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## Policies for Expanding Hepatitis C Testing and Treatment in United States Prisons and Jails

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## **POLICIES FOR EXPANDING HEPATITIS C TESTING AND TREATMENT IN UNITED STATES PRISONS AND JAILS**

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Tessa Bialek & Dr. Matthew J. Akiyama, M.D., M.Sc.\*

### ABSTRACT

*Hepatitis C virus (HCV) is highly prevalent in United States prisons and jails. In prisons and jails, rates of infection are ten to twenty times greater than national levels. And, more than thirty percent of all people living with HCV in the United States will spend time in prisons and jails in any given year. Rates are especially high among people who inject drugs (PWID), a population whose members are also likely to move between carceral settings and the community. Thus, addressing HCV among incarcerated populations would have a significant effect on the virus's transmission both in and out of confinement and is a crucial part of any HCV elimination strategy. Safe and effective HCV treatment is available. Direct-acting antivirals (DAAs) offered in an eight to twelve week course of oral treatment cure HCV in more than ninety percent of cases.*

*Widespread testing and treatment in prisons and widespread testing and treatment or linkage to community care in jails are essential public health approaches. But testing and treatment in confinement lags behind medical guidance and public health recommendations.*

*People incarcerated in prisons and detained in jails are entitled to adequate health care, and the U.S. Constitution prohibits deliberate indifference to their serious medical needs. In recent years, lawsuits filed by people with HCV in carceral facilities across the country have alleged violations of federal law for failure to provide DAA treatment.*

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\* This paper also appears, in slightly different form, as part of the Civil Rights Litigation Clearinghouse's policy white paper series, Learning from Civil Rights Lawsuits, and is available at: <https://clearinghouse.net/special-project/1/22>. The paper benefited at every stage from conversations with and feedback from people working on issues related to HCV in prisons and jails from various vantage points. This included individual interviews, generous feedback from many reviewers, and a workshop conducted via Zoom in November 2022 at which participants shared comments on the policy recommendations in Part III. In addition to the people acknowledged by name here, our work benefited greatly from the insights and knowhow of physicians who work in or in collaboration with jails and prisons, attorneys who have litigated these issues, and others with relevant experiences that they generously shared. This includes the folks from the National Hepatitis Corrections Network, National Viral Hepatitis Roundtable, Treatment Action Group, and Academic Consortium on Criminal Justice Health. The Clearinghouse's Advisory Committee members also offered helpful insights on the white paper series generally and on this topic in particular. Without intending to imply their endorsement of this paper or its recommendations, but to express our gratitude to them for sharing their expertise, suggestions, and critiques, we thank: Mandy Altman; Kevin Costello; Corene Kendrick; Kenneth Krayeske; Marsha Levick; Cindy Mann; Alan Mills; Jamelia Morgan; David Muhammad; Margo Schlanger; Kinda Serafi; Ronald D. Simpson-Bey; William Snowden; Anne C. Spaulding; Homer Venters; Samuel Weiss; and Alysse Wurcel. We are grateful, too, for the invaluable research assistance of University of Michigan Law School students Elena Meth and Hannah Shilling, and for the Michigan Journal of Law Reform team's thoughtful and thorough editorial work. All errors are our own.

Although litigation results have been mixed, settlement agreements in states across the country have expanded HCV testing and broadened access to DAA treatment. These settlement agreements reflect a growing understanding that widespread testing and treatment is cost-effective, avoid the harmful health consequences of disease progression, and meaningfully reduce community transmission.

This paper recommends model policies for prisons and jails to expand HCV testing and DAA treatment. The policy recommendations draw from relevant settlement agreements and current medical guidelines, supplemented by input from public health experts, medical professionals, and advocates. The paper proceeds as follows:

- **Part I** describes the HCV epidemic in United States prisons and jails, the recent sea change in treatment protocols, and relevant clinical guidance and public health recommendations.
- **Part II** sets out the legal landscape, including governing federal law and judicial decisions interpreting that law in this context, and describes settlement agreements in class action lawsuits addressing DAA access.
- Finally, **Part III** offers model policies for prisons and jails to expand testing and treatment and to support successful outcomes for people with HCV in their custody.

#### TABLE OF CONTENTS

I. HEPATITIS C VIRUS IN UNITED STATES PRISONS AND JAILS:	
A CRISIS AND AN OPPORTUNITY.....	3
A. An Overview: Hepatitis C Virus Prevalence in United States Prisons and Jails .....	4
B. A Treatment Sea Change: From Interferon to Direct Acting Antivirals .....	7
C. Medical Standard of Care: Universal Testing and Early-Stage DAA Treatment.....	11
D. Lagging Implementation of Universal Testing and Treatment in Prisons and Jails.....	17
II. THE LEGAL LANDSCAPE .....	24
A. The Eighth Amendment Standard: Deliberate Indifference to Serious Medical Need .....	24
B. Litigation Challenging the Prioritization of DAA Treatment.....	27
C. Class Action Settlement Agreements: Toward Universal Testing and Treatment.....	30

III. MODEL POLICIES .....	33
1. <i>Universal Opt-Out Screening</i> .....	35
1.1 Universal Opt-Out Screening .....	35
2. <i>Medical Evaluation and Consultation</i> .....	40
2.1 Medical Evaluation and Consultation for Patients with HCV Viremia .....	40
2.2 Enrollment in Substance Use Treatment and Support ..	41
3. <i>Provision of Treatment and Linkage to         Community Care</i> .....	43
3.1 Provision of DAA Treatment .....	43
3.2 Proper and Improper Considerations for Treatment.....	45
3.3 Linkage to Community Care .....	46
4. <i>Education for Patients While Incarcerated and         Upon Release</i> .....	50
4.1 HCV Education .....	50
5. <i>Recordkeeping</i> .....	52
5.1 Maintenance of Records .....	52
6. <i>Staffing and Staff Training</i> .....	53
6.1 Staffing to Support HCV Care.....	53
6.2 Staff Training.....	54
7. <i>Updates to Guidance and Protocols</i> .....	54
7.1 Regular Updates to Guidance and Protocols.....	54
8. <i>Definitions</i> .....	55
CONCLUSION .....	55

#### I. HEPATITIS C VIRUS IN UNITED STATES PRISONS AND JAILS: A CRISIS AND AN OPPORTUNITY

Hepatitis C virus (HCV) affects millions of people in the United States, and infection rates are rising. HCV disproportionately affects people in prisons and jails,<sup>1</sup> where rates of infection are magnitudes higher than in

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1. This paper generally uses “jails” to describe detention facilities for people who have not yet been sentenced and “prisons” to describe carceral facilities for people who have already been sentenced.

the community. If left untreated, HCV can have severe consequences, including death. Fortunately, HCV can be cured in most people. Direct-acting antiviral (DAA) treatment is effective and safe, with minimal side effects and a relatively short course of treatment. Costs of DAA treatment continue to decrease. Current medical guidance unambivalently recommends universal opt-out testing and DAA treatment for HCV without restrictions. However, most carceral system practices fall short of this recommendation. Where DAAs are available, most carceral systems prioritize treatment for people with advanced liver disease. This is a missed opportunity. Prisons and jails offer a crucial opportunity to test for and treat HCV in the disease's early stages among a high-risk, high-prevalence population, simultaneously minimizing harm to individual patients and reducing community transmission.

Section I.A offers an overview of HCV and its impact in United States jails and prisons. Section I.B describes the transition from interferon-based treatment to DAAs. Section I.C summarizes the prevailing standard of care and recommendations for testing and treatment. Finally, Section I.D describes the under-implementation of these recommendations in the carceral setting and begins to make the case for universal testing and expanded DAA treatment as essential to any meaningful eradication efforts.

#### A. An Overview: Hepatitis C Virus Prevalence in United States Prisons and Jails

Hepatitis C is a virus that infects the liver.<sup>2</sup> HCV spreads through contact with blood from a person who is infected, most often through sharing needles used to prepare and inject drugs.<sup>3</sup> For up to twenty percent of people exposed to the virus, HCV is a short-term, “acute” illness from which they spontaneously recover—but during the period of often asymptomatic infection, they may nonetheless spread the virus to others.<sup>4</sup> Those who do not spontaneously recover develop long-term, “chronic” infection, which damages the liver over time. Chronic HCV can

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2. *Viral Hepatitis: Hepatitis C Information*, CTRS. FOR DISEASE CONTROL & PREVENTION (July 28, 2020), <https://www.cdc.gov/hepatitis/hcv/index.htm> [<https://perma.cc/4Q47-1SNP>].

3. *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C*, THE AM. ASS'N FOR THE STUD. OF LIVER DISEASE & INFECTIOUS DISEASES SOC'Y OF AM., at 20 (Oct. 24, 2022) [hereinafter 2022 AASLD/IDSA Guidance], [https://www.hcvguide-lines.org/sites/default/files/full-guidance-pdf/AASLD-IDSA\\_HCVGuidance\\_October\\_24\\_2022.pdf](https://www.hcvguide-lines.org/sites/default/files/full-guidance-pdf/AASLD-IDSA_HCVGuidance_October_24_2022.pdf) [<https://perma.cc/N9PU-NDBE>].

4. See 2022 AASLD/IDSA Guidance, *supra* note 3, at 149–50; *Hepatitis C*, CLEVELAND CLINIC (Dec. 9, 2022), <https://my.clevelandclinic.org/health/diseases/15664-hepatitis-c> [<https://perma.cc/YKL2-GS2A>].

be lifelong if not treated and may cause serious health problems. Such problems include fibrosis of the liver, when scar tissue replaces healthy tissue, reducing liver function; cirrhosis, when scar tissue takes over most of the liver; liver failure; liver cancer; and death.<sup>5</sup> Moreover, active HCV infection increases a person's susceptibility to other illnesses, including chronic kidney disease,<sup>6</sup> depression,<sup>7</sup> neurological disorders,<sup>8</sup> malignancies,<sup>9</sup> and other extrahepatic (outside the liver) manifestations.<sup>10</sup> Disease trajectory is unpredictable, and the rate of disease progression varies from person to person.<sup>11</sup> But without treatment, HCV has high rates of morbidity and mortality.<sup>12</sup>

It is estimated that 2.4 million people in the United States live with HCV, but that number may be as high as 4.7 million; approximately half of people living with the virus do not know that they are infected.<sup>13</sup> The incidence of HCV in the United States is increasing; the rate of new infections reported to the Centers for Disease Control and Prevention

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5. *Viral Hepatitis: Hepatitis C Questions and Answers for the Public*, CTRS. FOR DISEASE CONTROL & PREVENTION (July 28, 2020), <https://www.cdc.gov/hepatitis/hcv/cfaq.htm#:~:text=Hepatitis%20C%20is%20often%20described,infection%20leads%20to%20chronic%20infection> [https://perma.cc/PPI6-D5XN].

6. Haesuk Park, Chao Chen, Wei Wang, Linda Henry, Robert L. Cook & David R. Nelson, *Chronic Hepatitis C Virus (HCV) Increases the Risk of Chronic Kidney Disease (CKD) While Effective HCV Treatment Decreases the Incidence of CKD*, 67 HEPATOLOGY 492 (2017), <https://aasldpubs.onlinelibrary.wiley.com/doi/epdf/10.1002/hep.29505> [https://perma.cc/96TD-HGSK].

7. See Curtis L. Cooper, Chrissi Galanakis, Jessie Donelle, Jeff Kwong, Rob Boyd, Lisa Boucher & Claire E. Kendall, *HCV-Infected Individuals Have Higher Prevalence of Comorbidity and Multimorbidity: A Retrospective Cohort Study*, 19 BMC INFECTIOUS DISEASES (2019), <https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-019-4315-6> [https://perma.cc/D6X9-5CAU].

8. See *id.*

9. See *id.*

10. See 2022 AASLD/IDSA Guidance, *supra* note 3, at 28–29 (describing extrahepatic manifestations of chronic HCV infection).

11. *E.g.*, G W McCaughan & J George, *Fibrosis Progression in Chronic Hepatitis C Virus Infection*, 53(3) GUT. 318 (Mar. 2004), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1773949/> [https://perma.cc/L9L8-TBS4].

12. See Anne C. Moorman, Loralee B. Rupp, Stuart C. Gordon, Yuna Zhong, Jian Xing, Mei Lu, Joseph A. Boscarino, Mark A. Schmidt, Yihe G. Daida, Eyasu H. Teshale, Philip R. Spradling & Scott D. Holmberg, *Long-Term Liver Disease, Treatment, and Mortality Outcomes Among Persons Diagnosed with Chronic Hepatitis C Virus Infection: Current Chronic Hepatitis Cohort Study Status and Review of Findings*, 32:2 INFECTIOUS DISEASE CLINICS N. AM. 253 (2018) (describing findings from a longitudinal study of more than 17,000 people with HCV in the United States, including “very high death rates” in the period from 2006–2010, a fifteen year lifespan reduction, and a 3.7-fold increase in hospitalizations), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6211170/> [https://perma.cc/CZ5B-TPCY].

13. See *Viral Hepatitis in the United States: Data and Trends*, Office of Infectious Disease and HIV/AIDS Policy, U.S. DEPT OF HEALTH & HUM. SERV. (June 7, 2016), <https://www.hhs.gov/hepatitis/learn-about-viral-hepatitis/data-and-trends/index.html> [https://perma.cc/QP29-9C7T].

(CDC) in 2018 was four times the rate reported in 2010.<sup>14</sup> The increased prevalence has been most pronounced in states most affected by the opioid epidemic,<sup>15</sup> with studies pointing to “substantial, simultaneous increases” in acute HCV and admissions for opioid injection.<sup>16</sup> As injection drug use drives new infections, HCV infection rates among young people, in particular, are on the rise. The CDC’s annual HCV data continues to show the highest rates of new infection and lowest treatment rates among adults under forty.<sup>17</sup>

HCV is disproportionately prevalent in United States prisons and jails compared to the general population. Among incarcerated populations, HCV antibody positivity rates (which indicate exposure to HCV) range from twelve to thirty-four percent, more than twenty times the national rate.<sup>18</sup> Estimates suggest that approximately thirty percent of all individuals living with HCV in the United States spend time in a carceral setting in a given year.<sup>19</sup> The high rates of HCV in prisons and jails can be attributed primarily to the ready transmission of HCV through injection drug use and the high rates of incarceration among people who inject drugs (PWID). Insufficient access to harm reduction measures and non-commercial tattooing practices may also contribute

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14. *See id.*

15. For example, between 2006–2012, acute HCV infections increased 364% in Kentucky, Tennessee, Virginia, and West Virginia. *Id.*

16. Press Release, CTRS. FOR DISEASE CONTROL & PREVENTION, Increase in Hepatitis C Infections Linked to Worsening Opioid Crisis, (Dec. 21, 2017), <https://www.cdc.gov/nchhstp/newsroom/2017/hepatitis-c-and-opioid-injection-press-release.html> [<https://perma.cc/EDV7-YXLL>]; see also David Powell, Abby Alpert, & Rosalie L. Pacula, *A Transitioning Epidemic: How the Opioid Crisis is Driving the Rise in Hepatitis C*, 38:2 PHARMS. & MED. TECH. HEALTH AFFAIRS (Feb. 2019), <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05232> [<https://perma.cc/K9Q4-G67C>] (tying tripling of rates of new HCV infection between 2010 and 2014 to uptick in opioid injections).

17. Press Release, CTRS. FOR DISEASE CONTROL & PREVENTION, Less Than 1/3 of People Diagnosed with Hepatitis C Receive Timely Treatment for the Deadly, Yet Curable, Infection (Aug. 9, 2022), <https://www.cdc.gov/nchhstp/newsroom/2022/2022-Hepatitis-Vital-Signs-press-release.html> [<https://perma.cc/TT5Y-5EBY>].

18. Liton Chandra Deb, Hannah Hove, Tracy K. Miller, Kodi Pinks, Grace Njau, John J. Hagan & Rick J. Jansen, *Epidemiology of Hepatitis C Virus Infection Among Incarcerated Populations in North Dakota*, 17(3) PLOS ONE, at 2 (2022), <https://doi.org/10.1371/journal.pone.0266047> [<https://perma.cc/537B-PQ8E>].

19. *See* 2022 AASLD/IDSA Guidance, *supra* note 3, at 179; *Treatment of HCV in a Correctional Setting*, HEPATITIS C ONLINE (Oct. 9, 2022), <https://www.hepatitisc.uw.edu/pdf/key-populations-situations/treatment-corrections/core-concept/all> [<https://perma.cc/38RQ-42WW>]; see also Aiden K. Varan, Daniel W. Mercer, Matthew S. Stein & Anne C. Spaulding, *Hepatitis C Seroprevalence Among Prison Inmates Since 2001: Still High but Declining*, 129 PUB. HEALTH REP. 187, 191 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3904899/> [<https://perma.cc/FC54-FM8Y>] (estimating that carceral populations represented 28.5% to 32.8% of the total HCV cases in the United States in 2006, down from 39% in 2003).

to new transmission within carceral settings.<sup>20</sup> The effects ramify outside prisons and jails. PWID have an elevated risk of acquiring the virus while incarcerated, even for short periods,<sup>21</sup> as well as immediately following release, and may thereafter drive high rates of new infection in the general population.<sup>22</sup> And more than ninety percent of people with HCV in prisons and jails are eventually released, risking further community transmission.<sup>23</sup> Moreover, HCV is disproportionately deadly in incarcerated populations. In 2019, the HCV-related death rate for people in United States prisons was more than double the rate for the overall population. And between 2013 and 2019, more than 1,000 people died in prison of HCV-related causes.<sup>24</sup>

### B. A Treatment Sea Change: From Interferon to Direct Acting Antivirals

Until about a decade ago, HCV treatment required a medication called interferon.<sup>25</sup> A synthetic version of interferon, which is made naturally by the body's immune system, stimulated an infected

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20. See Matthew J. Akiyama, Nadine Kronfli, Joaquin Cabezas, Yumi Sheehan, Prem H Thurairajah, Richard Lines & Andrew R Lloyd, *Hepatitis C Elimination Among People Incarcerated in Prisons: Challenges and Recommendations for Action Within a Health Systems Framework*, 6(5) LANCET GASTROENTEROL HEPATOL 391, 398 (2021), <https://pubmed.ncbi.nlm.nih.gov/33857445/> [<https://perma.cc/RQ43-B5MY>].

21. See Andreea Adelina Artenie, Matthew Hickman, Peter Vickerman, Jack Stone, Jason Grebely & Julie Bruneau, *Diversity of Incarceration Patterns Among People Who Inject Drugs and the Association with Incident Hepatitis C Virus Infection*, 96:103419 INT'L J. DRUG POL'Y, 1 (2021), <https://pubmed.ncbi.nlm.nih.gov/34452807/> [<https://perma.cc/HV6F-3CUE>].

22. See, e.g., *id.* at 1–2 (concluding that “[a]ny recent incarceration lasting less than two years, regardless of the setting and time in incarceration, was associated with an elevated risk of HCV acquisition among PWID,” citing, among other factors, the high-risk sharing practices and lack of sterile equipment when injection drug use occurs in the carceral setting as well as the likelihood that abrupt interruptions in drug use or treatment may precipitate high-risk behaviors upon release); Jack Stone et al., *Modeling the role of incarceration in HCV transmission and prevention amongst people who inject drugs in rural Kentucky*, 88 INT'L J. OF DRUG POL'Y, 8 (2021), <https://pubmed.ncbi.nlm.nih.gov/32151496/> [<https://perma.cc/JG6H-B8JA>] (last visited July 21, 2023) (describing the elevated acquisition risk associated with incarceration and recent release and concluding that incarceration contributes to two-fifths of ongoing HCV transmission among PWID in the County of focus).

23. 2022 AASLD/IDSA Guidance, *supra* note 3, at 179.

24. See Nicholas Florko, *Hundreds of Incarcerated People are Dying of Hep C—Even Though We Have a Simple Cure*, STAT (Dec. 15, 2022), <https://www.statnews.com/2022/12/15/hundreds-incarcerated-people-dying-hepatitis-c-despite-simple-cure/> [<https://perma.cc/6EYJ-JUD6>]. In Texas alone, more than sixty people have died of HCV in prisons since 2020. *Id.*

25. See Kui Li & Stanley M. Lemon, *Innate Immune Responses in Hepatitis C Virus Infection*, 35 SEMINARS IN IMMUNOPATHOLOGY 53, 53 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3732459/> [<https://perma.cc/KE5J-VDIG>] (“Until recently, pegylated interferon . . . or [interferon] plus ribavirin . . . was the standard-of-care treatment for chronic hepatitis C.”).



person's immune system against the virus.<sup>26</sup> As of 2011, the most common treatment regimen involved pegylated interferon,<sup>27</sup> administered via weekly injection, combined with a daily oral dose of ribavirin, over a course of twenty-four to forty-eight weeks.<sup>28</sup> This regimen produced inconsistent results, with sustained virological response (or HCV cure)<sup>29</sup> ranging from thirty to ninety percent of patients, depending on HCV genotype and stage of liver disease.<sup>30</sup> Barriers to interferon-based treatment were significant. Pre-treatment usually required virus genotyping and staging to determine treatment course.<sup>31</sup> Side effects could be severe, including flu-like symptoms, lowered white blood cell or platelet counts, and depression and other mood disorders.<sup>32</sup> Moreover, interferon and/or ribavirin were contraindicated for many people.<sup>33</sup>

During the interferon era, HCV treatment protocols in prisons and jails were underdeveloped or nonexistent,<sup>34</sup> and barriers to treatment were exacerbated in those settings. For example, before determining whether treatment could begin, many systems required liver biopsies and/or genotyping.<sup>35</sup> These procedures can be more complicated, and more

26. See, e.g., *Interferons and ribavirin*, THE HEPATITIS C TRUST, <http://hepctrust.nam.org.uk/information/treatment/current-treatments/interferons-and-ribavirin> [https://perma.cc/ZN65-6Y4T] (last visited Nov. 18, 2023).

27. Pegylated interferon is interferon that has been chemically modified to prolong the half-life and slow absorption, permitting a longer period between injections and increasing likelihood of cure. See D.E. Baker, *Pegylated Interferons*, 3 REVS. IN GASTRO. DISORDERS 93 (2001).

28. See Libin Rong & Alan S. Perelson, *Treatment of Hepatitis C Virus Infection with Interferon and Small Direct Antivirals: Viral Kinetics and Modeling*, 30 CRITICAL REV. IMMUNOLOGY 131 (2010), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2882097/> [perma.cc/H3CH-Q87U].

29. See 2022 AASLD/IDSA Guidance, *supra* note 3, at 24.

30. Philipp Solbach & Heiner Wedemeyer, *The New Era of Interferon-Free Treatment of Chronic Hepatitis C*, 31 VISZERALMEDIZIN 290, 290 (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4608630/> [perma.cc/SY73-XX6X].

31. See, e.g., Ahmed El-Shamy & Hak Hotta, *Impact of Hepatitis C Virus Heterogeneity on Interferon Sensitivity: An Overview*, 20 WORLD J. GASTROENTEROLOGY 7555, 7556 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4069287/> [perma.cc/B7U5-SWJL] (explaining that "HCV genotype is an important determinant of both treatment strategy and outcome").

32. See Robert Katz, *Hepatitis C Litigation: Healing Inmates as a Public Health Strategy*, 29 ANNALS HEALTH L. 127, 134 n. 69 (2020); see also Lotfollah Davoodi et al., *Psychiatric Side Effects of Pegylated Interferon- $\alpha$  and Ribavirin Therapy in Iranian Patients with Chronic Hepatitis C: A Meta-Analysis*, 16 EXPERIMENTAL & THERAPEUTIC MED. 971, 974 (2018).

33. See Solbach & Wedemeyer, *supra* note 30, at 290.

34. See Jennifer A. Tan, Tom A Joseph & Sammy Saab, *Treating Hepatitis C in the Prison Population is Cost-Saving*, 48 HEPATOLOGY 1387, 1393 (2008), <https://pubmed.ncbi.nlm.nih.gov/18924228/> [perma.cc/FPR9-8WUK] ("In some states, written protocols exist for the treatment of prisoners, and in others, selection for treatment is performed on a case-by-case basis. . . . A minority of states do not have any established programs for hepatitis C treatment.")

35. *Id.* at 1393 (citing 2005 Federal Bureau of Prisons recommendations suggesting liver biopsies for some and genotyping for all prospective treatment candidates and noting that liver biopsies were mandatory in certain states at that time).

often delayed, for people in custody compared to those not in custody. Some carceral systems required psychological screening before initiating treatment.<sup>36</sup> State prison systems often required a minimum remaining sentence of fifteen to eighteen months to ensure completion of treatment and follow-up, precluding treatment for people with less or uncertain time remaining on their sentences.<sup>37</sup> As one federal court of appeals described eligibility for treatment in a state prison system during that period, “[t]he selection of patients for interferon treatment is highly individualized and depends upon many factors. [E]ven if the appropriate threshold levels of inflammation and fibrosis are present, treatment may be inappropriate if the patient is too young or too old, had a previous organ transplant, or suffers from depression, other mental health problems, heart disease, or untreated chemical dependency.”<sup>38</sup>

In 2011, new HCV treatment options began to emerge that ultimately transformed the treatment landscape. That year, the U.S. Food and Drug Administration (FDA) began approving DAA medications for HCV to be administered in combination with interferon.<sup>39</sup> By 2014, the FDA began approving DAA drugs as a stand-alone treatment option.<sup>40</sup> DAAs directly target HCV at various stages of the viral life cycle to inhibit virus production.<sup>41</sup> DAAs are now widely available, safe, and highly effective

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36. See, e.g., *Iseley v. Talaber*, 232 F. App'x 120, 123–24 (3rd Cir. 2007), <https://clearinghouse.net/doc/136961/> [<https://perma.cc/LJT7-86RV>] (describing prison protocols requiring psychological screening before initiating interferon treatment).

37. Tan et al., *supra* note 34.

38. *Bender v. Regier*, 385 F.3d 1133, 1135 (8th Cir. 2004), <https://clearinghouse.net/doc/136963/> [<https://perma.cc/7RWY-4XVP>] (ultimately concluding that prison physician did not act with deliberate indifference in failing to provide interferon treatment before patient's release); see also *Coleman-Bey v. United States*, 512 F. Supp. 2d 44, 48 (D.D.C. 2007), <https://clearinghouse.net/doc/136965/> [<https://perma.cc/63KA-MW6S>]

(explaining that under then-governing FBOP policy, priority candidates for treatment included “patients with abnormal ALT values, with liver biopsy results showing significant fibrosis, and who are willing to undergo treatment and conform to treatment requirements (including abstention from alcohol and drug use)” and that “patients with a ‘history of psychiatric illness or with signs or symptoms of mental illness’ must be assessed, and, if necessary, treated and stabilized prior to [HCV] treatment”) (internal citation omitted).

39. Marie-Louise Vachon & Douglas T. Dieterich, *The Era of Direct-Acting Antivirals has Begun: The Beginning of the End for HCV?*, 31 SEMINARS IN LIVER DISEASE 399 (2011), <https://www.medscape.com/viewarticle/756591> [[perma.cc/JU6V-TDXT](https://perma.cc/JU6V-TDXT)].

40. Viktorija Basyte-Bacevice & Juozas Kupcinskas, *Evolution and Revolution of Hepatitis C Management: From Non-A, Non-B Hepatitis Toward Global Elimination*, 38 DIGESTIVE DISEASES 137, 139 (2020), <https://www.karger.com/Article/FullText/505434> [[perma.cc/DGC2-4GK5](https://perma.cc/DGC2-4GK5)].

41. Alison B. Jazwinski & Andrew J. Muir, *Direct-Acting Antiviral Medications for Chronic Hepatitis C Virus Infection*, 7(3) GASTROENTEROL HEPATOLOGY 154 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3079144/> [[perma.cc/SS6B-6S7J](https://perma.cc/SS6B-6S7J)]; Leon L. Seifert et al, *Update on Hepatitis C: Direct-Acting Antivirals*, 7 WORLD J. OF HEPATOLOGY 2829 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/> [[perma.cc/XBU2-QU8H](https://perma.cc/XBU2-QU8H)].

across genotypes. More than ninety percent of people with HCV can be cured with an eight to twelve week course of oral DAA therapy.<sup>42</sup> Side effects and contraindications are minimal.<sup>43</sup> DAA treatment requires minimal pre-treatment testing and is easily administered through daily pills.<sup>44</sup> DAA treatment not only cures HCV in the vast majority of patients, but it also reduces community transmission. Recent studies show that successful DAA treatment is preventive; that is, providing DAA treatment to more people not only resolves those individual cases but also reduces community transmission and overall HCV incidence.<sup>45</sup> DAA treatment has also proven cost-effective, reducing overall disease rates and avoiding expensive later-stage care.<sup>46</sup> This is increasingly true as the

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42. “What is the treatment for chronic hepatitis C?”, *Hepatitis C Questions and Answers for Health Professionals*, CTFS. FOR DISEASE CONTROL & PREVENTION (Aug. 7. 2020), <https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm#d8> [perma.cc/R4RT-9F4B].

43. See, e.g., Pin-Sheng Wu, Te-Sheng Chang, Sheng-Nan Lu, Hsiang-Jou Su, Shu-Zhi Chang, Chia-Wen Hsu & Mei-Yen Chen, *An Investigation of the Side Effects, Patient Feedback, and Physiological Changes Associated with Direct-Acting Antiviral Therapy for Hepatitis C*, 16:24 INT’L. J. ENV’T. RSCH. PUB. HEALTH 4981, 4986 (2019), <https://www.mdpi.com/1660-4601/16/24/4981> [perma.cc/S5QG-WEKG] (describing “manageable” side effects experienced by about one third of study participants and the generally “positive feedback” provided by patients at the end of treatment); see also 2022 AASLD/IDSA Guidance, *supra* note 3, at 24 (recommending DAA treatment for all except those with a short life expectancy, liver transplantation, or other directed therapy).

44. See discussion *infra* Part III. See also Ayman Geddawy, Yasmine F. Ibrahim, Nabil M. Elbahie & Mohammad A. Ibrahim, *Direct Acting Anti-Hepatitis C Virus Drugs: Clinical Pharmacology and Future Direction*, 5(1) J. TRANSLATIONAL INT’L MED. 5 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5490957/> [perma.cc/7J7U-UU7E] (describing various DAA treatment options, involving daily oral pills).

45. See Behzad Hajarizadeh, Jason Grebely, Marianne Byrne, Pip Marks, Janaki Amin, Hamish McManus, Tony Butler, Evan B Cunningham, Peter Vickerman, Natasha K Martin, John G McHutchison, Diana M Brainard, Carla Treloar, Georgina M Chambers, Luke Grant, Colette Mcgrath, Andrew R Lloyd & Gregory J Dore, *Evaluation of Hepatitis C Treatment-As-Prevention Within Australian Prisons (SToP-C): A Prospective Cohort Study*, 6 LANCET GASTROENTEROL HEPATOLOGY 533, 541 (2021), <https://pubmed.ncbi.nlm.nih.gov/33965006/> [perma.cc/O9SR-KNCE] (finding that DAA treatment scale-up led to reduced incidence of HCV in the prison setting); see also Jason Grebely, Gregory J. Dore, Frederick L. Altice, Brian Conway, Alain H. Litwin, Brianna L. Norton, Olav Dalgard, Edward J. Gane, Oren Shibolet, Ronald Nahass, Anne F. Luetkemeyer, Cheng-Yuan Peng, David Iser, Isaias Noel Gendrano, Michelle M. Kelly, Peggy Hwang, Ernest Asante-Appiah, Barbara A. Haber, Eliav Barr, Michael N. Robertson & Heather Platt, *Reinfection and Risk Behaviors After Treatment of Hepatitis C Virus Infection in Persons Receiving Opioid Agonist Therapy*, 175 ANNALS OF INTERNAL MED. 1221 (Sept. 2022), <https://www.acpjournals.org/doi/10.7326/M21-4119> [perma.cc/DN8V-GQK7].

46. See, e.g., Sabrina A. Assoumou, Abriana Tasillo, Claudia Vellozzi, Golnaz Eftekhari Yazdi, Jianing Wang, Shayla Nolen, Liesl Hagan, William Thompson, Liisa M Randall, Lara Strick, Joshua A Salomon & Benjamin P Linas, *Cost-Effectiveness and Budgetary Impact of Hepatitis C Virus Testing, Treatment, and Linkage to Care in US Prisons*, 70 CLINICAL INFECTIOUS DISEASES 1388 (Apr. 1, 2020), <https://pubmed.ncbi.nlm.nih.gov/31095676/> [perma.cc/LB97-R6WH].

costs of DAA treatment continue to decrease.<sup>47</sup> DAAs have replaced interferon as the universal standard of care for HCV.<sup>48</sup>

### *C. Medical Standard of Care: Universal Testing and Early-Stage DAA Treatment*

The American Association for the Study of Liver Diseases and the Infectious Diseases Society of America together promulgate *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C* (“AASLD/IDSA guidance” or “guidance”). This guidance offers “up-to-date recommendations to healthcare practitioners on the optimal screening, management, and treatment for persons with HCV infection in the United States, considering the best available evidence,”<sup>49</sup> including recommendations for HCV testing and treatment in prisons and jails.<sup>50</sup> It is updated regularly—most recently in October 2022—to reflect new data from peer-reviewed research.<sup>51</sup>

The AASLD/IDSA guidance informs appropriate HCV care in the United States. The CDC presents the AASLD/IDSA guidance as “Clinical Guidelines” for HCV screening and management.<sup>52</sup> The most recent (March 2021) version of the Federal Bureau of Prisons’ (FBOP) Clinical Guidance on the Evaluation and Management of Hepatitis C Virus (HCV) Infection—guidance on which many state prison systems base their own HCV treatment protocols—credits the January 2021 AASLD/IDSA guidance for its own 2021 revisions toward a simplified approach

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47. See e.g., Nicholas Florko, *With a Promising New Play to Pay for Pricey Cures, Two States Set Out to Eliminate Hepatitis C. But Cost hasn’t Been the Biggest Problem*, STAT (Sept. 13, 2022), <https://www.statnews.com/2022/09/13/louisiana-washington-hep-c-investigation/> [perma.cc/995M-8J6N] (noting that as of September 2022, medication for a course of DAA treatment retailed for roughly \$240,000, down from highs of as much as \$94,500); Nicholas Florko, *Prisons Say They Can’t Afford to Cure Everyone With Hepatitis C. But Some Are Figuring Out a Way*, STAT (Dec. 15, 2022), <https://www.statnews.com/2022/12/15/prisons-cant-afford-hep-c-drugs-but-some-figured-out-a-way/> [perma.cc/B3ZE-NLTM] (citing Harvard professor Jagpreet Chhatwal to explain that DAA treatment at current price points has reached the point of cost-effectiveness).

48. See, e.g., 2022 AASLD/IDSA Guidance, *supra* note 3, at 24; see also *Atkins v. Parker*, 972 F.3d 734, 736 (6th Cir. 2020), *cert. denied sub nom. Atkins v. Williams*, 141 S. Ct. 2512 (2021), <https://clearinghouse.net/doc/109713/> [https://perma.cc/8N73-FRRK] (“The antivirals are so effective that for the most part doctors have stopped using interferons entirely.”).

49. 2022 AASLD/IDSA Guidance, *supra* note 3, at 4.

50. 2022 AASLD/IDSA Guidance, *supra* note 3, at 179.

51. 2022 AASLD/IDSA Guidance, *supra* note 3, at 1.

52. *Viral Hepatitis: Hepatitis C Information*, *supra* note 2.

to testing and treating.<sup>53</sup> (Note, however, that the FBOP guidance does not fully align with the AASLD/IDSA guidance). Although the legal significance of the guidance remains contested,<sup>54</sup> several courts have recognized the AASLD/IDSA guidance as the standard of care that should guide HCV treatment in carceral settings.<sup>55</sup> The AASLD/IDSA guidance's primary recommendations are summarized below.

**Universal Testing:** The AASLD/IDSA guidance recommends one-time, routine, opt-out HCV testing for all people ages eighteen and older. It further recommends periodic repeat HCV testing for people with risk activities, exposures, or conditions, including “persons who were ever incarcerated.”<sup>56</sup> Indeed, numerous studies confirm that routine, one-time testing for all adults is cost-effective; it identifies “a substantial number of HCV cases that would otherwise be missed.”<sup>57</sup> Routine testing offers significant health care cost savings, “even when linkage to HCV treatment after testing [is] poor and the rate of HCV reinfection among injection drug users [is] high.”<sup>58</sup> Studies similarly demonstrate that routine HCV testing for people with risk exposure is cost-effective “because of increasing HCV incidence and prevalence among people who inject drugs and the decreasing cost of DAA therapy,” and because many people at greatest risk for infection and transmission do not report “their highly stigmatized risk activities.”<sup>59</sup> In that context, universal testing both casts a wider net and reduces the stigma of risk activity-

53. CLINICAL GUIDANCE, EVALUATION AND MANAGEMENT OF CHRONIC HEPATITIS C VIRUS (HCV) INFECTION, FED. BUREAU OF PRISONS 1 (Mar. 2021) [hereinafter “FBOP Guidance”], [https://www.bop.gov/resources/pdfs/hcv\\_guidance.20210513.pdf](https://www.bop.gov/resources/pdfs/hcv_guidance.20210513.pdf) [perma.cc/3QXL-62XP].

54. See, e.g., *Buffkin v. Hooks*, No. 1:18-CV-502, 2019 WL 1282785, at \*6 (M.D.N.C. Mar. 20, 2019), <https://clearinghouse.net/doc/136648/> [https://perma.cc/5ZL6-LMVD] (“this court finds that the guidance provides some evidence of a preferred public health policy but does not necessarily constitute the standard for judging deliberate indifference”); *Atkins v. Parker*, 412 F. Supp. 3d 761, 782 (M.D. Tenn. 2019), *aff’d*, 972 F.3d 734 (6th Cir. 2020), <https://clearinghouse.net/doc/109712/> [https://perma.cc/D3PG-ZRDV](same).

55. See, e.g., *Barfield v. Semple*, No. 3:18-CV-1198 (MPS), 2019 WL 3680331, at \*2 (D. Conn. Aug. 6, 2019), <https://clearinghouse.net/doc/112607/> [https://perma.cc/UZ4A-254M] (“The American Association for the Study of Liver Diseases (“AASLD”) and the Infectious Disease Society of America (“IDSA”) set forth the medical standard of care for the treatment of HCV.”); *Barfield*, 2019 WL 3680331, at \*11 (citing failure to adhere to the standard of care for HCV treatment in denying defendants’ motion to dismiss Eighth Amendment claim); *Postawko v. Missouri Dep’t of Corr.*, No. 2:16-CV-04219-NKL, 2017 WL 1968317, at \*2 (W.D. Mo. May 11, 2017), <https://clearinghouse.net/doc/89145/> [https://perma.cc/9K3Y-8PPB] (explaining that “[t]he CDC encourages health professionals to follow the evidence-based standard of care developed by the Infectious Diseases Society of America (“IDSA”) and the American Association for the Study of Liver Diseases (“AASLD”), which constitutes the medical standard of care,” and citing numerous failures to follow this standard in denying motion to dismiss in part).

56. 2022 AASLD/IDSA Guidance, *supra* note 3, at 12.

57. 2022 AASLD/IDSA Guidance, *supra* note 3, at 14.

58. 2022 AASLD/IDSA Guidance, *supra* note 3, at 14–15.

59. *Id.* at 14.

based testing. In particular, the guidance recommends that prisons and jails implement opt-out HCV testing<sup>60</sup> “because of the known benefits of care and treatment in reducing the risk of<sup>p</sup> serious illness or death, as well as “the potential public health benefit of reducing transmission through early treatment, viral clearance, and reduced risk behaviors.”<sup>61</sup>

The guidance’s support for universal testing aligns with the recommendations of other national health organizations. The CDC advises screening all adult patients at least once in their lifetime, as well as routine periodic testing for people with risk factors.<sup>62</sup> The U.S. Preventative Services Task Force’s Recommendation Statement on Screening for Hepatitis C Virus Infection in Teens and Adults similarly recommends one-time screening for all adults ages eighteen to seventy-nine, as well as periodic screening for people at continued risk.<sup>63</sup>

**Unrestricted Treatment:** The AASLD/IDSA guidance recommends DAA treatment for “all patients with acute or chronic HCV infection, except those with a short life expectancy that cannot be remediated” by treatment.<sup>64</sup> It explains that “[b]ecause of the many benefits associated with successful HCV treatment, clinicians should treat HCV-infected patients with antiviral therapy with the goal of achieving [virologic cure], preferably early in the course of chronic Hepatitis C before the development of severe liver disease and other complications.”<sup>65</sup> Early treatment is associated with better outcomes, including higher likelihood of cure and mortality reduction.<sup>66</sup> Numerous studies have shown meaningful reduction in liver-related mortality when HCV is treated at the earliest stages.<sup>67</sup> The AASLD/IDSA guidance makes clear that DAA treatment can and should be provided in prisons and jails; testing and treatment in those settings, and linkage to community care upon release, are key to HCV elimination efforts.<sup>68</sup> This recommendation aligns with recent CDC and World Health Organization guidance recommending

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60. *Id.* at 180–82.

61. *Id.* at 13.

62. *Screen All Patients for Hepatitis C*, CTRS. FOR DISEASE CONTROL & PREVENTION (June 14, 2021), <https://www.cdc.gov/knowmorehepatitis/hcp/Screen-All-Patients-For-HepC.htm> [perma.cc/F3LU-7CKD].

63. U.S. Preventative Serv’s Task Force, *Screening for Hepatitis C Virus Infection in Adolescents and Adults*, JAMA NETWORK (Mar. 2, 2020), <https://jamanetwork.com/journals/jama/fullarticle/2762186> [perma.cc/GSY3-7DWQ].

64. 2022 AASLD/IDSA Guidance, *supra* note 3, at 24.

65. *Id.* at 25.

66. *Id.* at 25–26.

67. *Id.* at 26.

68. *Id.* at 180, 182.

testing and treatment in primary care locations, including carceral settings, in order to maximize access.<sup>69</sup>

Since DAA treatment first became available, the infrastructure necessary to implement universal treatment has lagged. Many health care systems lack the staff, funding, and protocols to rapidly treat every patient with HCV.<sup>70</sup> Moreover, the high market price of DAA drugs made rapid treatment for all prohibitively expensive. In 2014, Sovaldi, one of the first drugs approved for DAA treatment, cost \$1,000 per pill and about \$84,000 for a typical course of treatment.<sup>71</sup> In the early era of DAAs, medical guidance and practice therefore often prioritized treatment for those with the most advanced liver disease.

But prices have fallen markedly since then. In 2019, Gilead, the originator company for several DAA drugs began offering “authorized generics,” marketed by a subsidiary company, at a list price of \$24,000 for a course of treatment.<sup>72</sup> By 2020, the cost of WHO-recommended DAA drugs in the United States ranged from approximately \$17,965 to \$111,659 per course of treatment, with course-of-treatment costs less than \$27,000 for at least three of the major DAAs on the market.<sup>73</sup> Now, years after the introduction of DAA treatment for HCV, prices have lowered to \$20,000 and below per course of treatment in the United States, and it seems likely that costs will continue to decrease.<sup>74</sup> Indeed, elsewhere in the world, DAAs are available for \$60 per course of

69. World Health Organization Publishes Updated Guidance On Hepatitis C Infection with New Recommendations on Treatment of Adolescents And Children, Simplified Service Delivery And Diagnostics, WORLD HEALTH ORG. (June 24, 2022), <https://www.who.int/news/item/24-06-2022-WHO-publishes-updated-guidance-on-hepatitis-C-infection> [perma.cc/6BU4-WQLH]; Press Release: Ctrs. for Disease Control & Prevention, Less Than 1/3 of People Diagnosed with Hepatitis C Receive Timely Treatment for the Deadly, Yet Curable, Infection (Aug. 9, 2022) <https://www.cdc.gov/nchhstp/newsroom/2022/2022-Hepatitis-Vital-Signs-press-release.html> [perma.cc/HRR7-GZYY].

70. See 2022 AASLD/IDSA Guidance, *supra* note 3, at 24.

71. Margot Sanger-Katz, \$1,000 Hepatitis Pill Shows Why Fixing Health Costs Is So Hard, N.Y. TIMES (Aug. 2, 2014), <https://www.nytimes.com/2014/08/03/upshot/is-a-1000-pill-really-too-much.html#:~:text=A%20new%20drug%20for%20the,a%20typical%20person's%20total%20treatment.> [https://perma.cc/XWR7-85UQ].

72. Melissa J. Barber, Dzintars Gotham, Giten Khwairakpam & Andrew Hill, *Price of A Hepatitis C Cure: Cost of Production and Current Prices for Direct-Acting Antivirals in 50 Countries*, 6 J. OF VIRUS ERADICATION 1 (2020), <https://www.sciencedirect.com/science/article/pii/S2055664020300017#bib28> [perma.cc/PA29-BZZ8]; Press Release: Gilead, Gilead Subsidiary to Launch Authorized Generics of Eplusa (Sofosbuvir/Velpatasvir) and Harvoni (Ledipasvir/Sofosbuvir) for the Treatment of Chronic Hepatitis C (Sept. 24, 2018), <https://www.gilead.com/news-and-press/press-room/press-releases/2018/9/gilead-subsidiary-to-launch-authorized-generics-of-eplusa-sofosbuvirvelpatasvir-and-harvoni-ledipasvir-sofosbuvir-for-the-treatment-of-chronic> [perma.cc/AQH5-9M4W].

73. Barber et al., *supra* note 72, at Table 1.

74. E.g., THE ACTUAL COST OF HCV TREATMENT, HEPATITIS C: STATE OF MEDICAID ACCESS FACT SHEET, STATEOFHEPC.ORG 2 (2023), <https://stateofhepc.org/wp-content/uploads/2023/02/State-of-Hep-C-Treatment-Costs-Fact-Sheet.pdf> [perma.cc/E8VY-RTD7].

treatment. This price threshold aligns with estimated manufacturing cost-based prices which, since the early days of DAA treatment, have generally been less than a couple hundred dollars per course of treatment, and sometimes far lower.<sup>75</sup> But even at the current price point, treatment is clearly cost-effective.<sup>76</sup> Even as early as 2014, when drug costs were at their highest, DAA treatment was shown to save money over the long run by reducing the need for higher-cost later-stage interventions like cirrhosis treatment and liver transplants.<sup>77</sup>

As prices continue to fall and studies repeatedly confirm the safety and efficacy of DAA treatment, medical guidance and practice has explicitly shifted away from prioritizing of patients based on disease severity.<sup>78</sup> The current AASLD/IDSA guidance explains that, at this juncture, there “have been opportunities to treat many of the highest risk patients and accumulate real-world experience regarding the tolerability and safety” of DAA treatment regimens.<sup>79</sup> Moreover, data demonstrates “the many benefits, both intrahepatic [inside the liver] and extrahepatic [outside the liver], that accompany HCV eradication.”<sup>80</sup> For those reasons, the guidance no longer recommends prioritization, and instead

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75. See WHO Highlights Progress in Accelerating Access to Hepatitis C Diagnostics and Treatment In Low- and Middle-Income Countries, WORLD HEALTH ORG. (Jan. 27, 2021), <https://www.who.int/news/item/27-01-2021-who-highlights-progress-in-accelerating-access-to-hepatitis-c-diagnostics-and-treatment-in-low-and-middle-income-countries> [perma.cc/8VY5-DXLP] (“Low- and middle-income countries can now aim to achieve a price as low as US \$60 per patient for a 12-week course of treatment with WHO-prequalified generic sofosbuvir and daclatasvir.”). Manufacturing cost-based prices for DAA treatment are far below United States market prices. See Barber et al., *supra* note 65 (“The estimated manufacturing cost-based prices for a 12-week course were US \$28 for sofosbuvir, US \$31 for ledipasvir, US\$58 for velpatasvir, and US\$4 for daclatasvir. For fixed-dose combinations, estimated cost-based prices were US \$58 for sofosbuvir/ledipasvir, US \$85 for sofosbuvir/velpatasvir, and US\$31 for sofosbuvir/daclatasvir.”). Indeed, even in the earliest days of DAA treatment, predicted manufacturing costs were generally less than a couple hundred dollars per course of treatment. See Andrew Hill, Saye Khoo, Joe Fortunak, Bryony Simmons & Nathan Ford, *Minimum Costs for Producing Hepatitis C Direct-Acting Antivirals for Use in Large-Scale Treatment Access Programs in Developing Countries*, 58 CLINICAL INFECTIOUS DISEASES 928 (2014), <https://pubmed.ncbi.nlm.nih.gov/24399087/> [perma.cc/CI6V-G28R] (“Predicted manufacturing costs (US dollars) for 12-week courses of HCV DAAs were \$21-\$63 for ribavirin, \$10-\$30 for daclatasvir, \$68-\$136 for sofosbuvir, \$100-\$210 for faldaprevir, and \$130-\$270 for simeprevir.”).

76. See Florko, *supra* note 24.

77. See Sanger-Katz, *supra* note 71.

78. By 2018, the National Academies of Sciences, Engineering, and Medicine’s report on A *National Strategy for the Elimination of Hepatitis B and C* recommended that all insurers should cover DAA Therapy for chronic HCV without restriction, in line with the then-AASLD/IDSA guidance describing the standard of care as DAA treatment for all, without reference to fibrosis score. See Phil Waters & Tina Broder, *Rationing Care: Barriers to Direct-Acting Antiviral Treatment in Medicaid Treatment Criteria*, 12 CLINICAL LIVER DISEASE 122 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6385924/#cld751-bib-0007> [perma.cc/MZ49-935R].

79. *Id.*

80. *Id.*



promotes DAA treatment for all except those with short life expectancies which cannot be remediated with treatment.<sup>81</sup>

**Supporting Recommendations:** Finally, the AASLD/IDSA guidance offers recommendations to support the success of testing and treatment programs. These supporting recommendations include counseling; interventions to facilitate cessation of alcohol consumption; evaluation for other conditions which can accelerate liver fibrosis, including Hepatitis B and HIV; vaccination against Hepatitis A and B; and education about how to prevent HCV transmission to others.<sup>82</sup> In jails, the guidance recommends coupling testing and treatment with counseling and linkage to follow-up community healthcare.<sup>83</sup> In prisons, the guidance recommends “harm reduction and evidence-based treatment for underlying substance use disorders.”<sup>84</sup>

*A Note on Medicaid Coverage for Early-Stage DAA Treatment:* In the Medicaid context, states and courts alike have recognized the benefits to early-stage DAA treatment. In 2015, the Centers for Medicare & Medicaid Services issued a letter to state Medicaid coordinators characterizing DAA treatment for chronic HCV as “effective, clinically appropriate, and medically necessary” and reproaching states for limiting treatment to beneficiaries with more advanced fibrosis.<sup>85</sup> Thereafter, several state Medicaid programs removed categorical barriers to treatment.<sup>86</sup> In some states that did not do so voluntarily, courts required such expansion of coverage.<sup>87</sup> As of 2022, fibrosis restrictions for treatment remain in only two states; in all other states, early-stage DAA treatment can be covered for Medicaid recipients (although other restrictions, such as prescriber requirements, may still apply).<sup>88</sup>

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81. *Id.*

82. 2022 AASLD/IDSA Guidance, *supra* note 3, at 18.

83. *Id.* at 180.

84. *Id.* at 182.

85. *Assuring Medicaid Beneficiaries Access to Hepatitis (HCV) Drugs*, DEP’T OF HEALTH & HUM. SERVS., Notice 172, 2 (Nov. 5, 2015), <https://www.medicaid.gov/medicaid-chip-pro-gram-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf> [perma.cc/WMT4-R6UX].

86. For a more comprehensive discussion, with examples, see Brief of Dr. Joseph Goldenson et al., as *amici curiae* in Support of Plaintiff-Appellant and in Support of Reversal, *Melnik v. Aranas*, No. 20-15471, 2021 WL 5768468 (9th Cir. Oct. 15, 2020), <https://clearinghouse.net/doc/136956/> [https://perma.cc/S3D6-B7VR].

87. See, e.g., *B.E. v. Teeter*, No. C16-227-JCC, 2016 WL 3033500, at \*1, \*6 (W.D. Wash. May 27, 2016) (requiring Washington’s Medicaid program to provide coverage for prescription medication to treat HCV without regard to fibrosis score); see also *Ryan v. Birch*, No. 17-cv-00904-KLM, 2017 WL 3896440 (D. Colo. Sept. 5, 2017) (denying motion to dismiss claim of improper denial of coverage for DAA treatment as medically necessary for every Medicaid enrollee with HCV).

88. See HEPATITIS C: THE STATE OF MEDICAID ACCESS, CTR. FOR HEALTH L. & POL’Y INNOVATION OF HARVARD L. SCH. & NAT’L VIRAL HEPATITIS ROUNDTABLE 3 (Jan. 4, 2022), <https://stateofhepc.org/wp->

D. Lagging Implementation of Universal Testing and Treatment in  
Prisons and Jails

In the early years after the introduction of DAAs, treatment rates in United States prisons and jails were dismal. A study of state prison systems found that, of the forty-one states reporting data, less than one percent of incarcerated people known to have HCV were receiving any form of treatment as of January 1, 2015.<sup>89</sup> That same study noted that prison systems generally did not conduct routine testing; only sixteen percent of responding prisons provided universal (opt-out) antibody testing upon admission.<sup>90</sup> During this time, medical guidance and practice prioritized patients with the greatest need, including those with advanced liver fibrosis.<sup>91</sup> Carceral systems similarly prioritized patients for DAA treatment based on disease progression,<sup>92</sup> but they also imposed barriers to treatment untethered to medical guidance or disease

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[content/uploads/2022/01/ HCV State-of-Medicaid-Access Jan-2022 v2.pdf](#) [perma.cc/4E5E-F12K] (as of January 2022, no fibrosis restrictions in 48 states, DC, and Puerto Rico; coverage only for F2 or higher in South Dakota and F3 or higher in Arkansas). States are also trending toward eliminating sobriety requirements for coverage. As of January 2022, 29 states and Puerto Rico had no sobriety restrictions, and another 13 states and DC required screening and counseling only. *Id.* at 5. Trends toward eliminating sobriety restrictions continue. For example, in December 2022, the United States executed a settlement agreement with Alabama’s Medicaid Agency to “ensure that Alabama Medicaid recipients with Hepatitis C (HCV) who also use alcohol or illicit drugs, including those with a substance abuse disorder (SUD), will be provided equal access to medications to treat their hepatitis,” under which Alabama withdrew its previous requirement of six months sobriety for DAA coverage. Press Release, U.S. Dep’t. of Just. C.R. Div., Justice Department Secures Agreement with Alabama Medicaid to Remove Unlawful Sobriety Mandate for Health Care Access (Dec. 5, 2022), <https://www.justice.gov/opa/pr/justice-department-secures-agreement-alabama-medicaid-remove-unlawful-sobriety-man-date-health> [perma.cc/4B2H-327V].

89. See *HCV Testing and Treatment in Correctional Settings*, INFECTIOUS DISEASES SOC. OF AM. (Oct. 24, 2022), <https://www.hcvguidelines.org/unique-populations/correctional> [perma.cc/N89S-4FC4]; see also Adam L. Beckman, Alyssa Bilinski, Ryan Boyko, George M. Camp, A. T. Wall, Joseph K. Lim, Emily A. Wang, R. Douglas Bruce & Gregg S. Gonsalves, *New Hepatitis C Drugs Are Very Costly and Unavailable to Many State Prisoners*, 35 HEALTH AFFS. 1893 (2016), <https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0296> [perma.cc/6VS6-S1GL]; 2022 AASLD/IDSA Guidance, *supra* note 3, at 179–80.

90. 2022 AASLD/IDSA Guidance, *supra* note 3, at 180.

91. Beckman et al., *supra* note 89.

92. See, e.g., Alan Prendergast, *Hep C: The Deadliest Killer in Colorado’s Prisons Is a Curable Virus*, WESTWORD (Dec. 13, 2016), <https://www.westword.com/news/hep-c-the-deadliest-killer-in-colorados-prisons-is-a-curable-virus-8591316> [perma.cc/QP87-P212] (as of 2016, the Colorado Department of Corrections offered DAA treatment to 20–25 people a year—just over 1% of incarcerated people known to have HCV at that time—and gave top priority to patients with the highest level of liver scarring or at higher risk of complications from liver disease); see also *Abu-Jamal v. Kerestes*, No. 3:15-CV-00967, 2016 WL 4574646, at \*9 (M.D. Pa. Aug. 31, 2016) (describing treatment protocol of the Pennsylvania Department of Corrections, pursuant to which DAAs were not provided until HCV had progressed to advanced compensated cirrhosis or early decompensated cirrhosis manifested by esophageal varices, and finding that the protocol constituted deliberate indifference to the known risks of untreated HCV).

progression. For example, some systems required a year or more left on one's sentence before beginning treatment,<sup>93</sup> an outdated timeframe seemingly tied to the long period previously required to complete interferon-based treatment.<sup>94</sup> Other systems apparently precluded treatment based on disciplinary record<sup>95</sup> or required completion of lengthy alcohol- and drug-treatment programs before initiating treatment.<sup>96</sup> Although cost alone cannot justify denial of necessary medical care, it is true that the high price of DAAs at that time functionally precluded universal treatment.<sup>97</sup> Indeed, for many carceral systems, the cost of universal DAA treatment would have outstripped entire healthcare budgets.<sup>98</sup>

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93. *E.g.*, Class Action Complaint ¶ 86, *West v. Gobeille*, No. 2:19-CV-00081, 450 F.Supp.3d 497 (D. Vt. May 21, 2019), <https://clearinghouse.net/doc/112626/> [<https://perma.cc/5CH9-LLHP>] (describing existing requirement of 12-18 months remaining on sentence to qualify for treatment); Third Amended Class Action Complaint ¶ 67, *Geissler v. Stirling*, No. 4:17-CV-01746, 2019 WL 3561875 (D.S.C. Aug. 21, 2018), <https://clearinghouse.net/doc/112690/> [<https://perma.cc/BD9T-D52Q>] (describing policy requiring twelve months left on sentence to initiate DAA treatment); Class Action Complaint, *Buffkin v. Hooks* ¶¶ 87-88, No. 1:18-CV-00502, 2019 WL 1282785 (M.D.N.C. June 15, 2018) <https://clearinghouse.net/doc/130429/> [<https://perma.cc/NNB2-VUYS>] (same).

94. *See supra* Section I.A.

95. *See, e.g.*, Class Action Complaint, *West*, *supra* note 93, ¶¶ 88, 90 (describing policies precluding treatment for incarcerated people with “chronic disciplinary issues” and requiring “a responsibility to learn from past behaviors and interact with society positively”); First Amended Class Complaint ¶ 41, *Aragon v. Raemisch*, No. 1:17-CV-1744 (D. Colo. Sept. 11, 2017), <https://clearinghouse.net/doc/97201/> [[perma.cc/8K6F-CUYA](https://perma.cc/8K6F-CUYA)] (describing CDOC policy denying treatment to anyone who has engaged in “high-risk behavior” including any disciplinary offense involving alcohol, prescription drugs, illegal drugs, sexual activity, or tattooing within the past twelve months); Class Action Complaint, *Buffkin*, *supra* note 93, ¶¶ 89-90 (noting policy denying treatment and evaluation to anyone with a drug or alcohol infraction within the last twelve months).

96. *See, e.g.*, Prendergast, *supra* note 92 (describing the experience of a person incarcerated in Colorado who did not qualify for DAA treatment unless, among other barriers, he completed alcohol and drug education programs that could last up to a year).

97. *See generally* Beckman et al., *supra* note 89 (describing relevant findings from a 2015 survey of departments of correction and concluding that “the substantial price of treatment prevents many state corrections departments from purchasing the quantities of medications necessary to treat all of those in need,” resulting in triaging). As A.T. Wall, then-Director of the Rhode Island Department of Corrections, explained in 2016: “Patients and prison officials alike want to cure hepatitis C infections. That requires financial resources and discounts we don’t have. What we desperately need are less costly drugs and more funding.” *Study: Modern Hepatitis C Drugs are Very Costly and Unavailable to Many State Prisoners*, YALE L. SCH. (Oct. 4, 2016), <https://law.yale.edu/yls-today/news/study-modern-hepatitis-c-drugs-are-very-costly-and-unavailable-many-state-prisoners> [[perma.cc/68QV-FHBR](https://perma.cc/68QV-FHBR)].

98. *See* Anne C. Spaulding, Jagpreet Chhatwal, Madeline G. Adeo, Robert T. Lawrence, Curt G. Beckwith & William von Oehsen, *Funding Hepatitis C Treatment in Correctional Facilities by Using a Nominal Pricing Mechanism*, 25 J. CORR. HEALTH CARE 15, 16 (2019) <http://doi.org/10.1177/1078345818805770> [[perma.cc/VC2B-RJH9](https://perma.cc/VC2B-RJH9)]; *see also* Florko, *supra* note 24 (noting that in 2019, Missouri estimated that it would have cost the prison system \$90 million, almost seventy percent of its medical budget, to treat every incarcerated person with HCV).

But even as DAA costs began to fall and medical guidance shifted away from prioritization toward universal testing and treatment, testing and DAA access in carceral settings have continued to lag. In the Indiana prison system between April 1, 2017 and January 19, 2018, only forty-one of approximately 3,476 people identified as having chronic HCV had completed or were receiving DAA treatment.<sup>99</sup> In Tennessee, as of July 2019, only approximately ten percent of people known to have HCV in the custody of the Tennessee Department of Corrections had been prescribed DAAs.<sup>100</sup> In 2021, only thirteen percent of the more than 900 incarcerated people known to have HCV in the Missouri prison system received DAA treatment,<sup>101</sup> New Hampshire treated only twenty-two of an estimated 250 incarcerated people with HCV. Only four percent of people with HCV in state custody in Iowa received DAA treatment.<sup>102</sup> South Dakota treated just seven incarcerated people in 2021, out of at least 382 known to have the virus.<sup>103</sup> Indeed, recent reporting on this issue indicates that as of 2021, at least a dozen states were treating fewer than twenty percent of people with HCV in their custody.<sup>104</sup> Today, many systems maintain policies that prioritize treatment for those with the most advanced liver disease,<sup>105</sup> despite evidence that treatment is likely to be most effective when offered in the earliest stages of the disease,<sup>106</sup>

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99. See *Stafford v. Carter*, No. 117CV00289JMSMJ, 2018 WL 4361639, at \*10 (S.D. Ind. Sept. 13, 2018).

100. See *Atkins*, *supra* note 54, at 765.

101. See *Florko*, *supra* note 24.

102. Nicholas Florko, *These 8 States Are Doing the Worst Job of Treating Hepatitis C in Prisons*, STAT (Dec. 15, 2022), <https://www.statnews.com/2022/12/15/states-worst-job-treating-hepatitis-c-in-prisons/> [perma.cc/78HJ-VPN2].

103. *Id.*

104. *Florko*, *supra* note 24.

105. See *e.g.*, Mont. Dep't. of Corr., Clinical Service Division Procedure 4.5.11A (Apr. 9, 2021) (restricting DAA treatment to those with a Fib-4 score of 1.45 or greater, those with a lower score instead “receive education regarding healthy lifestyle choices and annual monitoring”) <https://clearinghouse.net/resource/3840/> [perma.cc/PC2A-T34P]; Iowa Dep't of Corr., Hepatitis C Management Policy No. HSP-912 at IV(E), <https://clearinghouse.net/resource/3840/> [perma.cc/PC2A-T34P] (restricting treatment to those with evidence of advanced disease, such as cirrhosis, a Fibrosis score of at least F2, or with other signs of advanced disease or high-risk coinfections). South Dakota prioritizes treatment for incarcerated people with F3 fibrosis or other serious risk factors, like HIV. See *Florko*, *supra* note 102. Although the FBOP guidance does not mandate a rigid prioritization system, it notes that certain conditions “may require more urgent consideration for treatment,” including advanced hepatic fibrosis (defined as APRI greater than or equal to 2.0, Metavir or Batts/Ludwig stage 3 or 4 on liver biopsy, or known or suspected cirrhosis.). See *FBOP Guidance*, *supra* note 53, at 13.

106. 2022 AASLD/IDSA Guidance, *supra* note 3, at 25–26.

and many continue to impose barriers to treatment unrelated to disease progression.<sup>107</sup>

The failure to scale up HCV testing and treatment in prisons and jails is a missed opportunity to cure people with HCV and to prepare to meet the needs of future incarcerated populations. A “test all, treat all” approach, when combined with linkage to care at release, substantially reduces liver fibrosis severity and lifetime cumulative prevalence of cirrhosis and meaningfully increases the proportion of lifetime sustained virological response.<sup>108</sup> Prisons and jails offer a prime setting to identify and treat the virus in a high-risk, high-prevalence population, often at a time of relative stability from active substance abuse and with support for adherence to treatment. This in turn can reduce community transmission.<sup>109</sup> Outcomes demonstrate that DAA treatment can be provided safely, effectively, and with cure rates comparable to community care when prisons and jails endeavor to test for and treat HCV.<sup>110</sup> Successful models have included telehealth linkages to

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107. See e.g., *Woodcock v. Correct Care Sols.*, 861 F. App'x 654, 656, 658 (6th Cir. 2021), <https://clearinghouse.net/doc/112003/> [<https://perma.cc/WF25-4BVN>] (describing pre-2020 policy in Kentucky DOC that disqualified from DAA treatment incarcerated people who did not have a clear conduct record for twelve months prior or “had demonstrated an unwillingness or inability to adhere to rigorous medication regimes,” and noting 2020 clarifications that “the no-disciplinary-infractions-within-twelve-months exclusionary factor applies only to conduct that would compromise treatment.”); FBOF Guidance, *supra* note 53, at 13 (“Inmates must demonstrate a willingness and an ability to adhere to a rigorous treatment regimen.”); Clinical Service Division Procedure 4.5.11A, *supra* note 105 (Montana: providing inclusion criteria for treatment, including “no evidence of HCV risk behavior or correctional issues in previous six months, including prison tattoos and illicit drug use”); Hepatitis C Management, *supra* note 105, at V(F)(3) (setting out criteria for deferring DAA treatment for otherwise qualifying candidates for reasons including instances of substance abuse or other high risk behavior, such as tattoos, within the last twelve months). Nebraska even requires incarcerated people to sign a consent form before receiving treatment that claims “a diversity of medical opinion as to what constitutes the best way to manage HCV infection,” in an apparent effort to dissuade DAA treatment. See Florko, *supra* note 102.

108. See Sabrina A. Assoumou, Abriana Tasillo, Claudia Vellozzi, Golnaz Eftekhari Yazdi, Jianing Wang, Shayla Nolen, Liesl Hagan, William Thompson, Liisa M Randall, Lara Strick, Joshua A Salomon & Benjamin P Linas, *Cost-effectiveness and Budgetary Impact of Hepatitis C Virus Testing, Treatment, and Linkage to Care in US Prisons*, 70 *CLINICAL INFECTIOUS DISEASES* 1388 (July 2020), <https://pubmed.ncbi.nlm.nih.gov/31095676/> [[perma.cc/74EX-LV2M](https://perma.cc/74EX-LV2M)].

109. E.g., Tianhua He, Kan Li, Mark S. Roberts, Anne C. Spaulding, Turgay Ayer, John J. Grefenstette & Jagpreet Chhatwal, *Prevention of Hepatitis C by Screening and Treatment in United States Prisons*, 164 *ANNALS OF INTERNAL MEDICINE* 84, (2016); see also Akiyama et al., *supra* note 20, at 394.

110. See e.g., Justin Chan, Jessie Schwartz, Fatos Kaba, Angelica Bocour, Matthew J Akiyama, Laura Hobstetter, Zachary Rosner, Ann Winters, Patricia Yang & Ross MacDonald, *Outcomes of Hepatitis C Virus Treatment in the New York City Jail Population: Successes and Challenges Facing Scale Up of Care*, 7 *OPEN F. INFECTIOUS DISEASES* (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7580175/> [[perma.cc/TZB9-QL8W](https://perma.cc/TZB9-QL8W)]; see also Shan Liu, Daena Watcha, Mark Holodniy & Jeremy D Goldhaber-Fiebert, *Sofosbuvir-based Treatment Regimens for Chronic Genotype 1 Hepatitis C Virus Infection in U.S. Incarcerated Populations: A Cost-Effectiveness Analysis*, 161 *ANNALS OF INTERNAL MED.* 546 (2014), <https://pubmed.ncbi.nlm.nih.gov/25329202/> [[perma.cc/97SH-2WCY](https://perma.cc/97SH-2WCY)].

specialists,<sup>111</sup> including Project ECHO in New Mexico, through which health care providers in rural settings are linked to specialists at the University of New Mexico to support HCV care<sup>112</sup> and training for primary care on-site practitioners.<sup>113</sup> Numerous studies confirm that early-stage DAA treatment is a more cost-effective approach than treating advanced disease only, as it improves quality of life and decreases health care costs over the long term.<sup>114</sup> From a public health perspective, expanding testing and treatment in carceral settings is essential.

One reason prisons and jails give for not expanding testing and treatment is cost. The price of DAAs has been a high barrier to

111. See, e.g., Richard K. Sterling, Reena Cherian, Shawn Lewis, Kathleen Genter, Carolyn Driscoll, Kelly Martin, Mary Beth Goode, Scott Matherly, Mohammad S. Siddiqui, Velimir A. Luketic, R. Todd Stravitz, Puneet Puri, Hannah Lee, Paula Smith, Vaishali Patel & Arun J. Sanyal, *Treatment of HCV in the Department of Corrections in the Era of Oral Medications*, 24 J. CORR. HEALTH CARE 127 (2018); John Scott, Meaghan Fagalde, Atar Baer, Sara Glick, Elizabeth Barash, Hilary Armstrong, Kris V. Kowdley, Matthew R. Golden, Alexander J. Millman, Noele P. Nelson, Lauren Canary, Matthew Messerschmidt, Pallavi Patel, Michael Ninburg & Jeff Duchin, *A Population-Based Intervention to Improve Care Cascades of Patients With Hepatitis C Virus Infection*, 5 HEPATOLOGY COMM'NS 387 (2021).

112. See, e.g., Sanjeev Arora, Karla Thornton, Steven M. Jenkusky, Brooke Parish & Joseph V. Scaletti, *Project ECHO: Linking University Specialists with Rural and Prison-Based Clinicians to Improve Care for People with Chronic Hepatitis C in New Mexico*, 122 PUB. HEALTH REPORTS 74 (2007) (SUPPLEMENT 2); For more information about the model, see generally *ECHO Model*, PROJECT ECHO, <https://hsc.unm.edu/echo/what-we-do/about-the-echo-model.html> [perma.cc/D4IR-NGVS] (last visited July 9, 2023).

113. See, e.g., Sanjeev Arora, Karla Thornton, Glen Murata, Paulina Deming, Summers Kalishman, Denise Dion, Brooke Parish, Thomas Burke, Wesley Pak, Jeffrey Dunkelberg, Martin Kistin, John Brown, Steven Jenkusky, Miriam Komaromy & Clifford Qualls, *Outcomes of Treatment for Hepatitis C Virus Infection by Primary Care Providers*, 364 NEW ENG. J. MED. 2199 (2011); *Viral Hepatitis C ECHO Programs*, PROJECT ECHO, <https://hsc.unm.edu/echo/partner-portal/programs/new-mexico/hcv-community/> [perma.cc/F6XT-TCDW] (last visited July 9, 2023).

114. See Benjamin P. Linas, Jake R. Morgan, Mai T. Pho, Jared A. Leff, Bruce R. Schackman, C. Robert Horsburgh, Sabrina A. Assoumou, Joshua A. Salomon, Milton C. Weinstein, Kenneth A. Freedberg & Arthur Y. Kim, *Cost Effectiveness and Cost Containment in the Era of Interferon-Free Therapies to Treat Hepatitis C Virus Genotype 1*, 4 OPEN F. INFECTIOUS DISEASE (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5414108/> [perma.cc/6GY7-QK6M] (suggesting that approaches to cost savings should focus on negotiating for lower drug prices and not on delaying or rationing treatment); Janet Weiner & Benjamin P. Linas, *Issue Brief: Cost-Effective Screening and Treatment of Hepatitis C*, PENN LEONARD DAVID INST. OF HEALTH ECON. & CTR. FOR HEALTH ECONS. OF TREATMENT INTERVENTIONS FOR SUBSTANCE USE DISORDER, HCV, & HIV (Sept. 14, 2018), <https://ldi.upenn.edu/our-work/research-updates/cost-effective-screening-and-treatment-of-hepatitis-c/> [perma.cc/BQ2L-MNRK] (summarizing studies confirming the cost-effectiveness of widespread early-stage DAA treatment); David E. Kaplan, Marina Serper, Ankita Kaushik, Claire Durkin, Angie Raad, Fadoua El-Moustaid, Nathaniel Smith & Alon Yehoshua, *Cost-Effectiveness of Direct-Acting Antivirals for Chronic Hepatitis C Virus in the United States from a Payer Perspective*, 28 J. MANAGED CARE & SPECIALTY PHARMACY 1138 (2022), <https://www.jmcp.org/doi/full/10.18553/jmcp.2022.28.10.1138> [perma.cc/H44L-EXRV] (demonstrating that early DAA intervention is not only more cost-effective than other forms of HCV treatment, but that cost savings are seen quickly after treatment, making early treatment the most cost-effective option).

universal treatment in prisons and jails. Although DAA drugs are now much less expensive than they were a decade ago, the medications remain costly.<sup>115</sup> Therefore, even as costs continue to decline, it is vital that states direct additional funding to support testing and treatment in prisons and jails and that efforts are made on the state and federal level to reduce DAA drug costs.<sup>116</sup>

Universal testing and early-stage DAA treatment are cost-effective for communities in the long term.<sup>117</sup> States are likely to bear the downstream burden of health care costs as people are released back into the community, potentially spreading the virus and/or suffering the individual health consequences of untreated disease progression. In this context, it is economically rational for states to support prisons and jails in efforts to scale up testing and early-stage treatment.<sup>118</sup> That said, although universal testing and treatment is essential, it must not come at the cost of other essential jail and prison medical services.<sup>119</sup>

Fortunately, the combination of falling costs of DAAs and innovations in payment strategies can support efforts to fund universal treatment. For example, carceral systems might partner with entities exempt from the “best price” floors typically imposed on price negotiations under section 340B of the Public Health Service Act, such as federally qualified health centers and disproportionate share hospitals.<sup>120</sup> Texas, Alaska, Utah, and several other states have used this

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115. See *supra* Section I.3.

116. DAA prices far outstrip manufacturing costs. See, e.g., Andrew Hill et al., *supra* note 75.

117. See, e.g., Adam L. Beckman, Alyssa Bilinski, Lisa Puglisi, Talya Lockman-Fine & Gregg Gonsalves, *Follow California's Lead: Treat Inmates with Hepatitis C*, HEALTH AFFS. BLOG (July 24, 2018), <https://www.healthaffairs.org/doi/10.1377/fore-front.20180724.396136/full/> [perma.cc/X68B-6FY8] (describing California budget allocating \$105.8 million to treat incarcerated people with HCV in state prisons, explaining reasons why universal screening and treatment is cost-effective for states); see generally, John T. Nguyen, Josiah D. Rich, Bradley W. Brockmann, Fred Vohr, Anne Spaulding & Brian T. Montague, *A Budget Impact Analysis of Newly Available Hepatitis C Therapeutics and the Financial Burden on a State Correctional System*, 92 J. URB. HEALTH 635 (Aug. 2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4524840/> [perma.cc/G7D8-SX7S].

118. See Spaulding et al., *supra* note 98, at 16. In the settlement agreement between the Nevada Department of Corrections and plaintiff classes seeking universal DAA treatment, the parties cited recent remarks of Governor Sisolak, in 2020: “[I]f not treated in prison, treatment will most likely occur after the inmate has been released. A large percentage of inmates are on Medicaid and treatment later in the disease lifecycle is more costly than treatment in the early stages. As a result, treatment in prison is less costly to the State.” See Consent Decree ¶ 14, *In Re HCV Prison Litigation*, No. 3:19-cv-00577 (D. Nev. Oct. 29, 2020) [hereinafter “Consent Decree, *In Re HCV*”], <https://clearinghouse.net/doc/112688/> [perma.cc/5UHZ-SUAY].

119. Interview with Samuel Weiss, Executive Director, Rights Behind Bars (Oct. 12, 2022).

120. See Matthew J Akiyama, Rich Feffer, William H. von Oehsen, III, & Alain H. Litwin, *Drug Purchasing Strategies to Treat People with Hepatitis C in the Criminal Justice System*, 108 AM. J. PUB. HEALTH 607 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC588063/> [perma.cc/4HAD-ZBP9].

approach for DAA purchases.<sup>121</sup> Under such arrangements, people with HCV in state or local custody can be considered patients of the entity eligible for the program and receive significant discounts on DAAs.<sup>122</sup>

As another possibility, researchers have recommended pursuing a nominal pricing approach. This approach involves special permission from the U.S. Department of Health and Human Services for carceral facilities as “safety-net providers” within the meaning of Section 1927(c)(1)(D)(i)(VI) of the Social Security Act. If pharmaceutical companies were willing to accommodate a discounted price, such special permissions would enable prisons to purchase DAAs at less than ten percent of market rate.<sup>123</sup>

State departments of correction might also consider coordinating for pooled procurement with increased purchasing power,<sup>124</sup> working with county or state agencies to receive lower prices, or pushing for increased federal funding, as the federal government may ultimately bear much of the downstream cost of untreated HCV.<sup>125</sup> Alternatively, states could negotiate directly for a discounted price in exchange for purchasing from a single provider, as Virginia has done.<sup>126</sup> Finally, states might seek to support pre-release treatment and transition to community care by applying for a Section 1115 waiver to waive the Medicaid exclusion for incarcerated people and permit the provision of a targeted set of Medicaid funded services, in some cases up to ninety days before release.<sup>127</sup> The Centers for Medicaid and Medicare Services intends to soon release guidance to states on the scope of services that may be paid for using Medicaid funding while an individual is incarcerated, including medications provided during the incarceration period as well as medications to have in-hand upon release.

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121. See Florko, *supra* note 24.

122. See Beckman et al., *supra* note 89, at 1899 (describing the program and noting that, as of 2015, at least sixteen state departments of corrections were pursuing such an approach, resulting for some in the lowest DAA prices among the departments).

123. See Spaulding et al., *supra* note 98, at 20–22.

124. The Minnesota Multistate Contracting Alliance for Pharmacy, for example, is a group purchasing organization for government facilities to negotiate reduced prices, in which several states participate. See Anne C. Spaulding, Madeline G. Adey, Robert T. Lawrence, Jagpreet Chhatwal & William von Oehsen, *Five Questions Concerning Managing Hepatitis C in the Justice System*, 32 *INFECTIOUS DISEASE CLINIC OF N. AM.* 323, 337, <https://par.nsf.gov/servlets/purl/10066200> [perma.cc/KA99-9KBL].

125. See Beckman et al., *supra* note 89, at 1899.

126. See Florko, *supra* note 24.

127. See, e.g., Sweta Haldar & Madeline Guth, *State Policies Connecting Justice Involved Populations to Medicaid Coverage and Care*, Kaiser Family Foundation (Dec. 17, 2021), <https://www.kff.org/medicaid/issue-brief/state-policies-connecting-justice-involved-populations-to-medicare-coverage-and-care/> [perma.cc/L81S-EMR3].



## II. THE LEGAL LANDSCAPE

Over the last several years, people with HCV in United States prisons (and in at least two unified correctional systems<sup>128</sup>) have filed lawsuits seeking DAA treatment and challenging prison policies that prioritize DAA treatment for the people who are sickest or have the most advanced liver disease. The lawsuits principally argue that there is no medical justification for delaying or denying curative DAA treatment and that doing so violates medical standards of care and federal law. Many of these lawsuits have resulted in settlement agreements that change policy and practice and make significant strides in expanding HCV testing and treatment in carceral settings.

Section II.A reviews the governing legal standard under the Eighth Amendment's Cruel and Unusual Punishments Clause. Section II.B next offers an overview of the range of judicial decisions in relevant lawsuits. Finally, Section III.C describes several recent settlement agreements that offer a possible model for expanding HCV testing and treatment.

*A. The Eighth Amendment Standard: Deliberate Indifference to Serious Medical Need*

The Eighth Amendment prohibits “cruel and unusual punishments.”<sup>129</sup> Longstanding case law explains that under the clause each state and local government has an “obligation to provide medical care for those whom it is punishing by incarceration.”<sup>130</sup> People in custody “must rely on prison authorities to treat [their] medical needs; if the authorities fail to do so, those needs will not be met,” resulting in unconstitutional infliction of suffering.<sup>131</sup> Under this standard, everybody in custody, regardless of their crime or behavior, is entitled to adequate medical care.

A prison official violates the Eighth Amendment if they act with “deliberate indifference” to an incarcerated person’s “serious medical

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128. Two of the lawsuits that inform the recommendations in this paper arose in states—Connecticut and Vermont—that administer unified corrections systems, encompassing both people in pre-trial detention and incarcerated people who have already been sentenced. For more information about the Connecticut case, see *Barfield v. Cook*, No. 3:18-CV-1198 (MPS), 2019 WL 3562021 (D. Conn. Aug. 6, 2019), <https://clearinghouse.net/case/18232/> [<https://perma.cc/5NXW-AFWH>]. For more information about the Vermont case, see *West v. Gobeille*, 450 F. Supp. 3d 497 (D. Vt. 2020), <https://clearinghouse.net/case/18238/> [<https://perma.cc/A975-4LLZ>].

129. U.S. Const. amend. VIII.

130. *Estelle v. Gamble*, 429 U.S. 97, 103 (1976).

131. *Id.*

needs.”<sup>132</sup> The standard has both an objective and a subjective component: the medical need must be objectively serious,<sup>133</sup> and the official must have a sufficiently culpable state of mind, akin to recklessness, acting or failing to act while actually aware of a substantial risk that serious harm will result.<sup>134</sup> Put differently, the official “must both be aware of facts from which the inference could be drawn that a substantial risk of serious harm exists, and he must also draw the inference.”<sup>135</sup> Courts applying this standard have held that delaying or failing to provide treatment for a non-medical reason may violate the Eighth Amendment<sup>136</sup> and that effects on a person’s current *and* future health must be considered.<sup>137</sup> But mere medical malpractice or disagreement as to proper course of treatment does not support an Eighth Amendment claim.<sup>138</sup> Instead, to be actionable, the challenged action must significantly depart from accepted professional practice or standards.<sup>139</sup>

A state must provide sufficient funds to ensure that its prison system operates in compliance with the Constitution.<sup>140</sup> If a particular treatment or intervention is required under the Eighth Amendment, it cannot be withheld because of cost alone.<sup>141</sup> Courts considering this issue in the context of DAA treatment align in reasoning that a treatment decision “based exclusively on nonmedical considerations such as cost or

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132. See, e.g., *Erickson v. Pardus*, 551 U.S. 89, 90 (2007).

133. See, e.g., *Hoffer v. Sec’y, Fla. Dep’t of Corr.*, 973 F.3d 1263, 1270 (11th Cir. 2020), <https://clearinghouse.net/doc/111607/> [<https://perma.cc/422Z-ZDKK>].

134. E.g., *Bernier v. Allen*, 38 F.4th 1145, 1151 (D.C. Cir. 2022), <https://clearinghouse.net/doc/136957/> [<https://perma.cc/H4SG-KZ3V>].

135. *Farmerv. Brennan*, 511 U.S. 825, 837 (1994).

136. See, e.g., *Hathaway v. Coughlin*, 841 F.2d 48 (2d. Cir. 1988) (reversing grant of summary judgment because alleged delay of more than two years to arrange needed surgery may show deliberate indifferent to serious medical needs).

137. See e.g., *Helling v. McKinney*, 509 U.S. 25, 33–35 (1993). For a more nuanced discussion of the challenges of proving future harm given the often slow course of HCV progression and variable clinical consequences, see Alexandra M. Daniels & David M. Studdert, *Hepatitis C Treatment in Prisons—Incarcerated People’s Uncertain Right to Direct-Acting Antiviral Therapy*, 383 N. ENG. J. MED. 611, 612 (Aug. 2020).

138. *Estelle*, *supra* note 130, at 105–06.

139. See *Youngberg v. Romeo*, 457 U.S. 307, 323 (1982) (“[T]he decision, if made by a professional, is presumptively valid; liability may be imposed only when the decision by the professional is such a substantial departure from accepted professional judgment, practice, or standards as to demonstrate that the person responsible actually did not base the decision on such a judgment.”).

140. At least one court, however, has rejected the argument that an individual physician’s failure to obtain additional funding from the legislature for HCV treatment violated the Eighth Amendment. See *Atkins*, *supra* note 54, at 740.

141. See, e.g., *Roe v. Elyea*, 631 F.3d 843, 863 (7th Cir. 2011) (explaining that cost cannot be considered to the exclusion of reasonable medical judgment about health); see also *Youngberg*, *supra* note 139.

administrative convenience rather than any medical justification” may violate the Eighth Amendment.<sup>142</sup> Although at least one appellate court has held that cost can be considered in determining what type of medical care an incarcerated person receives, it emphasized that cost is “never . . . an absolute defense to what the constitution requires”—that is, if a particular course of treatment is essential to “minimally adequate care,” governmental poverty is not an excuse for failure to provide it.<sup>143</sup>

Most lawsuits seeking DAA treatment in carceral settings have been filed by people incarcerated in state prison systems after sentencing, rather than people detained pre-trial in state and local jail facilities. (Note, though, that two of the lawsuits described herein arose in states with unified systems, comprising pre-trial detention and post-sentencing incarceration).<sup>144</sup> There are likely many reasons for this, including that length of stays in jail tend to be uncertain and (usually) shorter than prison stays, complicating efforts to seek medical care and meaningfully challenge barriers to access.

The legal analysis in this paper, and in most of the cases described in this section, focuses on the Eighth Amendment, which applies to incarcerated people who have already been sentenced. The Fifth and Fourteenth Amendment Due Process Clauses provide similar rights for people detained pre-trial (federal and state/local, respectively). These rights may even be a bit more robust, although the precise contours are currently contested, with some federal courts of appeal applying the Eighth Amendment deliberate indifference standard exactly and others setting a less onerous standard in the pre-trial context.<sup>145</sup>

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142. *Bernier*, *supra* note 134, at 1151–52 (assuming without deciding, but noting that “other courts appear to agree at least that cost or other nonmedical rationale cannot be the only justification for prison officials’ treatment decisions—including decisions affecting inmates with Hepatitis C”); *see also* *Thomas v. Allen*, 679 F. App’x 216, 220 (3d Cir. 2017) (holding that incarcerated person plausibly alleged Eighth Amendment violation against prison medical providers in light of claim that he was denied DAA treatment *solely* because of cost).

143. *Hoffer v. Sec’y, Fla. Dep’t of Corr.*, 973 F.3d 1263, 1277 (11th Cir. 2020).

144. For more information about the Connecticut case, *see* *Barfield v. Cook*, *supra* note 128. For more information about the Vermont case, *see* *West v. Gobeille*, *supra* note 128.

145. *See, e.g.*, *Kingsley v. Hendrickson*, 576 U.S. 389 (2015) (holding that to prove an excessive force claim, a person in pre-trial detention must show that the officers’ use of force was objectively unreasonable, citing, *inter alia*, the differences between pre-trial detention and post-sentencing incarceration to reject a more stringent subjective standard). For an example of a current circuit split on the scope of the right in the pretrial context, *compare* *Darnell v. Pineiro*, 849 F.3d 17, 35 (2d Cir. 2017) (“[T]o establish a claim for deliberate indifference to conditions of confinement under the Due Process Clause of the Fourteenth Amendment, the pretrial detainee must prove that the defendant-official acted intentionally to impose the alleged condition, or recklessly failed to act with reasonable care to mitigate the risk that the condition posed to the pretrial detainee even though the defendant-official knew, or should have known, that the condition posed an excessive risk to health or safety,” a less stringent standard than under the Eighth Amendment) *with* *Strain v. Regalado*, 977 F.3d 984, 990 (10th Cir. 2020) (requiring, instead,

### B. Litigation Challenging the Prioritization of DAA Treatment

Lawsuits seeking HCV testing and DAA treatment in custody have typically argued: (1) HCV is an objectively serious medical condition, and (2) the failure to provide curative DAA treatment constitutes deliberate indifference.<sup>146</sup> Often, the parties do not dispute that HCV is a serious medical condition, even in the earliest stages of the disease, satisfying the objective component of the Eighth Amendment standard.<sup>147</sup> Thus, the contested issue is whether the failure to provide universal or early-stage DAA treatment constitutes deliberate indifference to that serious medical need. Courts addressing that question have come to varying conclusions.

Several courts have failed to hold prison systems accountable for delaying or denying DAA treatment.<sup>148</sup> Typically, the policies at issue in those cases involve regular monitoring of disease progression, with DAA treatment offered at a certain stage of liver disease and the flexibility to treat sooner on a case-by-case basis.<sup>149</sup> In denying liability, courts analyzing these policies reason that such a system does not withhold treatment, but rather offers treatment “in the form of diagnosing and

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plaintiff to establish that the “official knows of and disregards and excessive risk to inmate health or safety,” a subjective test more akin to that under the Eighth Amendment, pursuant to which the official must be aware of the facts from which the inference could be drawn and that a substantial risk of serious harm exists, and must draw the inference).

146. The Civil Rights Litigation Clearinghouse has collected dozens of class action and putative class action lawsuits bringing Eighth Amendment challenges in this context. *See, e.g., Cases Tagged “Hepatitis C Treatment in Jails and Prisons,”* C.R. LITIG. CLEARINGHOUSE, [https://clearinghouse.net/search/case/?special\\_collection=33558](https://clearinghouse.net/search/case/?special_collection=33558) [<https://perma.cc/V12A-P8EZ>] (last visited Aug. 19, 2022).

147. *See, e.g., Turner v. Wetzel*, No. 21-2879, 2022 WL 3572693, at \*2 (3d Cir. Aug. 19, 2022); *Hoffer*, 973 F.3d at 1270. Where defendants have disputed that early-stage HCV is a objectively serious medical condition, courts have rejected the argument. *See, e.g., Chimenti v. Wetzel*, No. CV 15-3333, 2018 WL 3388305, at \*12 (E.D. Pa. July 12, 2018) (“We conclude that the record contains evidence that patients who have chronic HCV and whose Metavir scores are less than F2 have serious medical needs, as they may suffer from fatigue and other nonhepatic symptoms of their infections and, if not treated with DAAs before their disease progresses, may suffer from liver inflammation, liver fibrosis, liver cancer and liver-related mortality that they would not suffer if they were treated with DAAs while their Metavir scores are in the F0 to F1 range.”).

148. *See e.g., Woodcock v. Correct Care Sols.*, 861 F. App’x 654, 660 (6th Cir. 2021) (rejecting challenge to Kentucky Department of Corrections’ HCV treatment protocol); *Hoffer*, 973 F.3d at 1272 (“the sole question before us is whether the Secretary’s approach to the treatment of F0- and F1-level inmates is so reckless—so conscience-shocking—that it violates the Constitution. As explained below, it is not.”); *Bernier v. Allen*, 38 F.4th 1145, 1158 (D.C. Cir. 2022) (reversing district court’s denial of qualified immunity, reasoning that that because plaintiff was treated and successfully cured of HCV, his argument that he should have received treatment earlier, and thus was entitled to damages from the medical director, was insufficient to establish an Eighth Amendment violation).

149. *See, e.g., Woodcock*, 861 F. App’x at 660–61; *Hoffer*, 973 F.3d at 1272.

monitoring HCV-infected inmates,<sup>150</sup> and that disagreement with course of treatment is not cognizable under the Eighth Amendment.<sup>151</sup> These courts have also favorably cited the flexibility to treat those with immediate need, regardless of place in the priority system.<sup>152</sup> Ultimately, these courts conclude that failing to provide a curative course of treatment (DAAs), without more, does not rise to the level of deliberate indifference.<sup>153</sup>

But as other courts have recognized, such decisions miss the mark. HCV's range of acceptable treatments no longer exists. Rather, DAA therapy is *the* medically accepted treatment at every stage of the disease.<sup>154</sup> Thus, in considering a case in which the plaintiff developed cirrhosis while waiting for DAA treatment in prison, the U.S. Court of Appeals for the Third Circuit recently held: "monitoring a condition rather than treating with an available medication" may constitute unconstitutional deliberate indifference.<sup>155</sup> In addressing the issue, several other courts have properly recognized that monitoring HCV until a person's health deteriorates is not adequate medical care, and that such deferment of DAA treatment may violate the Eighth Amendment. For example, *Barfield v. Semple* declined to dismiss an Eighth Amendment claim because "where, as alleged here, the CT DOC knew that delay in treatment would cause harm yet still chose merely to monitor the condition or provide only supporting care, it has exhibited deliberate indifference."<sup>156</sup> And *Postawko v. Missouri Dep't of Corr.* similarly denied in relevant part a motion to dismiss an Eighth Amendment claim, explaining that a "'wait and see' policy of relying solely on APRI scores and delaying DAA treatment until the disease has progressed to a far more serious level contravenes the applicable medical standard of care

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150. *Woodcock*, 861 F. App'x at 660.

151. *Id.*; see also *Hoffer*, 973 F.3d at 1272 (reasoning that the Florida Department of Corrections provided some medical care to incarcerated people not eligible for DAA treatment based on fibrosis score, namely: "diagnosing their illnesses, assessing their risk of future harm, and regularly monitoring and managing their disease progression," and explaining that "diagnosing, monitoring, and managing conditions—even where a complete cure may be available—will often meet the 'minimally adequate medical care' standard that the Eighth Amendment imposes.").

152. *Woodcock*, 861 F. App'x at 660–61.

153. See *id.*; see also *Hoffer*, 973 F.3d at 1272.

154. See *supra* Section I.C.

155. See, e.g., *Turner v. Wetzel*, No. 21-2879, 2022 WL 3572693, at \*3 (3d Cir. Aug. 19, 2022) (vacating and remanding district court's grant of summary judgment on Eighth Amendment claim).

156. *Barfield v. Semple*, No. 3:18-cv-1198 (MPS), 2019 WL 3680331, at \*12 (D. Conn. Aug. 6, 2019) (denying in part motion to dismiss Eighth Amendment claim).

without any medical justification.”<sup>157</sup> As these courts and others have recognized, prioritizing treatment for those with the most advanced fibrosis is shortsighted, dangerous, and contrary to prevailing medical standards and public health indicia. Although fibrosis progression may be slow, patients with chronic HCV are at risk for other serious conditions even in the early stages of the disease.<sup>158</sup> In addition, fibrosis progression is unpredictable, and progression estimates may be inexact.<sup>159</sup> Furthermore, delaying treatment until later stages may be less effective in curing the disease and may not reverse the liver damage that occurred while waiting for care.<sup>160</sup> As medical guidance and practice continues to support universal, early-stage DAA treatment, the litigation tide may find that delaying or denying such treatment violates the Eighth Amendment.<sup>161</sup>

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157. *Postawko v. Missouri Dep’t of Corr.*, No. 2:16-cv-04219-NKL, 2017 WL 1968317, at \*7 (W.D. Mo. May 11, 2017).

158. *See, e.g.*, Samuel Weiss, *The Other Infectious Disease Ravaging America’s Prisons and Jails*, THE APPEAL (May 14, 2020), <https://theappeal.org/hepatitis-c-prison/> [<https://perma.cc/4MK5-JW57>].

159. *See id.*; *see also* Daniels & Studdert, *supra* note 137, at 611.

160. *See e.g.*, Weiss, *supra* note 158.

161. Numerous lawsuits have also alleged that delay or denial of DAA treatment violates Title II of the Americans with Disabilities Act (ADA) and/or Section 504 of the Rehabilitation Act, which prohibit exclusion or discrimination on the basis of disability in federally conducted or supported services, and state and local government services, respectively. 29 U.S.C. § 794(a); 42 U.S.C. § 12132. Lawsuits bringing ADA and/or Rehabilitation Act claims in this context principally argue that chronic Hepatitis C is a disability within the meaning of the statute(s), and that the prison system subjects incarcerated people with that disability to discrimination by withholding medical treatment in line with the recommended standard of care, while offering standard-of-care treatment to persons with different disabilities or who are not disabled. *See e.g.*, Third Amended Class Action Complaint at 21–22, *Lignons v. Minn. Dep’t of Corr.*, No. 0:15-cv-02210 (D. Minn. Dec. 1, 2017), <https://clearinghouse.net/doc/98906/> [<https://perma.cc/EP4D-M6KY>]; Corrected First Amended Complaint at 64–66, *Barfield v. Semple*, No. 3:18-cv-01198 (D. Conn. Dec. 21, 2018), <https://clearinghouse.net/doc/112606/> [<https://perma.cc/CV5M-OE6F>]; Amended Class Action Complaint at 19–20, *In re HCV Prison Litigation*, No. 3:19-cv-00577 (D. Nev. Dec. 9, 2019), <https://clearinghouse.net/doc/112675/> [<https://perma.cc/KL5Y-HU95>]; Verified Class Action Complaint for Declaratory and Injunctive Relief at 39–40, *Hoffer v. Jones*, No. 4:17-cv-00214, (N.D. Fla. May 11, 2017), <https://clearinghouse.net/doc/88705/> [<https://perma.cc/SR58-88RY>]. ADA and Rehabilitation Act claims have not met much success, however, with some courts distinguishing between claims that a person is not treated for their disability (not actionable) as compared to not treated because of their disability (actionable), *see e.g.*, Ruling on Motion to Dismiss at 32–35, *Barfield v. Semple*, No. 3:18-CV-01198 (D. Conn. Aug. 6, 2019), <https://clearinghouse.net/doc/112607/> [<https://perma.cc/T5MN-YU9N>], or concluding ADA and Rehabilitation Act claims are poorly suited to class action lawsuits, *see e.g.*, *Hoffer v. Inch*, 382 F. Supp. 3d 1288, 1296–98 (N.D. Fla. 2019), *rev’d in part, vacated in part sub nom.*; Order on Cross-Motions for Summary Judgment at 10, *Hoffer v. Sec’y, Fla. Dep’t of Corr.*, 973 F.3d 1263 (11th Cir. 2020), <https://clearinghouse.net/doc/107239/> [<https://perma.cc/USX7-ALSZ>].

*C. Class Action Settlement Agreements: Toward Universal  
Testing and Treatment*

The litigated outcomes described above are inconsistent, often out of step with clear medical consensus, and, in some cases, stymie efforts to expand testing and treatment.<sup>162</sup> However, the parties have sometimes been able to reach agreements to change testing and treatment protocols. In seeming recognition of the urgency and opportunity of the moment,<sup>163</sup> settlement agreements in several states have resulted in widespread expansion of HCV testing and treatment in state correctional systems.<sup>164</sup> For example:

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162. See, e.g., *Hoffer*, 973 F.3d at 1279 (reversing district court rulings requiring universal DAA treatment regardless of level of fibrosis).

163. See, e.g., Proposed Consent Decree for Chronic Hepatitis C Treatment at 1, *Geissler v. Stirling*, No. 4:17-cv-01746 (D. S.C. June 8, 2020) [hereinafter Consent Decree, *Geissler*], <https://clearinghouse.net/doc/131291/> [<https://perma.cc/NEN9-KYLL>] (“This Court and the Parties recognize the need to test inmates of the South Carolina Department of Corrections (“SCDC”) for HCV and to provide treatment to those inmates who have the disease. Such a commitment is necessary to: (a) treat inmates diagnosed with HCV with Medication that substantially increases the chances of the diagnosed inmate being cured of HCV; (b) significantly reduce the spread of HCV among the SCDC inmate population; and (c) significantly reduce the spread of HCV among the general population of South Carolina as inmates are released from incarceration.”).

164. Class action settlement agreements have been adopted in: Colorado, see ACLU and Colorado Department of Corrections Reach Historic Settlement to Treat All Colorado Prisoners with Hepatitis C, ACLU (Sept. 12, 2018, 2:00 PM), <https://www.aclu.org/press-releases/aclu-and-colorado-department-corrections-reach-historic-settlement-treat-all-colorado> [<https://perma.cc/BW7G-CVEH>]; Connecticut, see Proposed Superseding Settlement Agreement and Release, *Barfield v. Cook*, No. 3:18-cv-01198 (D. Conn. Mar. 11, 2022) [hereinafter Superseding Settlement Agreement, *Barfield*], <https://clearinghouse.net/doc/133751/> [<https://perma.cc/82P9-ER33>]; Indiana, see Stipulation to Enter Into Settlement Agreement, *Stafford v. Carter*, No. 1:17-cv-00289 (S.D. Ind. Aug. 9, 2019) [hereinafter Settlement Agreement, *Stafford*], <https://clearinghouse.net/doc/103100/> [<https://perma.cc/B4QW-JHMH>]; Massachusetts, see Settlement Agreement, *Fowler v. Turco*, No. 1:15-cv-12298 (D. Mass. Mar. 9, 2018), <https://clearinghouse.net/doc/101643/> [<https://perma.cc/94DM-FIAS>]; Minnesota, see Settlement Agreement and Release, *Ligons v. Minn. Dep’t of Corr.*, No. 0:15-cv-02210 (D. Minn. Mar. 15, 2019) [hereinafter Settlement Agreement, *Ligons*], <https://clearinghouse.net/doc/106687/> [<https://perma.cc/E6C3-8NKX>]; Missouri, see Private Settlement Agreement, *Postawko v. Missouri Dep’t of Corr.*, No. 2:16-cv-04219 (W.D. Mo. Oct. 26, 2020) [hereinafter Settlement Agreement, *Postawko*], <https://clearinghouse.net/doc/111454/> [<https://perma.cc/35AQ-6FNF>]; Nevada, see Consent Decree, *In re HCV*, *supra* note 118; North Carolina, see Consent Decree, *Buffkin v. Hooks*, No. 1:18-cv-00502 (M.D.N.C. Mar. 8, 2021) [hereinafter Consent Decree, *Buffkin*], <https://clearinghouse.net/doc/131006/> [<https://perma.cc/3FKI-DAV3>]; South Carolina, see Consent Decree, *Geissler*, *supra* note 163; Pennsylvania, see Settlement Agreement and General Release, *Chimenti v. Pennsylvania*, No. 2:15-cv-03333 (E.D. Pa. Nov. 19, 2018) [hereinafter Settlement Agreement, *Chimenti*], <https://clearinghouse.net/doc/102382/> [<https://perma.cc/46A3-BWUR>]; Texas, see Settlement Agreement, *Roppolo v. Linthicum*, No. 2:19-cv-262 (S.D. Tex. Mar. 1, 2021), <https://clearinghouse.net/doc/133979/> [<https://perma.cc/9Z4G-N382>]; and Vermont, see Settlement Agreement and Release of All Claims, *West v. Gobeille*, No. 2:19-cv-00081 (D. Vt. June 11, 2021) [hereinafter Settlement Agreement, *West*],

- In Indiana, implementation of a 2020 settlement agreement pursuant to which approximately 3,350 people with HCV in Indiana Department of Corrections' custody will receive DAA treatment by 2023 is proceeding apace with the agreement's phased-in universal treatment approach.<sup>165</sup>
- Litigation and a resulting settlement agreement in Connecticut resulted in more than 20,000 people in the custody of the Connecticut Department of Correction tested for HCV in a three-year period, and DAA treatment, so far, for at least 977 of the 2,123 people who tested positive during that period.<sup>166</sup>
- Pursuant to a 2018 settlement agreement, the Colorado Department of Corrections agreed to spend \$41 million over two years to provide DAA treatment to more than 2,000 people with HCV in its custody—up from the twenty to twenty-five treated per year previously— and removed pre-treatment requirements such as completion of drug and alcohol classes and deterioration of the liver.<sup>167</sup>
- A 2021 settlement in Maine resulted in universal opt-out testing at intake and near-universal eligibility for treatment. The state provided DAA treatment to 205 people in Maine Department of Corrections custody in 2021.<sup>168</sup>

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<https://clearinghouse.net/doc/130168/> [<https://perma.cc/HZB6-GBQH>]. In Idaho, a class action settlement agreement is pending court approval. See Private Settlement Agreement and Release, *Turney v. Atencio*, No. 1:18-cv-00001 (D. Ida. Aug. 31, 2021) [hereinafter Proposed Settlement Agreement, *Turney*], <https://clearinghouse.net/doc/133977/> [<https://perma.cc/A54X-32CF>].

165. See Settlement Agreement, *Stafford*, *supra* note 164.

166. See Lisa Backus, *977 CT Prison Inmates Receive Hepatitis C Treatment As Part of Lawsuit Settlement*, CT INSIDER (June 1, 2022), <https://www.ctinsider.com/hartford/article/977-CT-DOC-in-mates-receive-Hepatitis-C-treatment-17213342.php> [<https://perma.cc/4NLO-CAPF>]; see also Superseding Settlement Agreement, *Barfield*, *supra* note 164.

167. See Alan Prendergast, *State Settles Prison Hep C Lawsuit With \$41 Million Treatment Plan*, WESTWORD (Sept. 12, 2018), <https://www.westword.com/news/colorado-settles-prison-hepatitis-c-lawsuit-with-41-million-treatment-plan-10775724> [<https://perma.cc/4QSI-KUUS>].

168. Nicholas Florko, *Getting Hepatitis C Treatment Opens New Doors for the Incarcerated*, STAT (Dec. 15, 2022), <https://www.statnews.com/2022/12/15/hepatitis-c-treatment-new-doors-for-incarcerated/> [<https://perma.cc/6QZ3-DHVW>]; see also Case: *Loisel v. Clinton*, CIVIL RIGHTS LITIGATION CLEARINGHOUSE, <https://clearinghouse.net/case/18240/> [<https://perma.cc/5DGA-3ULY>] (last visited July 21st, 2023).



- In Texas, a 2021 settlement will phase in near-universal DAA treatment, with initial priority determined by disease progression but eventual eligibility for almost everyone with HCV, with the state agreeing to treat at least 1,200 people in state custody each year through January 1, 2028.<sup>169</sup>
- In Vermont, a 2021 settlement agreement requires adherence to a policy providing for opt-out testing for all people in its unified corrections system, as well as treatment “as soon as possible” for incarcerated people with sufficient time remaining on their sentence to complete a course of DAA treatment.<sup>170</sup>

These settlement agreements offer a starting point for those providing health care in prisons and jails to implement testing and treatment in line with the accepted medical standard of care.

The recommendations in this Article derive from these and other settlement agreements. They are intended to guide proactive implementation that might avoid some of the pitfalls of litigation. Indeed, although litigation can draw the attention and resources necessary to make important changes—including, crucially, funding to scale up DAA treatment<sup>171</sup>—there are also significant downsides. Litigation is expensive for all involved and often slow, and once a lawsuit has been resolved, problems may linger, or new problems may arise, with no clear path to resolution.<sup>172</sup> The adversarial nature of litigation may frustrate cooperation between state and local carceral systems, advocates, and persons with HCV. Further, procedural barriers to litigation may frustrate reform. In this context, pursuing policy changes that draw from litigation outcomes, including settlement agreements, appears to be a promising path forward.

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169. See Ex. 1: Settlement Agreement, Plaintiffs’ Motion to Approve Settlement, Roppolo v. Linthicum, No. 2:19-cv-262 (S.D. Tex. Mar. 1, 2021), <https://clearinghouse-umich-production.s3.amazonaws.com/media/doc/133979.pdf> [<https://perma.cc/9UXE-WY9Y>]; see also Matthew Clarke, *Texas Agrees to Settlement Providing Prisoners Hep C Treatment, Will Pay \$950,000 in Attorney Fees*, PRISON LEGAL NEWS (Jan. 1, 2022), <https://www.prisonlegalnews.org/news/2022/jan/1/texas-agrees-settlement-providing-prisoners-hep-c-treatment-will-pay-950000-attorney-fees/> [<https://perma.cc/8UEA-GQT3>].

170. See Settlement Agreement, *West*, *supra* note 164; see also Ex. 2 Decl. of Kevin Costello, *West v. Gobielle*, No. 02:19-cv-00081-WKS (D. Vt. June 11, 2021), <https://clearinghouse.net/doc/136284/> [<https://perma.cc/V7VS-V7RK>].

171. See lawsuits cited in notes 164–70.

172. These conclusions were informed by interviews conducted in 2022 and 2023 by the authors with several people involved in prison conditions litigation and prison-related advocacy, on Hepatitis C-related issues and beyond. See *infra* note 173.

This Article relies on litigation documents among its major sources. Settlement agreements are particularly valuable because they codify collaboratively developed solutions to problems. But other types of litigation documents can be similarly informative. Of course, litigation documents also have drawbacks: they are static and therefore may become outdated; they may prioritize the views of lawyers and omit the voices of non-parties; and they may offer an incomplete picture of what works in practice. For this reason, we have supplemented the litigation documents, relying on conversations with and feedback from people working on these issues to help fill in gaps and account for more recent developments.<sup>173</sup>

### III. MODEL POLICIES

The following model policies guide expansion of HCV testing and treatment in United States prisons and jails. They derive from settlement agreements in recent litigation addressing this issue, updated to comport with current medical guidance as well as to incorporate input from medical professionals and advocates working on these issues.

These model policies are intended to serve as a starting point for prisons and jails, and those providing health care in those settings, to implement current clinical standards and best practices, promote robust compliance with federal law, and strengthen efforts toward HCV elimination.

Of course, implementation of these policies will differ based on the particular characteristics and capacities of the myriad systems that might seek to implement them. To that end, we have written these policies so that they can be easily copied and pasted into a document that refines and adapts them for a particular facility or system. We have made them available at [https://clearinghouse.net/resource/3838/\[https://perma.cc/FW7T-8CAN\]](https://clearinghouse.net/resource/3838/[https://perma.cc/FW7T-8CAN]) in an unfootnoted word processing text format to facilitate such copying and tailoring.

We understand that resource limitations, including inadequate funding, staffing, and community supports, may impede full and immediate implementation in certain systems. In those circumstances,

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173. The co-authors collectively conducted seven interviews, via Zoom, between October 2022 and February 2023. Interviewees included attorneys who have worked on the cases described herein, public health educators and advocates, and physicians working in and with carceral facilities. In addition, both co-authors conducted a workshop, via Zoom, receiving feedback on the proposed policies, from numerous people with experience working on these issues, and solicited written comments from practitioners on various versions of the draft. *See supra* Acknowledgments.

we intend that these policy recommendations serve as a starting point for meaningful expansion of HCV testing and treatment. They might also inform requests for and designation of resources to support fuller implementation in the future.

Finally, we flag the following considerations as among those essential to meaningful and broad-reaching implementation of the policies in all carceral settings:

- **Access and Accessibility:** Policies implementing HCV testing and treatment must apply and be accessible to all people in custody, including people in segregation or other restricted housing as well as people with disabilities who might require interpreter services, mobility support, or other modifications and accommodations to ensure equal access.<sup>174</sup>
- **Community Partnerships:** Collaboration with local health departments and other community health providers is crucial to support successful outcomes, especially for people with HCV who are released while on treatment or before beginning treatment. These community entities may be essential for, among other things: disseminating test results to people released before receiving them; initiating or continuing DAA treatment; assessing and confirming cure; and/or providing counseling, substance abuse treatment, and other support. Such partnerships may be especially important for jail systems because people detained in jails are more likely to have shorter stays or uncertain terms of detention that might necessitate community

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174. Indeed, Section 504 of the 1973 Rehabilitation Act, 29 U.S.C. § 794 *et seq.* (1973), and Title II of the ADA, 42 U.S.C. § 12131 *et seq.* (1990), prohibit exclusion or discrimination on the basis of disability in federally conducted or supported services, and state and local government services, respectively. Between the two statutes, every prison and jail in the United States is covered. The ADA's Title II covers all nonfederal jails and prisons—its definition of “public entity” includes state and local government agencies, without respect to federal support. *See* 42 U.S.C. § 12131(1). The Rehabilitation Act also covers all federal facilities and also covers most state and local jails and prisons because they receive federal financial assistance. *See* 29 U.S.C. § 794(b)(1)(A) (1973). Moreover, the Supreme Court has held specifically that Title II of the ADA's reference to “services, programs, or activities” encompasses the operation of jails and prisons. *Pa. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 209 (1998). Private prisons operated under contract with federal, state or local entities are covered by the “directly or through contractual, licensing, or other arrangements” language found in both the ADA and Rehabilitation Act regulations. *See, e.g.*, 28 C.F.R. § 35.130(b)(1) (1991); 28 C.F.R. § 39.130(b)(1) (1984); *see also* *Marks v. Colo. Dep't of Corr.*, 976 F.3d 1087, 1097 (10th Cir. 2020) (holding that the Rehabilitation Act applied to private prisons that receive federal funding).

care to begin or complete treatment.<sup>175</sup> Prison and jail systems should work proactively to develop robust partnerships with community providers.

- **Timeframes for Implementation:** The timeframes for implementation proposed herein represent what we understand to be reasonable and advisable in a well-resourced prison or jail system. Prompt testing and initiation of treatment is essential to reducing transmission and supporting cure. As discussed in the note accompanying Policy 3.1, however, we acknowledge that given resource constraints, some systems may need to modify the proposed timeframes to align with what is more immediately practicable.

### 1. Universal Opt-Out Screening

#### 1.1. Universal Opt-Out Screening<sup>176</sup>

- A. All patients without a current documented HCV infection shall be offered HCV screening:

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175. Note, however, that jails may increasingly house people who have already been sentenced and for whom the traditional framework of a short stay and more complex treatment framework may not apply. See E. Ann Carson, *Prisoners in 2020—Statistical Tables*, BUREAU OF JUST. STAT., U.S. DEPT OF JUST. 25 tbl. 12 (Dec. 2021), <https://bjs.ojp.gov/content/pub/pdf/p2ost.pdf> [<https://perma.cc/89GA-ZZ63>] (six percent of sentenced incarcerated people held in local jails in 2020).

176. See, e.g., Consent Decree, *Geissler*, *supra* note 163, at 10 (¶¶ 42–45); Settlement Agreement, *Ligons*, *supra* note 164, at 5–6 (§ I(B)(1)); Settlement Agreement, *Postawko*, *supra* note 164, at 3, 7 (§§ I(C); III(B)(1)); CONN. DEPT OF CORR., ADMIN. DIRECTIVE 8.18, at 1 (Aug. 7. 2019), <https://drive.google.com/file/d/1Pmlyh8r1ZOovQj7ulS4HEGroYfhsTo6q/view> [<https://perma.cc/LKT5-GN55>] (§ 5(b)); ME. DEPT OF CORR., POL'Y 18.8.3: MGMT. & TREATMENT OF HEPATITIS C, at 3–4 (Mar. 16, 2021), <https://drive.google.com/file/d/1eH3zS8pZnCFEANlw8ci87gHpi8bGfeXe/view> [<https://perma.cc/25MS-2UV2>]; see also WASH. DEPT OF CORR., POL'Y DIRECTIVE 670.000, at § II(B) (June 3, 2022), <https://drive.google.com/file/d/1owzq4zE1n3-Ky5CnHRUhXX95TdYEuJ17/view> [<https://perma.cc/6MLQ-HFUJ>], (“Screening will be conducted for incarcerated individuals at intake, unless refused, for . . . hepatitis C”); PENN. DEPT OF CORR., POL'Y STATEMENT 13.2.1, (Apr. 4, 2022), [https://drive.google.com/file/d/1SjmHqqckqfmXS\\_K7BvUTQdGOadiINjNx/view](https://drive.google.com/file/d/1SjmHqqckqfmXS_K7BvUTQdGOadiINjNx/view) [<https://perma.cc/R9NY-VZPM>] (§§ 8-02(4)(b), 20-1(B)(a)); Kristin Walsh & Maya Yoshida-Cervantes, *Hepatitis C Screening in the Santa Clara Cty. Jail: Update and Progress*, Presentation at th<sup>e</sup> 7th Ann. Nat'l Hepatitis Corr. Network Meeting (Mar. 20, 2019), <https://www.hcvinprison.org/images/stories/Walsh - HCV Screening in the Santa Clara County Jail - Updates and Progress.pdf> [<https://perma.cc/RUG7-UJAS>]; *Viral Hepatitis: Testing Recommendations for Hepatitis C Virus Infection*, CTRS. FOR DISEASE CONTROL & PREV. (July 29, 2020), <https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm> [<https://perma.cc/2RV7-H5KV>] (describing ongoing risk factors supporting routine testing including people who currently

1. If no documented test results within the last twelve months, at intake or, if not tested at intake, at first clinical evaluation;
2. If no documented test results within the last twelve months, at the time of the patient's first clinical evaluation, and/or any medical appointment or consultation thereafter;
3. If no documented test results within the last twelve months, at any time requested by the patient;
4. Every twelve months, for patients with ongoing HCV risk factors as identified by the Centers for Disease Control and Prevention; and
5. At any time, regardless of previous testing, as is clinically indicated (*e.g.*, if risk factors are reported since last testing) or recommended by medical staff.

HCV testing shall be offered, ordered, and performed in accordance with (C) and (D) unless the patient affirmatively and voluntarily opts out of such testing.

- B. At the time of offering HCV testing, staff shall make practicable efforts to provide the patient with information about signs and symptoms of HCV, risk factors, modes of transmission, prevention, treatment options, and potential complications if left untreated.
- C. Whenever available, [entity] shall implement reflex testing, through which a sample for HCV RNA testing is sent concurrently with an antibody test to enable confirmation of active HCV infection with a single test order.
- D. When reflex testing is not available, [entity] shall first order an HCV antibody test and, if the HCV antibody test is positive, [entity] shall provide, within three business days of receiving results or as soon as is practicable thereafter, a reflexive HCV RNA viral load test.
- E. [Entity] medical staff shall promptly review positive antibody and RNA test results with the patient. [Entity] medical staff shall also review with the patient recommended immunizations (Hepatitis A and B,

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inject drugs and share needles, syringes, or other drug preparation equipment, and people with particular medical conditions); 2022 AASLD/IDSA Guidance, *supra* note 3, at 182–83.

influenza, and pneumococcal), information about transmission and risks, available counseling, education, and other resources, and treatment options.

«**For jails, add:** If a patient is released before test results are available, [entity] shall make reasonable efforts to provide test results after release, which may include coordination with local health departments and/or other community health providers.»

- F. [Entity] shall make available, at no cost, copies of any HCV antibody and RNA test results in accordance with existing [entity] policies for provision of medical records.
- G. Under no circumstances shall a patient be disciplined or otherwise disadvantaged for requesting or inquiring about HCV testing or treatment.

#### Commentary

Clinical guidance uniformly recommends universal one-time testing for all adults.<sup>177</sup> The CDC recommends routine testing for people with ongoing risk factors: people who currently inject drugs and share needles, syringes, or other equipment, and people with certain medical conditions including people who have ever received maintenance hemodialysis.<sup>178</sup> And the AASLD/IDSA guidance recommends periodic, repeat testing for people who engage in at-risk activities, and annual testing for people who inject drugs, among other risk categories.<sup>179</sup> Given the high prevalence of HCV and risks associated with incarceration, this Article's policy recommendations maximize HCV testing access in prisons and jails by offering testing at various contact points with broad ranging healthcare staff (e.g. nurses, physician's assistants, and physicians). The aim of such policy recommendations is to ensure one-time testing for all and promoting routine testing as appropriate.

Diagnosing a current HCV infection is a two-step process.<sup>180</sup> First, a screening test for HCV antibodies provides information about past exposure to HCV. A negative HCV antibody result indicates that the

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177. See *supra* Section I.C.

178. Viral Hepatitis: Testing Recommendations for Hepatitis C Virus Infection, *supra* note 176.

179. See AASLD/IDSA Guidance, *supra* note 3, at 12–13.

180. *Hepatitis C Questions and Answers for Health Professionals*, CTRS. FOR DISEASE CONTROL & PREV., *supra* note 42.

person has never been exposed to the virus, ruling out HCV infection.<sup>181</sup> A positive HCV antibody result indicates prior exposure and should be followed by an HCV RNA test for current infection. An HCV RNA test may include a qualitative nucleic acid test to detect the presence of HCV RNA in the bloodstream, to diagnose current infection, as well as a quantitative nucleic acid test to detect levels of HCV RNA.<sup>182</sup> Under the reflex testing model, the laboratory performs the antibody test first and, if positive, immediately performs an HCV RNA test on the same specimen.<sup>183</sup> This streamlined option enables prompt diagnosis from a single blood draw, and may be especially useful in the jail setting to ensure prompt test results for people in short-term detention.

Widespread HCV testing in prisons and jails is essential to identify active infections so that people with HCV can promptly be treated.<sup>184</sup> In prison, universal testing enables identification and treatment of those with current HCV infections, reducing spread inside the facility as well as in the community upon release. In jail, universal testing also provides an opportunity to identify current infection even among those with short stays, which may be a crucial first step in connecting HCV positive patients to treatment opportunities in jail or in the community.<sup>185</sup> In addition, universal testing reduces the stigma that may accompany risk-based, selective testing.<sup>186</sup> Moreover, universal testing in carceral settings has a high yield, given the high prevalence of HCV compared to the general population, presenting a prime opportunity to identify (and initiate treatment) in a high-risk population as an essential part of any strategy to eliminate HCV infection in the United States.<sup>187</sup>

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181. *Id.*

182. *Id.*

183. See, e.g., *Hepatitis C Reflex Testing*, N.Y. STATE DEPT OF HEALTH (Sept. 2020), [https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis\\_c/providers/reflex\\_testing.htm](https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis_c/providers/reflex_testing.htm) [<https://perma.cc/8XX5-UFS4>].

184. See He et al., *supra* note 109 (“Our results suggest that the universal opt-out screening of inmates for HCV is highly cost-effective for at least 10 years and would reduce ongoing HCV transmission, the incidence of advanced liver diseases, and liver-related deaths. The majority of the benefits of interventions in prisons would accrue in the community, as a larger proportion of releasees to the community would have been cured of the disease.”); see also Akiyama et al., *supra* note 20, at 391.

185. See, e.g., Ben T. Schoenbachler, Bryce D. Smith, Arlene C. Seña, Alison Hilton, Sallie Bachman, Mulamba Lunda & Anne C. Spaulding, *Hepatitis C Virus Testing and Linkage to Care in North Carolina and South Carolina Jails, 2012-2014*, 131 PUB. HEALTH REPS.98 (2016), <https://journals.sagepub.com/doi/epdf/10.1177/00333549161310S215> [<https://perma.cc/WM92-L4SB>] (describing testing and linkage-to-care programs in North Carolina and South Carolina jails, noting that “because behaviors that place people at risk for HCV infection (e.g., injection drug use) are associated with incarceration, correctional facilities are strategic venues for HCV testing and linkage to care”).

186. *Treatment of HCV in a Correctional Setting*, HEPATITIS C ONLINE, *supra* note 19, at 2.

187. See *id.*

It is essential that prisons and jails have policies in place that maximize opportunities for testing and encourage people to test. To that end, facilities should reevaluate any policies or practices that might discourage testing. Facilities should also promote testing at any point at which a person comes in non-emergency contact with medical staff—for example, during medical appointments, upon intake or transfer, at the time of performing other medical tests, and the like. An opt-out testing approach, which requires testing absent affirmative refusal after receiving information about the test, is most likely to maximize willingness to be tested.<sup>188</sup> Universal opt-out testing has been found to be the most effective, and cost-effective, testing method.<sup>189</sup> A testing strategy modeled on this approach informs people that it is the facility's policy to test as part of routine medical care, unless they explicitly decline to be tested (“I will be testing you unless you decline” or even “Our policy is to test everyone for HCV, is that okay with you?,” rather than, for example, “Would you like to be tested?”).<sup>190</sup>

Finally, note that especially in the high-volume, quick-turnover jail setting, cooperation with community health providers and/or patient navigators is likely necessary to support delivery of test results. For example, if a person is released from detention before receiving the results of an HCV test, it may become a community health provider's responsibility to follow up with that person to share test results and discuss next steps.

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188. FBOP Guidance, *supra* note 53, at 6.

189. See *supra* note 184; 2022 AASLD/IDSA Guidance, *supra* note 3, at 180–82. The Federal Bureau of Prisons' Clinical Guidance for the Evaluation and Management of Hepatitis C Virus (HCV) Infection, relying on AASLD/IDSA Guidance, similarly promotes an opt-out approach to testing for all incarcerated people, including new intakes and those already in the population. See FBOP Guidance, *supra* note 53, at 6.

190. Scripts like this one, developed to assist in implementing opt-out HIV testing, may be useful. See *Implementing Opt-Out HIV Screening in Your Health Center*, HEALTH INFO. TECH., EVAL., & QUALITY CTR. (Nov. 20, 2020), <https://hiteqcenter.org/Resources/HITEQ-Resources/implementing-opt-out-hiv-screening-in-your-health-center> [<https://perma.cc/DJQ3-YRXX>] (recommending language like “In my practice, I recommend HIV testing for many of my patients, so I am planning to test you for HIV today unless you decline to be tested,” supplemented by information about HIV and the testing process). Another model (also developed for HIV testing), suggests: “As part of routine care, we will ...test for HIV. HIV testing is voluntary so please let me know if you do not want to be treated.” *Opt-Out Testing: Gateway to Treatment & Prevention*, CIGATELLI ASSOC. INC. ET AL. (2018), [https://www.pcdc.org/wp-content/uploads/Resources/Category-C-PCDC-Opt-out-HIV-Testing-Final-Cleared-3.29.18\\_R.pdf](https://www.pcdc.org/wp-content/uploads/Resources/Category-C-PCDC-Opt-out-HIV-Testing-Final-Cleared-3.29.18_R.pdf) [<https://perma.cc/PIX9-Q5KU>].



## 2. Medical Evaluation and Consultation

### 2.1 Medical Evaluation and Consultation for Patients with HCV Viremia<sup>191</sup>

- A. Within four weeks of diagnosis, or as soon as practicable, every patient with a positive HCV RNA test shall be provided appropriate consultation, testing, and assessment, unless the patient affirmatively and voluntarily opts out of such evaluation. Evaluation shall include, at minimum:
  1. Initial consultation with a medical provider, including:
    - a. A targeted medical history;
    - b. A physical exam;
    - c. An order for immunization for Hepatitis A and B, if indicated;
    - d. Order for pneumococcal vaccine and influenza vaccine, if indicated;
    - e. Explanation of the process for scheduling periodic evaluations, treatment eligibility and options, including the benefits of DAA treatment, the importance of adherence, and the risks of refusing treatment; and
    - f. Explanation about the natural history of the infection, dangers of high-risk behaviors, risks and modes of transmission, and specific measures to prevent transmission during incarceration and upon release, and treatment options.
  2. Laboratory testing performed before or during the initial consultation, including:
    - a. Complete blood count (CBC);
    - b. Complete metabolic profile (CMP);
    - c. Prothrombin time (PT) with international normalized ratio (INR), if indicated;
    - d. HIV testing;

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191. For exemplary language, see, Settlement Agreement, *Postawko*, *supra* note 164, at 7 (§ III(A)(5)); Settlement Agreement, *Lignons*, *supra* note 164, at 6–7 (§ I(B)(2)); Settlement Agreement, *Chimenti*, *supra* note 164, at 5 (§ 4); FBOP Guidance, *supra* note 163, at 8–11; NEV. DEP'T OF CORR., MED. DIRECTIVE 319.02 (July 2020), [https://drive.google.com/file/d/1bb9VBxZV-2\\_7AavtjEo6zTxGAY\\_xaIH/view](https://drive.google.com/file/d/1bb9VBxZV-2_7AavtjEo6zTxGAY_xaIH/view) [<https://perma.cc/8VPL-VHYW>].

- e. Hepatitis B surface antigen, surface antibody, and Hepatitis B core total antibody testing;
  - f. Hepatitis A antibody testing;
  - g. HCV genotyping (though this may not be necessary where pangenotypic DAAs are available); and
  - h. Any additional testing that [entity] medical staff determines is indicated.
3. Assessment for advanced fibrosis and cirrhosis, which may include some or all of the following:
    - a. Examination for symptoms and signs of cirrhosis, including: low albumin or platelets; elevated bilirubin or INR; ascites; and hepatic encephalopathy;
    - b. Calculation of an AST-Platelet Ratio Index (APRI) score from the results of the AST and the platelet count; or
    - c. Other fibrosis tests, such as elastography, where available.
  4. Patients with cirrhosis shall receive surveillance for hepatocellular carcinoma with liver ultrasound examination every six months.
  5. Patients who have decompensated cirrhosis (*i.e.*, Child-Turcotte-Pugh (CTP) class B or class C) shall be managed under the guidance of a liver specialist.
- B. [Entity] shall make available to each patient, at no cost, copies of all records related to that patient's HCV work up and related test results in accordance with existing [entity] policies for provision of medical records.
  - C. Any patient with an active HCV infection who has not yet completed DAA treatment resulting in cure shall be reevaluated and, as medically indicated, retested pursuant to part (A) at least every six months.

## 2.2 Enrollment in Substance Use Treatment and Support

- A. If evaluation and consultation indicate that a patient will benefit from counseling and/or treatment support for substance use disorder, medical staff shall make

- appropriate referrals and [entity] shall facilitate the appropriate appointments and/or enrollment.
- B. Under no circumstances shall DAA treatment offered by [entity] be conditioned on enrollment in or successful completion of such programs or on abstention from substances for any period.

### Commentary

Prior to the emergence of DAA therapy, the post-diagnosis, pre-treatment workup required more extensive testing and counseling to safely initiate treatment and prepare patients for treatment-related adverse effects.<sup>192</sup> But, the advent of DAA drugs has changed this. Now, the essential components of the pre-treatment workup are more limited, and include counseling on the importance of adherence to the treatment regimen, assessment of drug-drug interactions, and preventive care including vaccination.<sup>193</sup> Counseling on the importance of adherence to treatment protocols is perhaps the most crucial component in achieving HCV cure, as studies demonstrate that better adherence results in greater likelihood of treatment success (although adherence does not need to be 100% for that to be true).<sup>194</sup> Patients should also be educated

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192. See, e.g., Hsu-Heng Yen, Yang-Yuan Chen, Jun-Hung Lai, Hung-Ming Chen, Chih-Ta Yao, Siou-Ping Huang, I-Ling Liu, Ya-Huei Zeng, Fang-Chi Yang, Fu-Yuan Siao, Mei-Wen Chen & Pei-Yuan Su, *Pan-Genotypic Direct Acting Antiviral Agents for Undetermined or Mixed-Genotyping Hepatitis C Infection: A Real World Multi-Center Effectiveness Analysis*, 11 J. CLIN. MED. 1853 (Apr. 2022), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8999637/> [<https://perma.cc/LM4P-9MM6>] (noting that side effects, increased risks, and the need to genotype before beginning treatment limited interferon-based treatment).

193. See *id.* (concluding that stringent genotyping is no longer required for effective HCV treatment); see also Sunil S. Solomon, Sandra Wagner-Cardoso, Laura Smeaton, Leonard A Sowah, Chanelle Wimbish, Gregory Robbins, Irena Brates, Christine Scello, Annie Son, Anchalee Avihingsanon, Benjamin Linas, Donald Anthony, Estevão Portela Nunes, Dimas A Kliemann, Khuanchai Supparatpinyo, Cissy Kityo, Pablo Tebas, Jaclyn Ann Bennet, Jorge Santana-Bagur, Constance A Benson, Marije Van Schalkwyk, Nelson Cheinquer, Susanna Naggie, David Wyles & Mark Sulkowski, *A Minimal Monitoring Approach for the Treatment of Hepatitis C Virus Infection (ACTG A5360 [MINMON]): A Phase 4, Open-Label, Single-Arm Trial*, 7 LANCET GASTRO. HEPATOL 307 (2022), <https://pubmed.ncbi.nlm.nih.gov/35026142/> [<https://perma.cc/VD8Q-E77C>] (describing successful treatment outcomes with use of pangenotypic DAA treatment, without pre-treatment genotyping); 2022 AASLD/IDSA Guidance, *supra* note 3, at 40–41 (describing the recommended components of pre-treatment evaluation).

194. See Brianna L. Norton, Matthew J Akiyama, Linda Agyemang, Moonseong Heo, Irene- Pericot-Valverde & Alain H Litwin, *Low Adherence Achieves High HCV Cure Rates Among People Who Inject Drugs Treated with Direct-Acting Antiviral Agents*, 7 OPEN F. INFECTIOUS DISEASE, Oct. 2020, at 3, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7590860/> [<https://perma.cc/CFZ4-FVWR>].

on the proper administration of DAA medications such as the dose and frequency, effects of administering with or without food, missed doses, and adverse events.<sup>195</sup> Before treatment initiation, interacting co-medication should be stopped or switched to an alternative with less risk for potential interaction during HCV treatment, and the patient should be counseled on the need to inform the healthcare provider about any changes to their medication regimen.<sup>196</sup> For complicated drug interactions (such as those with antiepileptics where cessation of the interacting drug could lead to poor medical outcomes), consultation with specialists may be necessary.<sup>197</sup>

Given the safety and tolerability of DAA therapy, studies are emerging that suggest that additional laboratory testing and staging of liver fibrosis can be minimal—DAA treatment can be started even while much of this follow-up testing is in progress. For example, in a recent study, conducted in multiple resource-limited settings, a ninety-five percent sustained virological response (SVR, or cure) was achieved with participants receiving no pre-treatment genotyping, receiving the entire treatment course at entry, having no scheduled visits or laboratory monitoring, and having only two points of remote contact: at week four to assess adherence and at the end of the study to assess SVR.<sup>198</sup> Therefore, while full workup is still recommended as part of holistic care for a patient with HCV, evidence suggests that only a minimal workup is required before DAA treatment can be safely and effectively initiated.<sup>199</sup>

### 3. Provision of Treatment and Linkage to Community Care

#### 3.1. Provision of DAA Treatment<sup>200</sup>

- A. Any patient with a current HCV infection is a candidate for treatment with DAAs and shall be offered DAA

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195. AASLD/IDSA Guidance, *supra* note 3, at 40.

196. *Id.*

197. See, e.g., Aijaz Ahmed, Glen A. Lutchman & Paul Y. Kwo, *Drug-Drug Interactions in Hepatitis C Virus Treatment: Do They Really Matter?*, 5:10 CLINICAL LIVER DISEASE 111, 111–12 (Nov. 2017) (describing various adjustments to DAA treatment for different kinds of drug-drug interactions).

198. See Solomon et al., *supra* note 193.

199. *Id.*

200. See ME. DEP'T OF CORR., POL'Y 18.8.3: MGMT. & TREATMENT OF HEPATITIS C, *supra* note 176, at 4–6 (Procedure D); Settlement Agreement, *West*, *supra* note 164, at 10 (¶ 6); Settlement Agreement, *Stafford*, *supra* note 164, at 11 (§ IV(9)); Settlement Agreement, *Lignons*, *supra* note 164, at 8–10 (§§ I(B)(6), I(C)(3)); Settlement Agreement, *Chimenti*, *supra* note 164, at 5–6 (§ 4); CONN. DEP'T OF CORR., ADMIN. DIRECTIVE 8.18, *supra* note 176, at (1–2) (§ 6(a)); Consent Decree, *Geissler*, *supra* note 163, at 9–10; Consent Decree, *In re HCV*, *supra* note 118, at 8 (¶ 38); AASLD/IDSA

treatment within twelve weeks\* from initial medical evaluation unless medical considerations, in accordance with Policy 3.2, indicate that treatment with DAAs is not medically appropriate at that time.

- B. All patients eligible for DAA treatment shall be informed of the safety and efficacy of DAA treatment as well as the risks of delaying or refusing treatment. All patients offered DAA treatment shall have the opportunity to discuss treatment in person with a member of [entity] medical staff.
- C. All eligible patients shall receive DAA treatment, unless, after receiving the information and counseling in (B), the patient affirmatively and voluntarily declines the treatment. Any such refusal shall be documented.
- D. Any eligible patient who initially declines DAA treatment may request such treatment at any time through the typical process for requesting medical care and shall be provided treatment within twelve weeks\* of making such a request, unless additional workup is required.
- E. [Entity] medical staff shall confirm HCV cure (sustained virological response) twelve weeks after treatment completion. If the patient is released from custody before that time, [entity] staff shall make all practicable efforts to link that patient to community care to obtain confirmation of cure.
- F. [Entity] shall ensure that any patient who enters custody or shifts location while undergoing DAA treatment is maintained on the prescribed medication without interruption through completion of the course of treatment, unless medical staff affirmatively determine that it is medically necessary to discontinue or change the treatment or the patient affirmatively and voluntarily declines to continue the treatment.
- G. Under no circumstances shall a patient be disciplined or otherwise disadvantaged for requesting or inquiring about HCV treatment.

\*We propose a policy requiring that DAA treatment be offered and, unless declined, initiated within twelve weeks of a positive HCV test result. This policy aligns with our understanding of what is possible in a

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Guidance at 65; FBOP Guidance, *supra* note 53, at 22; Ex. 2: Hepatitis C Virus Treatment Program, *supra* note 170.

well-resourced carceral healthcare setting and supports the goal of expanding treatment to patients with shorter periods of detention or incarceration. Moreover, a twelve-week timeframe is on the short end of, but not entirely out of step with, the timeframes enshrined in relevant settlement agreements.<sup>201</sup> Even so, we acknowledge that this timeframe may require some modification to better match the needs and resources of a particular setting.

For example, in the jail setting, it may be preferable to implement a policy that promotes an even shorter turnaround time between testing and treatment in order to maximize the number of patients who can complete a course of treatment before release. A policy written for jails might read, instead:

*Any patient with a current HCV infection is a candidate for treatment with DAAs and shall be offered DAA treatment within twelve weeks, and ideally within four weeks, from initial medical evaluation unless medical considerations, in accordance with Policy 3.2, indicate that treatment with DAAs is not medically appropriate at that time.*

Conversely, a setting that does not yet have sufficient staffing or resources may opt to start with a policy that permits a period longer than weeks before initiating treatment. We urge that such a system should aim to eventually implement (and formalize) a twelve-week timeframe.

### 3.2 Proper and Improper Considerations for Treatment<sup>202</sup>

- A. The decision whether or not to offer direct-acting antiviral treatment shall be based solely on medical considerations.

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201. See, e.g., Settlement Agreement, *Stafford*, *supra* note 164, at 10 (§ IV(6)) (after an initial phased-in treatment period, requiring treatment “immediately,” regardless of disease stage, for people newly incarcerated and/or reinfected); Settlement Agreement, *Ligons*, *supra* note 164, at 10 (“Antiviral treatment for prisoners who are eligible for DAAs under the Updated Guidelines shall begin within 3 months of determination of the prisoner’s fibrosis levels 1-4 or fibrosis stage 0 and any of the co-occurring conditions.”); Consent Decree, *Geissler*, *supra* note 163, at 9 (requiring treatment to be offered within 120 days of diagnosis).

202. See, e.g., Consent Decree, *Geissler*, *supra* note 163, at 7, 9 (§§ 37, 38(h)); Settlement Agreement, *West*, *supra* note 164, at 10 (§ 6); Settlement Agreement, *Stafford*, *supra* note 164, at 11 (§ IV(9)); Settlement Agreement, *Ligons*, *supra* note 164, at 8–9 (§ I(B)(6)); FBOP Guidance, *supra* note 46, at 12–14.

- B. Under no circumstances shall the crime of conviction, prior or present substance abuse, completion or failure to complete particular programs, or disciplinary record be a factor in determining treatment or providing medication.
- «**For jails:** replace “crime of conviction” with “nature of charges”»
- C. The following medical considerations may be appropriate reasons for deferring or declining treatment:
1. Contraindications based on drug interactions or concurrent medical conditions;
  2. Planned medical treatment, such as surgery, that may interfere with the medication or continuity of treatment with DAAs;
  3. Life expectancy less than eighteen months that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy; and
  4. Current pregnancy, which should be considered on a case-by-case basis, taking into account the lack of data on DAA safety during pregnancy and the risk of transmitting HCV to the baby.

### 3.3 Linkage to Community Care<sup>203</sup>

- A. A patient expected to be released before completing a full course of DAA treatment shall not be disqualified from beginning treatment while in [entity] custody. Instead, [entity] staff shall take all practicable measures to link the patient with community programs for continuity of care at the time of release. [Entity] medical staff shall consider the availability and likelihood of community care in determining whether to commence treatment in this circumstance, including whether to provide the full remaining doses of DAA treatment to the patient upon release or work with discharge planning staff and community providers to ensure the patient is able to receive prescriptions and continue treatment in the community.

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203. See 2022 AASLD/IDSA Guidance, *supra* note 3, at 183–84; FBOP Guidance, *supra* note 46, at 13.

- B. A patient otherwise eligible for DAA treatment who is released before beginning treatment shall receive all practicable support from [entity] staff in connecting to community programs for prompt initiation and supervision of treatment upon release.
- C. A patient who has been treated for and cured of HCV while in custody but who has cirrhosis shall receive all practicable support from [entity] staff in connecting with follow-up care in the community upon release, including referrals as necessary.
- D. [Entity] staff shall make all practicable efforts to provide discharge planning for all patients with treated or untreated HCV and comorbid substance use disorder, including resources for commencing or continuing substance abuse treatment in the community, if medically appropriate.
- E. [Entity] staff shall provide patients who have tested positive for HCV, and who are released from [entity] custody without receiving DAA treatment and/or achieving SVR information about:
  - 1. The progression of HCV infection and potential health complications;
  - 2. Community treatment options and payment mechanisms;
  - 3. Medicaid, as well as assistance enrolling, if eligible;
  - 4. How to make an appointment with a community medical professional to discuss HCV and treatment options;
  - 5. Behaviors that may increase risk of transmission or increase progression of HCV; and
  - 6. How [entity] medical files may be provided to medical doctors and clinics in the community, and how to request those records in accordance with [entity] policies.



## Commentary

Universal, early-stage DAA treatment aligns with current medical guidance and best practice, including the predominant guidance for HCV care in United States jails and prisons. The AASLD/IDSA guidance recommends early-stage DAA treatment for all, and FBOP guidance provides that any person in federal custody with HCV is eligible to be considered for DAA treatment regardless of stage of disease.<sup>204</sup> The benefits of DAA treatment are clear: SVR rates of ninety percent (or more) result in significant improvements to individual patient and community health.<sup>205</sup> HCV treatment improves individual health outcomes by reducing risk of liver fibrosis, hepatocellular carcinoma, and extrahepatic manifestations.<sup>206</sup> It is also important as a form of treatment prevention in high-risk populations. DAA treatment is effective in carceral settings, resulting in meaningful reduction in HCV transmission in jails, prisons, and the community.<sup>207</sup> In short, offering DAA treatment to all patients with HCV, without restriction and even at the earliest stages of the disease, aligns with medical guidance and maximizes health benefits at the individual, facility, and community level.

Under a universal treatment model, anyone with an active HCV infection is eligible for DAA treatment without restriction, except in the rare circumstance that DAA treatment cannot be administered, such as the presence of drug-drug interactions. Disease stage is irrelevant to determining eligibility for treatment. Similarly, conduct before or during incarceration, including prior or current substance use, must not be considered when determining if treatment is appropriate. The AASLD/IDSA guidance makes clear that “data do not support exclusion of HCV-infected persons from consideration for Hepatitis C therapy based on alcohol intake or use of illicit drugs.”<sup>208</sup> Moreover, studies of injection-drug use and alcohol use found no impact of abstinence for any duration on sustained virological response twelve weeks after completing a course of DAA treatment.<sup>209</sup>

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204. 2022 AASLD/IDSA Guidance, *supra* note 3, at 179–83; FBOP Guidance, *supra* note 46, at 12.

205. See Hajarizadeh et al., *supra* note 45 (describing efficacy of DAA treatment as prevention in Australian prisons); 2022 AASLD/IDSA Guidance, *supra* note 3, at 7 (“Successful treatment of HCV-infected persons at greatest risk for transmission represents a formidable tool to help stop HCV transmission in those who continue to engage in high-risk behaviors.”).

206. FBOP Guidance, *supra* note 53, at 12.

207. *Id.*

208. 2022 AASLD/IDSA Guidance, *supra* note 3, at 21.

209. *Treatment of HCV in a Correctional Setting*, *supra* note 19, at 2.

Comprehensive DAA treatment in prisons and jails is possible for a subset of the population which spends enough time before release or transfer to complete a course of oral therapy. This typically takes eight to twelve weeks,<sup>210</sup> with twelve additional weeks for follow-up and to assess sustained virological response. Most people detained in United States jails, however, are not incarcerated long enough to complete a course of DAA therapy and follow-up.<sup>211</sup> Therefore, linkage to community care is a crucial part of treatment. With adequate community support, impending release should not preclude initiating DAA treatment. Following a holistic model similar to those implemented to support patients with HIV, jails can rely on discharge planners or care navigation teams to assess predicted length of stay and then to connect patients to community partners to initiate or continue treatment and/or to assess SVR upon release.<sup>212</sup> These programs are most effective when they include linkage to mental health, substance use, and housing services, and when combined with community services such as mobile clinics, needle exchange centers, and drug rehabilitation programs.<sup>213</sup> The success of community care linkage also requires promoting awareness about HCV and the safety, efficacy, and tolerability of DAA treatment in carceral settings.<sup>214</sup> Crucially, and especially with community supports in place, DAA treatment can effectively be initiated in jail or prison even if release is likely before the course of treatment will be completed. Indeed, in one recent study, people who were released during DAA treatment achieved a seventy-five percent cure rate.<sup>215</sup> Shortening the time between jail admission and initiation of DAA treatment is crucial to maximizing successful treatment<sup>216</sup> and minimizing risks of failed treatment and viral resistance to treatment.<sup>217</sup>

Finally, staffing, financial, and other resource limitations may mean it is impossible for a carceral system to offer DAA treatment to everyone

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210. Matthew J. Akiyama, Jonathan Ross, Fatimah Rimawi, Aaron Fox, Alison O. Jordan, Janet Wiersema, Alain H. Litwin, Fatos Kaba & Ross MacDonald, *Knowledge, attitudes, and acceptability of antiviral hepatitis C treatment among people incarcerated in jail: A qualitative study*, 15 PLOS ONE, Dec. 2, 2020, at 2 <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0242623> [<https://perma.cc/SNZ2-8AD9>].

211. The average length of stay in a United States jail in June 2020 was 28 days. See Todd D. Minton and Zhen Zeng, *Jail Inmates in 2020 – Statistical Tables*, BUREAU OF JUST. STATS., U.S. DEP'T OF JUST., at 4 (Dec. 2021), <https://bjs.ojp.gov/content/pub/pdf/ji2ost.pdf> [<https://perma.cc/KQ5U-CLFD>].

212. Akiyama et al., *supra* note 20, at 395.

213. *Id.* at 395–96.

214. Akiyama et al., *supra* note 210, at 10.

215. See Chan, *supra* note 110.

216. *Id.*

217. 2022 AASLD/IDSA Guidance, *supra* note 3, at 179.

with HCV immediately and all at once. At the outset of a program to scale-up HCV testing and treatment, a system might opt to stage initial treatment, within a relatively short time frame, to manage capacity for what is likely to be a frontloaded treatment burden. Such prioritization decisions should be guided by medical need, and may include consideration of advanced hepatic fibrosis; liver transplant; hepatocellular carcinoma; comorbid medical conditions associated with HCV and/or associated with more rapid progression of fibrosis; evidence of progressive fibrosis; chronic kidney disease; age; and continuity of care for people who began treatment before entering custody.<sup>218</sup> Ultimately, everyone with HCV must receive prompt treatment, with the goal of quickly gaining the capacity to treat soon after diagnosis.

#### 4. Education for Patients While Incarcerated and Upon Release

##### 4.1 HCV Education<sup>219</sup>

- A. [Entity] shall provide to all people entering custody education about HCV signs and symptoms, risk factors, modes of transmission, prevention, screening options, including how to request testing, and treatment options, including how to request treatment and that treatment is available to all patients with current HCV infections. Education materials shall explain that the virus is more prevalent in carceral settings and that the public health recommendation is to test all incarcerated people.
- B. At least annually, [entity] shall review and update all information and materials disseminated under this policy.

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218. FBOF Guidance, *supra* note 53, at 13–14.

219. See, e.g., Settlement Agreement, *Ligons*, *supra* note 164, at 10 (§ II); Consent Decree, *Buffkin*, *supra* note 164, at (§ 3(a)(i)); see also, Consent Decree, *Geissler*, *supra* note 163, at Ex. C (Hepatitis C Virus (HCV) Educational Pamphlet).

## Commentary

The AASLD/IDSA guidance recommends that people with current HCV infection be educated on how to prevent liver damage, including the potentially deleterious effects of alcohol.<sup>220</sup> In many states, state and local entities as well as non-governmental organizations offer education and training in carceral settings on topics including disease transmission and prevention, opportunities for treatment, and resources for support.<sup>221</sup> Some such programs capacitate peer educators to share information about HCV risks, prevention, and harm reduction.<sup>222</sup> Numerous studies demonstrate that formal education about HCV, such as provision of resources and live trainings, has real benefits, including increased willingness to undertake and comply with treatment regimens.<sup>223</sup> Formal education can also help reduce stigma about the virus.<sup>224</sup>

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220. 2022 AASLD/IDSA Guidance, *supra* note 3, at 18–19.

221. See, e.g., Correctional Health Program, HEPATITIS EDUC. PROJECT, <https://hepeducation.org/programs/correctional-health-education/> [<https://perma.cc/Z561-YHBI>] (last visited July 22, 2023).

222. See, e.g., Karla Thornton, Miranda L Sedillo, Summers Kalishman, Kimberly Page & Sanjeev Arora, *The New Mexico Peer Education Project: Filling a Critical Gap in HCV Prison Education*, 29 J. HEALTH CARE POOR UNDERSERVED 1544 (2018); <https://pubmed.ncbi.nlm.nih.gov/30449762/> [<https://perma.cc/UK6M-PL5R>]; Peer Education Programs, NAT'L HEPATITIS CORR. NETWORK, <https://www.hcvinprison.org/resources/71-main-content/content/200-peereducation> [<https://perma.cc/Q33C-l7E1>] (last visited July 22, 2023) (listing and describing examples).

223. See, e.g., Miranda Surjadi, Cara Torruellas, Claudia Ayala, Hal F. Yee, Jr. & Mandana Khalili, *Formal Patient Education Improves Patient Knowledge of Hepatitis C in Vulnerable Populations*, 56 DIGESTIVE DISEASES & SCI. 213 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3008930/> [<https://perma.cc/7F8X-JH8W>]; Samali Lubega, Uchenna Agbim, Miranda Surjadi, Megan Mahoney & Mandana Khalili, *Formal Hepatitis C Education Enhances HCV Care Coordination, Expedites HCV Treatment, and Improves Antiviral Response*, 33 LIVER INT'L 999 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3692599/> [<https://perma.cc/QN8T-5M7B>]; Diana Partida, Jesse Powell, Margaret Ricco, Jessica Naugle, Catherine Magee, Barry Zevin, Carmen L Masson, J Konadu Fokuo, Daniel Gonzalez & Mandana Khalili, *Formal Hepatitis C Education Increases Willingness to Receive Therapy in an On-site Shelter-Based HCV Model of Care in Persons Experiencing Homelessness*, 9:4 OPEN FORUM INFECT. DIS. (Mar. 2022), <https://academic.oup.com/ofid/article/9/4/ofac103/6540486> [<https://perma.cc/9EZG-4XPH>].

224. Interview with Mandy Altman, Correctional Health Program Manager, Hepatitis Education Project, Director, Nat'l Hepatitis Corr. Network (Nov. 3, 2022).

### 5. Recordkeeping

#### 5.1 Maintenance of Records<sup>225</sup>

- A. [Entity] shall maintain HCV testing records that include, for every person in custody:
1. Date(s) that HCV testing was offered, if applicable;
  2. Date(s) that HCV testing was refused, if applicable;
  3. Date(s) that HCV testing was requested, if applicable;
  4. Date(s) that HCV antibody testing was performed;
  5. Results of HCV antibody testing;
  6. Date(s) that HCV RNA testing was performed; and
  7. Results of HCV RNA testing.
- B. [Entity] shall maintain records for every patient diagnosed with HCV, including:
1. Date and results of any HCV diagnostic testing;
  2. Date and results of other relevant tests such as HAV and HBV serologies, HIV testing, and liver fibrosis testing;
  3. Date(s) DAA treatment was offered;
  4. Date(s) DAA treatment began, if applicable;
  5. Date(s) DAA treatment was refused, if applicable;
  6. Date(s) DAA treatment ended and whether SVR was achieved;
  7. Estimated release date of the patient from custody; and
  8. Documentation of efforts to coordinate community care for patients released or anticipating release before beginning or completing DAA treatment.

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225. See, e.g., Consent Decree, *Geissler*, *supra* note 163, at 10–12 (¶¶ 46–47); Consent Decree, *In re HCV*, *supra* note 118, at 8 (¶ 40); Settlement Agreement, *Stafford*, *supra* note 164, at 12 (§ IV(15)(ii)); Superseding Settlement Agreement, *Barfield*, *supra* note 164, ¶ 4.

- C. [Entity] shall record, every six months, and make publicly available:
  - 1. The total number of patients tested for HCV in the six-month period;
  - 2. The total number of patients who tested positive for HCV in the six-month period;
  - 3. The total (cumulative) number of patients with current HCV infection in [entity] custody, including total (cumulative) number of patients with current HCV infection at each facility; and
  - 4. The total number of patients with current HCV infection who, during the six-month period, met the following criteria:
    - a. Began a course of DAA treatment;
    - b. Completed a course of DAA treatment;
    - c. Were deemed ineligible for DAA treatment; and
    - d. Refused DAA treatment.
- D. [Entity's] quality improvement committee or equivalent shall undertake ongoing assessment of the HCV testing and treatment program and protocols to identify issues and recommend improvements.

## *6. Staffing and Staff Training*

### *6.1 Staffing to Support HCV Care*

- A. [Entity] shall ensure sufficient medical staff, with the requisite training and expertise to screen for and diagnose HCV, to evaluate disease progression, and to meet testing and treatment needs.
- B. [Entity] shall ensure sufficient staff with the requisite training and expertise to provide reentry support and linkage to HCV treatment in the community for patients released before starting or completing treatment.

## 6.2 Staff Training<sup>226</sup>

- A. [Entity] shall provide and support training to medical staff—including on-site, through community partnerships, and/or via continuing medical education opportunities—as needed to ensure sufficient expertise to screen for, diagnose, evaluate, and treat HCV.
- B. [Entity] shall provide training to all staff about HCV, including risk factors, transmission, signs and symptoms, and available testing and treatment.

## 7. Updates to Guidance and Protocols

### 7.1 Regular Updates to Guidance and Protocols<sup>227</sup>

- A. [Entity] shall regularly update the HCV testing and treatment protocols contained herein to align with updates to future testing and treatment recommendations established by nationally recognized authorities, including, but not limited to, AASLD/IDSA Guidance, the Federal Bureau of Prisons, the National Commission on Correctional Health Care, National Institutes of Health, the Centers for Disease Control and Prevention, and others, as deemed medically appropriate.
- B. [Entity] shall designate at least one member of medical staff to be responsible, annually, for surveying relevant resources and updating guidance and protocols as appropriate.

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226. See e.g., Settlement Agreement, *Postawko*, *supra* note 164, at 10 (§ III(D)). Some non-governmental organizations may be available to support staff training efforts. Interview with Mandy Altman, *supra* note 224.

227. See, e.g., CONN. DEPT OF CORR., ADMIN. DIRECTIVE 8.18, *supra* note 176, at 1 (§ 4); Proposed Settlement Agreement, *Turney*, *supra* note 164, at 10–11 (¶ 3.5).

### 8. Definitions

- 8.1 [Entity]: As used throughout this policy, [entity] refers to the prison or jail system and/or to those responsible for providing healthcare in those settings. The term is used generally to mean the entity or any staff member(s), as defined in Policies 8.2 and 8.3.
- 8.2 Medical Staff: As used throughout this policy, “medical staff” means any person with medical training performing duties for [entity], including as an employee, contractor, or volunteer, including carrying out [entity] services, programs, and activities.
- 8.3 Staff: As used throughout this policy, “staff” means any person performing duties for [entity], including as an employee, contractor, or volunteer, including carrying out [entity] services, programs, and activities.

### CONCLUSION

In sum, the prevalence of HCV in United States prisons and jails is a challenge that must be confronted. As DAA treatment becomes more firmly established as the *only* adequate treatment for HCV at all stages, prisons and jails must ensure that their HCV testing and treatment protocols provide constitutionally adequate care. The benefits of expanding HCV testing and DAA treatment among this high-risk, high-prevalence population are clear: early-stage treatment is cost-effective, and not only cures the disease in treatment recipients but also reduces community transmission. The proposed model policies offer a path forward for jails and prisons to provide universal opt-out testing, pre-treatment evaluation, early-stage DAA treatment, education, and other support to ensure successful health outcomes and promote disease elimination.



