate resolution of this matter.

d. There is no evidence of any collusion between the parties entering into the Stipulation. The Court is satisfied that the Stipulation is the result of arms-length negotiations.

e. The class is represented by counsel who are experienced in litigation concerning prison condition, and the attorneys' fees and costs are reasonable.

f. The stage of the proceedings and amount of discovery weigh in favor of finding that the Stipulation is fair, reasonable, and adequate. The settlement was arrived at only after lengthy discovery, extensive briefing, and lengthy negotiations.

For the foregoing reasons, the Court finds that the Stipulation is a fair, reasonable, and adequate resolution of this matter.

IT IS THEREFORE ORDERED that the Stipulation [Filing No. 268], will remain actively in effect until July 1, 2025. At that time, absent written agreement or order of the Court as noted on page 15 of the Stipulation, this case will automatically be dismissed without prejudice.

IT IS SO FOUND AND ORDERED on this _____ day of _____,
2019.

United States District Court Judge
Southern District of Indiana

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