



WHITE PAPER SERIES

Learning from Civil Rights Lawsuits:

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

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A project of the Civil Rights Litigation Clearinghouse and the University of Michigan Law School

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This project and related materials are available for reading or download at clearinghouse.net/policy/1/22. Materials include a large-print version of this document, as well as case summaries, litigation documents, and other referenced resources.

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The National Hepatitis Corrections Network and Treatment Action Group helped shape the recommended policies in Part III of this white paper and endorse them for consideration and adoption. The Academic Consortium on Criminal Justice Health and the National Viral Hepatitis Roundtable also endorse the recommended policies for consideration and adoption.

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Executive Summary

Hepatitis C virus (HCV) is highly prevalent in United States prisons and jails, where rates of infection are 10 to 20 times greater than national levels and where more than 30% of all people living with HCV in the United States will spend time 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 transmission of the virus both inside and outside 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 8-12 week course of oral treatment, cure HCV in more than 90% of cases. Widespread testing and treatment in prisons and widespread testing and treatment or linkage to community care in jails is an essential public health approach. 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. 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, avoids the harmful health consequences of disease progression, and meaningfully reduces community transmission.

This white 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.

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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, where rates of infection are magnitudes higher than in 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. But most carceral system practices fall short of this recommendation and, where DAAs are available, 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 early stages of the disease, among a high-risk, high-prevalence population, simultaneously minimizing harm to individual patients and reducing community transmission.

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

Hepatitis C is a virus that infects the liver.¹ HCV is spread through contact with blood from a person who is infected, most often through sharing needles used to prepare and inject drugs.² For up to 20% 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.³ Those who do not spontaneously recover develop long-term, “chronic” infection, during which the liver becomes progressively more damaged. Chronic HCV can be lifelong if not treated and may cause serious health problems, including: 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.⁴ Moreover, active HCV infection increases a person’s susceptibility to other illnesses, including chronic kidney disease,⁵ depression,⁶ neurological disorders,⁷ malignancies,⁸ and other extra-hepatic manifestations.⁹ Disease trajectory is unpredictable, and the rate of disease progression varies from person to person.¹⁰ But without treatment, HCV has high rates of morbidity and mortality.¹¹

It is estimated that 2.4 million people in the United States are living 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.¹² The incidence of HCV in the United States is increasing; the rate of new infections reported to the Centers for Disease Control and Prevention (“CDC”) in 2018 was four times that reported in 2010.¹³ The increased prevalence has been most pronounced

in states most affected by the opioid epidemic,¹⁴ with studies pointing to “substantial, simultaneous increases” in acute HCV and admissions for opioid injection.¹⁵ As injection drug use continues to drive new infections, rates among young people, in particular, are on the rise. The CDC’s annual HCV data continues to show highest rates of new infection, and lowest treatment rates, among adults under 40.¹⁶

HCV is disproportionately prevalent in United States prisons and jails compared to the general population. Recent studies show that among incarcerated populations, HCV antibody positivity rates, which indicate exposure to HCV, range from 12 to 34%, more than 20 times the national rate.¹⁷ Estimates suggest that approximately 30% of all individuals living with HCV in the United States spend time in a carceral setting in a given year.¹⁸ These 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 contribute to new transmission within carceral settings.¹⁹ The effects ramify outside prisons and jails. The young PWID driving high rates of new infection in the United States are also a population more likely to be in and out of prisons and jails, likely without knowing that they have contracted and may be spreading HCV. Recent short-term incarceration is associated with an elevated risk of HCV acquisition among PWID.²⁰ And more than 90% of people with HCV in prisons and jails are eventually released, risking further community transmission.²¹ 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 more than 1000 people died in prison of HCV-related causes between 2013 and 2019.²²

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

Until about a decade ago, a medication called interferon was necessary for HCV treatment. A synthetic version of interferon, which is made naturally by the body’s immune system, was given in the form of an injection to stimulate the immune system against the virus. By 2011, the most common treatment regimen involved pegylated interferon, administered via weekly injection, combined with a daily oral dose of ribavirin, over a course of 24 to 48 weeks.²³ This regimen produced wide-ranging results, with sustained virological response (or HCV cure²⁴) in anywhere from 30 to 90% of patients, depending on HCV genotype and stage of liver disease.²⁵ Barriers to interferon-based treatment were significant. Pre-treatment usually required virus genotyping and staging to determine treatment course.²⁶ Side effects could be severe, including flu-like symptoms, lowered white blood cell or platelet counts, and depression and other mood disorders.²⁷ Moreover, interferon and/or ribavirin were contraindicated for many people.²⁸

During the interferon era, HCV treatment was often not offered at all in prisons and jails. Even when offered, barriers to treatment were exacerbated in those settings. For example, before

determining whether treatment could begin, many systems required liver biopsies and/or genotyping,²⁹ procedures that can be more complicated, and more often delayed, for people in custody than for those in the community. Some carceral systems required psychological screening before initiating treatment.³⁰ State prison systems often required a minimum remaining sentence of 15 to 18 months to ensure completion of treatment and follow up, precluding treatment for people with less, or uncertain, time remaining on their sentences.³¹ As one federal court of appeals described eligibility for treatment in a state prison system during that period: “The 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.”³² Moreover, as of 2008, most states had not established *any* program or protocols for HCV treatment in their prison systems.³³

In 2011, the HCV treatment landscape began to transform. That year, the U.S. Food and Drug Administration began approving DAA medications for HCV to be administered in combination with interferon.³⁴ And in 2014, the FDA began approving DAA drugs as a stand-alone treatment option.³⁵ DAAs directly target HCV at various stages of the viral life cycle to inhibit virus production.³⁶ DAAs are now widely available, safe, and highly effective across genotypes. More than 90% of people with HCV can be cured with an 8- to 12-week course of oral DAA therapy.³⁷ Side effects are minimal, as are contraindications. DAA treatment requires minimal pre-treatment testing and is easily administered through daily pills. DAA treatment not only cures HCV in the vast majority of patients, it also reduces community transmission. Recent studies show that successful DAA treatment is preventive; that is, DAA treatment scale up is associated with reduced overall HCV incidence.³⁸ DAA treatment has also proven cost-effective, reducing overall disease rates and avoiding expensive later-stage care.³⁹ This is increasingly true as the costs of DAA treatment continue to decrease.⁴⁰ DAAs have replaced interferon as the universal standard of care for HCV.⁴¹

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,”⁴² including recommendations for HCV testing and treatment in prisons and jails.⁴³ It is updated regularly—most recently in October 2022—to reflect new data from peer-reviewed research.⁴⁴

The AASLD/IDSA guidance is the predominant guide to appropriate HCV care in the United States. The CDC presents the AASLD/IDSA guidance as “Clinical Guidelines” for HCV screening

and management.⁴⁵ 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 to testing and treating.⁴⁶ (Note, however, that the FBOP guidance does not fully align with the AASLD/IDSA guidance.) And although the legal significance of the guidance remains contested,⁴⁷ several courts have recognized the AASLD/IDSA guidance as the standard of care that should guide HCV treatment in carceral settings.⁴⁸

Universal Testing: The AASLD/IDSA guidance recommends one-time, routine, opt-out HCV testing for all people age 18 and older, and periodic repeat HCV testing for people with risk activities, exposures, or conditions, including “persons who were ever incarcerated.”⁴⁹ The guidance recommends that prisons and jails implement opt-out HCV testing.⁵⁰ Generally, universal screening is recommended “because of the known benefits of care and treatment in reducing the risk of” serious illness or death, as well as “the potential public health benefit of reducing transmission through early treatment, viral clearance, and reduced risk behaviors.”⁵¹ Moreover, numerous studies confirm that routine, one-time testing for all adults is cost effective because it identifies “a substantial number of HCV cases that would otherwise be missed.”⁵² 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.”⁵³ 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.”⁵⁴ In that context, universal testing both casts a wider net and reduces the stigma of risk activity-based testing.

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.⁵⁵ 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 18-79, as well as periodic screening for people at continued risk.⁵⁶

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.⁵⁷ It explains: “[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.”⁵⁸ Early treatment is associated with better outcomes, including higher likelihood of cure and mortality reduction.⁵⁹ Numerous studies have shown meaningful reduction in liver-related mortality when HCV is treated at the earliest stages.⁶⁰ The AASLD/IDSA guidance makes clear that DAA treatment can and should be provided in prisons and jails, and that testing

and treatment in those settings, and linkage to community care upon release, are key to HCV elimination efforts.⁶¹ This recommendation aligns with recent CDC and World Health Organization guidance recommending testing and treatment in primary care locations, including carceral settings, in order to maximize access.⁶²

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.⁶³ 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.⁶⁴ 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.⁶⁵ 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.⁶⁶ Now, years after the introduction of DAA treatment for HCV, prices are down to \$20,000 and lower per course of treatment in the United States. It seems likely that costs will continue to decrease—indeed, elsewhere in the world, DAAs are available for \$60 per course of treatment, which is more in line with estimated manufacturing cost-based prices that, since the early days of DAA treatment, have generally been less than a couple hundred dollars per course of treatment, and sometimes far lower.⁶⁷ But even at this point treatment is clearly cost effective.⁶⁸ 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.⁶⁹

As prices have continued to fall and studies repeatedly confirm the safety and efficacy of DAA treatment, medical guidance and practice has explicitly shifted away from prioritization.⁷⁰ 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.⁷¹ Moreover, data demonstrates “the many benefits, both intrahepatic and extrahepatic, that accompany HCV eradication.”⁷² For those reasons, the guidance no longer recommends prioritization, and instead promotes DAA treatment for all except those with short life expectancies that cannot be remediated with treatment.⁷³

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 that 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.⁷⁴ In jails, the guidance recommends coupling testing and treatment with counseling and linkage to follow-up community healthcare.⁷⁵ In prisons, the guidance recommends “harm reduction and evidence-based treatment for underlying substance use disorders.”⁷⁶

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.⁷⁷ Thereafter, several state Medicaid programs removed categorical barriers to treatment;⁷⁸ and in some states that did not do so voluntarily, courts required such expansion of coverage.⁷⁹ 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).⁸⁰

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 41 states reporting data, less than 1% of incarcerated people known to have HCV were receiving any form of treatment as of January 1, 2015.⁸¹ That same study noted that routine testing was generally not conducted; only 16% of responding prisons provided universal (opt-out) antibody testing upon admission.⁸² During this time, medical guidance and practice prioritized patients with the greatest need, including those with advanced liver fibrosis.⁸³ Carceral systems similarly prioritized patients for DAA treatment based on disease progression,⁸⁴ but also imposed barriers to treatment untethered to medical guidance or disease progression. For example, some systems required a year or more left on one’s sentence before beginning treatment⁸⁵—an outdated timeframe seemingly tied to the long period previously required to complete interferon-based treatment. Other systems apparently precluded treatment based on disciplinary record,⁸⁶ or required completion of lengthy alcohol- and drug-treatment programs before initiating treatment.⁸⁷ 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 treatment⁸⁸: for many carceral systems, the cost of universal DAA treatment would have outstripped entire healthcare budgets.⁸⁹

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. To provide some of many examples: In the Indiana prison system between April 1, 2017 and January 19, 2018, only 41 of approximately 3,476 people identified as having chronic HCV had completed or were receiving DAA treatment.⁹⁰ In Tennessee, as of July 2019, only approximately 10% of people known to have HCV in the custody of the Tennessee Department of Corrections had been prescribed DAAs.⁹¹ In 2021, only 13% of the more than 900 incarcerated people known to have HCV in the Missouri prison system received DAA

treatment,⁹² New Hampshire treated only 22 of an estimated 250 incarcerated people with HCV, and only 4% of people with HCV in state custody in Iowa received DAA treatment.⁹³ South Dakota treated just seven incarcerated people in 2021, out of at least 382 known to have the virus.⁹⁴ Indeed, recent reporting on this issue indicates that as of 2021, at least a dozen states were treating fewer than 20% of people with HCV in their custody.⁹⁵ Today, many systems maintain policies that prioritize treatment for those with the most advanced liver disease,⁹⁶ despite evidence that treatment is likely to be most effective when offered in the earliest stages of the disease,⁹⁷ and many continue to impose barriers to treatment unrelated to disease progression.⁹⁸

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.⁹⁹ 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, which in turn can reduce community transmission.¹⁰⁰ When prisons and jails endeavor to test for and treat HCV, outcomes demonstrate that DAA treatment can be provided safely, effectively, and with cure rates comparable to community care.¹⁰¹ Successful models have included telehealth linkages to specialists,¹⁰² 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,¹⁰³ as well as training for primary care on-site practitioners.¹⁰⁴ 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.¹⁰⁵ From a public health perspective, then, expanding testing and treatment in carceral settings is essential.

FUNDING FOR DAA TREATMENT

The price of DAAs has been a high barrier to universal treatment in prisons and jails. Although DAA drugs are now many-fold less expensive than they were a decade ago, the medications remain costly.¹⁰⁶ 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.¹⁰⁷

Universal testing and early-stage DAA treatment are cost-effective for communities in the long term.¹⁰⁸ 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.¹⁰⁹ That said, although universal testing and treatment is essential, it must not come at the cost of other essential jail and prison medical services.¹¹⁰

Fortunately, the falling costs of DAAs combined with 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, for DAA purchases,¹¹¹ as Texas, Alaska, Utah, and several other states have done.¹¹² Under such arrangements, people with HCV in state/local custody can be considered patients of the entity eligible for the program and receive significant discounts on DAAs.¹¹³ As another possibility, researchers have recommended pursuing a nominal pricing approach, seeking 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, which would enable prisons to purchase DAAs at less than 10% of market rate, if pharmaceutical companies were willing to provide them at that price.¹¹⁴ State departments of correction might also consider coordinating for pooled procurement with increased purchasing power,¹¹⁵ 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.¹¹⁶ Alternatively, states could negotiate directly for a discounted price in exchange for purchasing from a single provider, as Virginia has done.¹¹⁷ 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 90 days before release.¹¹⁸ The Centers for Medicaid and Medicare Services intends soon to 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. *Following the release of that guidance, the Clearinghouse intends to release a template 1115 waiver that will describe options and considerations for including Hepatitis C testing and treatment as part of the set of targeted services.*

II. The Legal Landscape

Over the last several years, people with HCV in United States prisons (and in at least two unified correctional systems¹¹⁹) 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.

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

Longstanding case law explains that under the Eighth Amendment’s Cruel and Unusual Punishments Clause, each state and local government has an “obligation to provide medical care for those whom it is punishing by incarceration.”¹²⁰ 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.¹²¹ 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 he or she acts with “deliberate indifference” to an incarcerated person’s “serious medical needs.”¹²² The standard has both an objective and a subjective component: the medical need must be objectively serious,¹²³ 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.¹²⁴ 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.”¹²⁵ Courts applying this standard have held that delaying or failing to provide treatment for a non-medical reason may violate the Eighth Amendment,¹²⁶ and that effects on a person’s current *and* future health must be considered.¹²⁷ But mere medical malpractice or disagreement as to proper course of treatment does not support an Eighth Amendment claim.¹²⁸ Instead, to be actionable, the challenged action must significantly depart from accepted professional practice or standards.¹²⁹

A state must provide sufficient funds to ensure that its prison system operates in compliance with the Constitution.¹³⁰ If a particular treatment or intervention is required under the Eighth Amendment, it cannot be withheld because of cost alone. 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 administrative convenience rather than any medical justification” may violate the Eighth Amendment.¹³¹ 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.¹³²

LEGAL CHALLENGES TO HCV TESTING AND TREATMENT FOR PATIENTS IN PRE-TRIAL DETENTION

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. 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.¹³³) 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.¹³⁴

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.¹³⁵ 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.¹³⁶ 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. 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.¹³⁷ 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 monitoring HCV-infected inmates,”¹³⁸ and that disagreement with course of treatment is not cognizable under the Eighth Amendment.¹³⁹ These courts have also favorably cited the flexibility to treat those with immediate need, regardless of place in the priority system.¹⁴⁰ Ultimately, these courts conclude that the failure to provide a curative course of treatment (DAAs), without more, does not rise to the level of deliberate indifference.

But as other courts have recognized, such decisions miss the mark. There is no longer a range of acceptable treatments for HCV. Rather, DAA therapy is *the* medically accepted treatment at every stage of the disease. 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.¹⁴¹ Several other courts to address the issue 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. See, e.g., *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 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”); *Postawko v. Missouri Dep’t of Corr.*, No. 2:16-cv-04219-NKL, 2017 WL 1968317, at *7 (W.D. Mo. May 11, 2017) (“similarly denying in part motion to dismiss 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 without any medical justification”).¹⁴² 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 the course of fibrosis progression may be slow, patients with chronic HCV are at risk for other serious conditions even in the early stages of the disease.¹⁴³ In addition, fibrosis progression is unpredictable, and estimates of progression may be inexact.¹⁴⁴ Furthermore, later-stage treatment may be less effective in curing the disease, and may not reverse the liver damage incurred while waiting for care.¹⁴⁵ As medical guidance and practice continues uniformly to support universal, early-stage DAA treatment, the litigation tide may turn toward cases finding that delaying or denying such treatment violates the Eighth Amendment.¹⁴⁶

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.¹⁴⁷ Sometimes, however, the parties have been able to reach agreements to change testing and treatment

protocols. In seeming recognition of the urgency and opportunity of the moment,¹⁴⁸ settlement agreements in several states have resulted in widespread expansion of HCV testing and treatment in state correctional systems.¹⁴⁹ For example:

- In Indiana, implementation of a 2020 settlement agreement pursuant to which approximately 3350 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.¹⁵⁰
- 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.¹⁵¹
- 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 20-25 treated per year previously—and removed pre-treatment requirements such as completion of drug and alcohol classes and deterioration of the liver.¹⁵²
- 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 2021.¹⁵³
- 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, 2028.¹⁵⁴
- 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.¹⁵⁵

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

The recommendations in this white paper derive from these and other settlement agreements and 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 change—including, crucially, funding to scale up DAA treatment—there may also be significant downsides. Litigation is expensive for all involved, and often slow. Once a lawsuit has been resolved, problems may linger, or new problems may arise, with no clear path to resolution. The adversarial nature of litigation may frustrate cooperation between state and local carceral systems, advocates, and persons with HCV. And procedural barriers to litigation may frustrate reform. In this context, policy change outside of, but informed by, litigation outcomes including settlement agreements seems a promising path forward.

DRAWING POLICY LESSONS FROM LITIGATION DOCUMENTS

This white paper relies on litigation documents among its major sources. Settlement agreements in particular are valuable because they codify collaboratively developed solutions to problems. But other types of litigation documents can be similarly informative.

Topic	Type of document
Conditions, problems, needs	Complaint, expert reports, monitoring reports
What the law requires	Opinions, briefs
Training	Post-settlement reports, exhibits
Reforms, policies	Settlements, post-settlement reports
Results of reforms	Post-settlement reports, enforcement

Of course, litigation documents may 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 us fill in gaps and account for more recent developments.¹⁵⁶

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.

Statement of Purpose and Guiding Considerations

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 necessarily 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 make them available at <https://clearinghouse.net/resource/3838/> 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, 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.

The following considerations are essential for meaningful implementation of these policies.

- **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.¹⁵⁷
- **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 prior to being initiated on 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 care to begin or complete treatment.¹⁵⁸ 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 for HCV

1.1 Universal Opt-Out HCV Screening¹⁵⁹

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

1. *If no documented test results within the last 12 months, at intake or, if not tested at intake, at first clinical evaluation; and*
2. *If no documented test results within the last 12 months, at the time of the patient's first clinical evaluation, and/or any medical appointment or consultation thereafter; and*
3. *If no documented test results within the last 12 months, at any time requested by the patient; and*
4. *Every 12 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 to the patient 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, 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.¹⁶⁰ The CDC recommends routine testing for people with ongoing risk factors, including: 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.¹⁶¹ And the AASLD/IDSA guidance recommends periodic, repeat testing for people with risk activities, and annual testing for people who inject drugs, among other risk categories.¹⁶² Given the high prevalence of HCV and risks associated with incarceration, the policy recommendations above seek to 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) with the aim of ensuring one-time testing for all and promoting routine testing as appropriate.

Diagnosing a current HCV infection is currently a two-step process.¹⁶³ First, a screening test for HCV antibodies provides information about past exposure to HCV. A negative HCV antibody result indicates that the person has never been exposed to the virus, ruling out HCV infection.¹⁶⁴ 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.¹⁶⁵ 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.¹⁶⁶ 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.¹⁶⁷ 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.¹⁶⁸ In addition, universal testing reduces the stigma that may accompany risk-based, selective testing.¹⁶⁹ 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.¹⁷⁰

It is essential that prisons and jails have policies in place that maximize opportunities for testing and that encourage people to test. To that end, facilities should reevaluate any policies or practices that might discourage testing, and should 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, pursuant to which all are tested, absent affirmative refusal, after receiving information, is most likely to maximize willingness to be tested.¹⁷¹ Universal opt-out testing has been found to be the most effective, and cost effective, testing method.¹⁷² 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?”).¹⁷³

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 the responsibility of a community health provider to follow up with that person to share test results and discuss next steps.

2. Medical Evaluation and Consultation

2.1 Medical Evaluation and Consultation for Patients with HCV Viremia¹⁷⁴

- A.** *Within 4 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 prior to 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;
 - e. Hepatitis B surface antigen, surface antibody, and Hepatitis B core total antibody testing;
 - f. Hepatitis A antibody testing;
 - g. HCV genotyping, though not necessary where pangenotypic DAAs 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;
 - c. Other fibrosis tests, such as elastography where available;
 4. Patients with cirrhosis shall receive surveillance for hepatocellular carcinoma with liver ultrasound examination every 6 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 6 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 of time.*

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. But, with the advent of DAA drugs that can be safely and effectively administered in most patients, this has changed. 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. Counseling on the importance of adherence to treatment protocols, and support for such adherence, 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).¹⁷⁵ Patients should also be educated 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. Prior to 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. For complicated drug interactions (such as those with antiepileptics where cessation of the interacting drug could lead poor medical outcomes), consultation with specialists may be necessary.

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 95% 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.¹⁷⁶ 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.

3. Provision of Treatment and Linkage to Community Care

3.1 Provision of DAA Treatment¹⁷⁷

- A. Any patient with a current HCV infection is a candidate for treatment with DAAs and shall be offered DAA treatment within 12 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 12 weeks* after making such a request unless additional work up is required.*
- E. [Entity] medical staff shall confirm HCV cure (sustained virological response) 12 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.*

*A NOTE ON THE PROPOSED TIMEFRAME FOR INITIATING TREATMENT

We propose a policy requiring that DAA treatment be offered and, unless declined, initiated within 12 weeks of a positive HCV test result. This policy aligns with our understanding of what is possible in a well-resourced carceral health care setting and supports the goal of expanding treatment to patients with shorter periods of detention or incarceration. Moreover, a 12-week timeframe is on the short end, but not entirely out of step with, the timeframes enshrined in relevant settlement agreements.¹⁷⁸ But 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 12 weeks, and ideally within 4 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 doesn't yet have sufficient staffing or resources may opt to start with a policy that permits a period longer than 12 weeks before initiating treatment. We urge that such a system aim to eventually implement (and formalize) a 12-week timeframe.

3.2 Proper and Improper Considerations for Treatment¹⁷⁹

- A. *The decision whether or not to offer direct acting antiviral treatment shall be based solely on medical considerations.*
- 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 18 months that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy;*
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 Care¹⁸⁰

- 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 attempt to link to 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 to continue treatment in the community.*
- 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 to 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. *that [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 or without HCV is eligible to be considered for DAA treatment regardless of stage of disease.¹⁸¹ The benefits of DAA treatment are clear: SVR rates of 90% (or more) result in significant improvements to individual patient and community health. HCV treatment improves individual health outcomes by reducing risk of liver fibrosis, hepatocellular carcinoma, and extrahepatic manifestations.¹⁸² It is also important as a form of treatment as 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.¹⁸³ 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 levels.

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 in determining whether 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.”¹⁸⁴ Moreover, studies of injection-drug use and alcohol use have found no impact of abstinence for any duration on sustained virological response 12 weeks after completing a course of DAA treatment.¹⁸⁵

Comprehensive DAA treatment in prisons and jails is possible for a subset of the population that spends enough time before release or transfer to complete a course of oral therapy, typically 8-12 weeks,¹⁸⁶ with 12 additional weeks for follow up and to assess sustained virological response. Most people detained in United States jails, however, will not spend enough time there to complete a course of DAA therapy and follow up.¹⁸⁷ 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 also 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.¹⁸⁸ These programs tend

to be 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.¹⁸⁹ The success of community care linkage also requires promoting awareness about HCV and the safety, efficacy, and tolerability of DAA treatment in carceral settings.¹⁹⁰ 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 the course of DAA treatment achieved 75% cure rate.¹⁹¹ Shortening the time between jail admission and initiation of DAA treatment is crucial to maximizing successful treatment,¹⁹² and minimizing risks of failed treatment and viral resistance to treatment.¹⁹³

Finally, staffing, financial, and other resource limitations may mean that it is impossible for a carceral system to offer DAA treatment to everyone 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 may appropriately 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 prior to entering custody.¹⁹⁴ Ultimately, everyone with HCV must receive prompt treatment, with the goal of quickly gaining the capacity to treat everyone soon after diagnosis.

4. Education for Patients while Incarcerated and upon Release

4.1 HCV Education¹⁹⁵

- 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.*

Commentary

The AASLD/IDSA guidance recommends that people with current HCV infection be educated about how to prevent liver damage, including the potentially deleterious effects of alcohol.¹⁹⁶ 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.¹⁹⁷ And some such programs capacitate peer educators to share information about HCV risks, prevention, and harm reduction.¹⁹⁸ Numerous studies have demonstrated 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.¹⁹⁹ Formal education can also help reduce stigma about the virus.²⁰⁰

5. Recordkeeping

5.1 Maintenance of Records²⁰¹

- 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; and*
 8. *Documentation of efforts to coordinate community care for patients released or anticipating release before beginning or completing DAA treatment.*
- 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;*
 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;*
 - 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 Training²⁰²

- 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 Protocols²⁰³

- 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.*

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.

Endnotes

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- 3 See 2022 AASLD/IDSA Guidance, *supra* note 2, at 149-150; Hepatitis C, Cleveland Clinic (Dec. 9, 2022), <https://my.clevelandclinic.org/health/diseases/15664-hepatitis-c>.
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[hepatitis/learn-about-viral-hepatitis/data-and-trends/index.html](https://www.cdc.gov/hepatitis/learn-about-viral-hepatitis/data-and-trends/index.html).

- 13 *Id.*
- 14 For example, between 2006 to 2012, acute HCV infections increased 364% in Kentucky, Tennessee, Virginia, and West Virginia. *Id.*
- 15 Press Release: Increase in Hepatitis C Infections Linked to Worsening Opioid Crisis, Centers for Disease Control and Prevention (Dec. 21, 2017), <https://www.cdc.gov/nchhstp/newsroom/2017/hepatitis-c-and-opioid-injection-press-release.html>; see also David Powell et al., *A Transitioning Epidemic: How the Opioid Crisis is Driving the Rise In Hepatitis C*, 38:2 PHARMACEUTICALS & MEDICAL TECHNOLOGY HEALTH AFFAIRS (Feb. 2019), <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05232> (tying tripling of rates of new HCV infection between 2010 and 2014 to uptick in opioid injections).
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- 32 *Bender v. Regier*, 385 F.3d 1133, 1135 (8th Cir. 2004) (ultimately concluding that prison physician did not act with deliberate indifference in failing to provide interferon treatment before patient's release), available at <https://clearinghouse.net/doc/136963/>; see also *Coleman-Bey v. United States*, 512 F. Supp. 2d 44, 48 (D.D.C. 2007) (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”), available at <https://clearinghouse.net/doc/136965/>.
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- 38 See Behzad Hajarizadeh et al., *Evaluation of Hepatitis C Treatment-As-Prevention Within Australian Prisons (SToP-C): A Prospective Cohort Study*, 6 LANCET GASTROENTEROL HEPATOL 533 (2021), <https://pubmed.ncbi.nlm.nih.gov/33965006/>; see also Jason Grebely, et al., *Reinfection and Risk Behaviors After Treatment of Hepatitis C Virus Infection in Persons Receiving Opioid Agonist Therapy*, ANNALS OF INTERNAL MEDICINE (Sept. 2022), <https://www.acpjournals.org/doi/10.7326/M21-4119>.
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- 62 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/>

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- 69 See Sanger-Katz, *supra* note 64.
- 70 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(5) CLIN. LIVER DIS. (Hoboken) 122 (Nov. 2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6385924/#cld751-bib-0007>.

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- 82 2022 AASLD/IDSA Guidance, *supra* note 2, at 179-180.
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- 84 *E.g.*, Alan Prendergast, *Hep C: The Deadliest Killer in Colorado's Prisons Is a Curable Virus*, WESTWORD (Dec. 13, 2016) (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), <https://www.westword.com/news/hep-c-the-deadliest-killer-in-colorados-prisons-is-a-curable-virus-8591316/>; *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), available at <https://clearinghouse.net/doc/84782/>.
- 85 *E.g.*, Class Action Complaint, *West v. Gobeille*, No. 2:19-cv-00081 (D. Vt. May 21, 2019), ¶ 86 (describing existing requirement of 12-18 months remaining on sentence to qualify for treatment), available at <https://clearinghouse.net/doc/112626/>; Third Amended Class Action Complaint, *Geissler v. Stirling*, No. 4:17-cv-01746 (D.S.C. Aug. 21, 2018), ¶ 67 (describing policy requiring 12 months left on sentence to initiate DAA treatment), available at <https://clearinghouse.net/doc/112690/>; Class Action Complaint, *Buffkin v. Hooks*, No. 1:18-cv-00502 (M.D.N.C. June 15, 2018), ¶¶ 87-88 (same), available at <https://clearinghouse.net/doc/130429/>.
- 86 *E.g.*, Class Action Complaint, *West*, *supra* note 85, ¶¶ 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, *Aragon v. Raemisch*, No. 1:17-cv-1744 (D. Colo. Sept. 11, 2017), ¶ 41 (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), available at <https://clearinghouse.net/doc/97201/>; Class Action Complaint, *Buffkin*, *supra* note 85, ¶¶ 89-90 (noting policy denying treatment and evaluation to anyone with a drug or alcohol infraction within the last twelve months).
- 87 See, *e.g.*, Prendergast, *supra* note 84 (describing experience of 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).

- 88 See generally Beckman et al., *supra* note 81 (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 LAW SCHOOL (Oct. 4, 2016), <https://law.yale.edu/yls-today/news/study-modern-hepatitis-c-drugs-are-very-costly-and-unavailable-many-state-prisoners>.
- 89 See Anne C. Spaulding et al., *Funding Hepatitis C Treatment in Correctional Facilities by Using a Nominal Pricing Mechanism*, 25:1 J. Correctional Health Care 15, 16 (Jan. 2019), available at <http://doi.org/10.1177/1078345818805770>; see also Florko, *supra* note 22, (noting that in 2019, Missouri estimated that it would have cost the prison system \$90 million, almost 70% of its medical budget, to treat every incarcerated person with HCV).
- 90 *Stafford v. Carter*, No. 117CV00289JMSMJ, 2018 WL 4361639, at *10 (S.D. Ind. Sept. 13, 2018), available at <https://clearinghouse.net/doc/103098/>.
- 91 *Atkins v. Parker*, 412 F. Supp. 3d at 765 (M.D. Tenn. 2019).
- 92 Florko, *supra* note 22.
- 93 Nicholas Florko, *These 8 States Are Doing the Worst Job of Treating Hepatitis C in Prisons*, STAT (Dec. 15, 2022).
- 94 *Id.*
- 95 Florko, *supra* note 22.
- 96 *E.g.*, Clinical Service Division Procedure 4.5.11A, Mont. Dep’t of Corr. (April 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”); State of Iowa Department of Corrections, Policy and Procedures. Chapter 6: Health Services, Sub Chapter: Infection Control, Subject: Hepatitis C Management. Policy Number HSP-912, Part IV(E) (restricting treatment to those with evidence of advanced disease, such as Fibrosure score of at least F2 or cirrhosis, or with other signs of advanced disease or high-risk coinfections). These and other policy documents referenced in this paper are available in .pdf form in a Google drive folder at this link: <https://clearinghouse.net/resource/3840/>. South Dakota prioritizes for treatment incarcerated people with F3 fibrosis or other serious risk factors, like HIV. See Florko, *supra* note 93. 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 46, at 13.
- 97 2022 AASLD/IDSA Guidance, *supra* note 2, at 25-26.

- 98 *E.g., Woodcock v. Correct Care Sols.*, 861 F. App'x 654, 656, 658 (6th Cir. 2021) (describing pre-2020 policy in Kentucky DOC that disqualified from DAA treatment incarcerated people who did not have a clear conduct record for 12-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”), available at <https://clearinghouse.net/doc/112003/>; FBOP Guidance, *supra* note 46, at 13 (“Inmates must demonstrate a willingness and an ability to adhere to a rigorous treatment regimen.”); Clinical Service Division Procedure 4.5.11A, Mont. Dep’t of Corr. (April 9, 2021), (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”), available at <https://clearinghouse.net/resource/3840/>; State of Iowa Department of Corrections, Policy and Procedures. Chapter 6: Health Services, Sub Chapter: Infection Control, Subject: Hepatitis C Management. Policy Number HSP-912, Part 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 12 months), available at <https://clearinghouse.net/resource/3840/>. 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 93.
- 99 See Sabrina A. Assoumou et al., *Cost-effectiveness and Budgetary Impact of Hepatitis C Virus Testing, Treatment, and Linkage to Care in US Prisons*, 70(7) CLINICAL INFECTIOUS DISEASES 1388 (2020), available at <https://pubmed.ncbi.nlm.nih.gov/31095676/>.
- 100 *E.g., Tianhua He et al., Prevention of Hepatitis C by Screening and Treatment in U.S. Prisons*, 164 ANNALS OF INTERNAL MEDICINE 84, (2016); Akiyama et al., *supra* note 13, at 394.
- 101 See, e.g., Justin Chan et al., *Outcomes of Hepatitis C Virus Treatment in the New York City Jail Population: Successes and Challenges Facing Scale Up of Care*, 7(7) OPEN FORUM INFECTIOUS DISEASES (2020), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7580175/>; Shan Liu et al., *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 MEDICINE 546 (2014), <https://pubmed.ncbi.nlm.nih.gov/25329202/>.
- 102 See e.g., Richard K. Sterling et al., *Treatment of HCV in the Department of Corrections in the Era of Oral Medications*, 24 J. CORR. HEALTH CARE 127 (2018); John Scott, *A Population-Based Intervention to Improve Care Cascades of Patients With Hepatitis C Virus Infection*, 5 HEPATOLOGY COMM’NS 387 (2021).
- 103 See e.g., Sanjeev Arora et al., *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); About the ECHO Model, Project Echo, <https://hsc.unm.edu/echo/what-we-do/about-the-echo-model.html>.
- 104 See e.g., Sanjeev Arora et al., *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/>.

- 105 See Benjamin P. Linas et al., *Cost Effectiveness and Cost Containment in the Era of Interferon-Free Therapies to Treat Hepatitis C Virus Genotype 1*, 4(1) OPEN FORUM INFECTIOUS DISEASE (Dec. 2016) (suggesting that approaches to cost savings should focus on negotiating for lower drug prices and not on delaying or rationing treatment), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5414108/>; Janet Weiner & Benjamin P. Linas, *Issue Brief: Cost-Effective Screening and Treatment of Hepatitis C*, PENN LEONARD DAVID INSTITUTE OF HEALTH ECONOMICS AND CENTER FOR HEALTH ECONOMICS OF TREATMENT INTERVENTIONS FOR SUBSTANCE USE DISORDER, HCV, AND HIV (Sept. 14, 2018) (summarizing studies confirming the cost-effectiveness of widespread early-stage DAA treatment), <https://ldi.upenn.edu/our-work/research-updates/cost-effective-screening-and-treatment-of-hepatitis-c/>; David E. Kaplan et al., *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), (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), available at <https://www.jmcp.org/doi/full/10.18553/jmcp.2022.28.10.1138>.
- 106 See Section I(3) *supra*.
- 107 DAA prices far outstrip manufacturing costs. See, e.g., Andrew Hill et al., *supra* note 67.
- 108 See, e.g., Adam L. Beckman et al., *Follow California's Lead: Treat Inmates with Hepatitis C*, HEALTH AFFAIRS BLOG (July 24, 2018) (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), <https://www.healthaffairs.org/doi/10.1377/forefront.20180724.396136/full/>; see also, generally, John T. Nguyen et al., *A Budget Impact Analysis of Newly Available Hepatitis C Therapeutics and the Financial Burden on a State Correctional System*, 92(4) J. URBAN HEALTH 635 (Aug. 2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4524840/>.
- 109 See Spaulding et al., *supra* note 89, 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, *In Re HCV Prison Litigation*, No. 3:19-cv-00577 (D. Nev. Oct. 29, 2020) ¶14 [*hereinafter* “Consent Decree, *In Re HCV*”], available at <https://clearinghouse.net/doc/112688/>.
- 110 Interview with Samuel Weiss, Executive Director, Rights Behind Bars (October 12, 2022).
- 111 Matthew J Akiyama et al., *Drug Purchasing Strategies to Treat People with Hepatitis C in the Criminal Justice System*, 108 Am. J. PUB. HEALTH 607 (May 2018), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5888063/>.
- 112 See Florko, *supra* note 68.
- 113 See Beckman et al., *supra* note 81, 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).

- 114 See Spaulding et al., *supra* note 89, at 20-22.
- 115 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 et al., *Five Questions Concerning Managing Hepatitis C in the Justice System*, at 337, <https://par.nsf.gov/servlets/purl/10066200>.
- 116 See Beckman et al., *supra* note 81, at 1899.
- 117 See Florko, *supra* note 68.
- 118 See, e.g., Sweta Haldar and Madeline Guth, *State Policies Connecting Justice Involved Populations to Medicaid Coverage and Care*, KAISER FAMILY FOUNDATION (December 17, 2021), <https://www.kff.org/medicaid/issue-brief/state-policies-connecting-justice-involved-populations-to-medicaid-coverage-and-care/>.
- 119 Two of the lawsuits that inform the recommendations in this white 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*: <https://clearinghouse.net/case/18232/>. For more information about the Vermont case, see *West v. Gobeille*: <https://clearinghouse.net/case/18238/>.
- 120 *Estelle v. Gamble*, 429 U.S. 97, 103 (1976).
- 121 *Id.*
- 122 See, e.g., *Erickson v. Pardus*, 551 US 89, 90 (2007).
- 123 E.g., *Hoffer v. Sec’y, Fla. Dep’t of Corr.*, 973 F.3d 1263, 1270 (11th Cir. 2020), available at <https://clearinghouse.net/doc/111607/>.
- 124 E.g., *Bernier v. Allen*, 38 F.4th 1145, 1151 (D.C. Cir. 2022), available at <https://clearinghouse.net/doc/136957/>.
- 125 *Farmer v. Brennan*, 511 U.S. 825, 837 (1994).
- 126 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).
- 127 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).
- 128 *Estelle*, 429 U.S. at 105-106.

- 129 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.”).
- 130 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*, 972 F.3d at 740.
- 131 *Bernier*, 38 F.4th 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), available at <https://clearinghouse.net/doc/136954/>.
- 132 *Hoffer*, 973 F.3d at 1277.
- 133 See *id.*
- 134 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, 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).
- 135 The Civil Rights Litigation Clearinghouse has collected dozens of class action and putative class action lawsuits bringing Eighth Amendment challenges in this context. Those cases are available here: https://clearinghouse.net/search/case/?special_collection=33558.
- 136 E.g. *Turner v. Wetzel*, No. 21-2879, 2022 WL 3572693, at *2 (3d Cir. 2022), available at <https://clearinghouse.net/doc/136959/>; *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.”), available at <https://clearinghouse.net/doc/99138/>
- 137 *E.g. Woodcock*, 861 F. App’x at 660-661; *Hoffer*, 973 F.3d at 1272.
- 138 *Woodcock*, 861 F. App’x at 660.
- 139 *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 fibrosure 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.”).
- 140 *Woodcock*, 861 F. App’x at 660-661.
- 141 *E.g. Turner* 2022 WL at *3 (vacating and remanding district court’s grant of summary judgment on Eighth Amendment claim).
- 142 See also *Stafford v. Carter*, No. 117CV00289JMSMJD, 2018 WL 4361639, at *22 (S.D. Ind. Sept. 13, 2018) (granting summary judgment for plaintiffs on their Eighth Amendment claim, reasoning that “the undisputed evidence in this case establishes that Plaintiffs’ need for medical treatment is toward the high end of the range, and Defendants’ deliberate refusal to provide that treatment constitutes a violation of the Eighth Amendment”), available at <https://clearinghouse.net/doc/103098/>; *Chimenti v. Pennsylvania Dep’t of Corr.*, No. CV 15-3333, 2017 WL 3394605, at *7 (E.D. Pa. Aug. 8, 2017) (“[T]he Amended Complaint sufficiently alleges that the DOC’s use of its Hepatitis C Protocol to ration medical treatment with DAAs based solely on cost, even though there is no other recommended medical treatment for Chronic Hepatitis C, disregards an excessive risk to the health of the infected inmates and thus constitutes deliberate indifference to a serious medical need.”), available at <https://clearinghouse.net/doc/99134/>; *Melnik v. Aranas*, No. 20-15471, 2021 WL 5768468, at *2 (9th Cir. Dec. 6, 2021) (reversing district court’s grant of qualified immunity to a physician, reasoning that a reasonable official should have been on notice that delaying HCV treatment for non-medical reasons and contrary to existing department of corrections policy would violate the Eighth Amendment), available at <https://clearinghouse.net/doc/136955/>.
- 143 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/>.
- 144 See *id.*; see also Daniels & Studdert, *supra* note 127, at 611.
- 145 *E.g.*, Weiss, *supra* note 143.
- 146 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. *E.g.*, Third Amended Complaint, *Ligons v. Minn. Dep't of Corr.*, No. 0:15-cv-02210, ¶¶162-174 (D. Minn. Dec. 1, 2017), available at <https://clearinghouse.net/doc/98906/>; Corrected First Amended Complaint, *Barfield v. Semple*, No. 3:18-cv-01198, ¶¶359-370 (D. Conn. Dec. 21, 2018), available at <https://clearinghouse.net/doc/112606/>; Amended Class Action Complaint, *In Re HCV Prison Litigation*, No. 3:19-cv-00577, ¶¶135-143 (D. Nev. Dec. 9, 2019), available at <https://clearinghouse.net/doc/112675/>; Class Action Complaint for Declaratory and Injunctive Relief, *Hoffer v. Jones*, No. 4:17-cv-00214, ¶¶152-163 (N.D. Fla. May 11, 2017), available at <https://clearinghouse.net/doc/88705/>. 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), *E.g.*, Ruling on Motion to Dismiss, *Barfield v. Semple*, No. 3:18-CV-1198, at 32-35 (D. Conn. Aug. 6, 2019), available at <https://clearinghouse.net/doc/112607/>, or concluding ADA and Rehabilitation Act claims are poorly suited to class action lawsuits, *e.g.*, *Hoffer v. Inch*, 382 F. Supp. 3d 1288, 1296-1298 (N.D. Fla. 2019), *rev'd in part, vacated in part sub nom. Hoffer v. Sec'y, Fla. Dep't of Corr.*, 973 F.3d 1263 (11th Cir. 2020), available at <https://clearinghouse.net/doc/107239/>.

- 147 See, *e.g.*, *Hoffer*, 973 F.3d at 1279 (reversing district court rulings requiring universal DAA treatment regardless of level of fibrosis).
- 148 See, for example, the Consent Decree for Chronic Hepatitis C Treatment in *Geissler v. Stirling*, No. 4:17-cv-01746 (D. S.C. June 8, 2020), which, in its introduction, explains: “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.” *Id.* § I(2), available at <https://clearinghouse.net/doc/131291/>.
- 149 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), <https://www.aclu.org/press-releases/aclu-and-colorado-department-corrections-reach-historic-settlement-treat-all-colorado>; 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*”], available at <https://clearinghouse.net/doc/133751/>; Indiana, see Stipulation to Enter Into Settlement Agreement, *Stafford v. Carter* (S.D. Ind. Aug. 9, 2019) [*hereinafter* “Settlement Agreement, *Stafford*”], available

- at <https://clearinghouse.net/doc/103100/>; Massachusetts, see Settlement Agreement, *Fowler v. Turco*, (D. Mass. Mar. 9, 2018), available at <https://clearinghouse.net/doc/101643/>; 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*"], available at <https://clearinghouse.net/doc/106687/>; 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*"], available at <https://clearinghouse.net/doc/111454/>; Nevada, see Consent Decree, *In Re HCV*, *supra* note 109; North Carolina, see Consent Decree, *Buffkin v. Hooks*, No. 1:18-cv-00502 (M.D. N.C. Mar. 8, 2021) [hereinafter "Consent Decree, *Buffkin*"], available at <https://clearinghouse.net/doc/131006/>; South Carolina, see Consent Decree, *Geissler*, *supra* note 148; 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*"], available at <https://clearinghouse.net/doc/102382/>; Texas, see Settlement Agreement, *Roppolo v. Linthicum*, No. 2:19-cv-262 (S.D. Tex. Mar. 1, 2021), available at <https://clearinghouse.net/doc/133979/>; 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*"], available at <https://clearinghouse.net/doc/130168/>. 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*"], available at <https://clearinghouse.net/doc/133977/>.
- 150 See Settlement Agreement, *Stafford*, *supra* note 149.
- 151 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>; see also Superseding Settlement Agreement, *Barfield*, *supra* note 149.
- 152 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>.
- 153 Nicholas Florke, *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/>; see also case information about *Loisel v. Clinton*, 1:19-cv-00081 (D. Maine), at <https://clearinghouse.net/case/18240/>.
- 154 See Exhibit 1: Settlement Agreement, Plaintiffs' Motion to Approve Settlement, *Roppolo v. Linthicum* (S.D. Tex. March 1, 2021), available at <https://clearinghouse-umich-production.s3.amazonaws.com/media/doc/133979.pdf>; 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/>.
- 155 See Settlement Agreement, *West*, *supra* note 149; see also Exhibit 2: Hepatitis C Virus Treatment Program, VitalCore Health Strategies Health Services Policy and Procedure (January 1, 2021), <https://clearinghouse.net/doc/136284/>.

- 156 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 *Acknowledgments*.
- 157 Indeed, Section 504 of the 1973 Rehabilitation Act, 29 U.S.C. §§ 794 *et seq.*, and Title II of the ADA, 42 U.S.C. §§ 12131 *et seq.*, 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 24 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). 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); 28 C.F.R. § 39.130(b)(1); 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).
- 158 Note, however, that jails may increasingly house people who have already been sentenced and as to 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 Justice Statistics, U.S. DEP'T OF JUSTICE (Dec. 2021), at 25 tbl. 12 (6% of sentenced incarcerated people held in local jails in 2020), <https://bjs.ojp.gov/content/pub/pdf/p20st.pdf>.
- 159 Consent Decree, *Geissler*, *supra* note 148, ¶¶ 42-45; Settlement Agreement, *Lignons*, *supra* note 149, § I(B)(1); Settlement Agreement, *Postawko*, *supra* note 149, §§ I(R); III(B)(1); Conn. Dep't of Corr. Administrative Directive 8.18 § 5(b) (Aug. 7. 2019), available at <https://clearinghouse.net/resource/3840/>; Maine Dep't of Corr. Policy 18.8.3: Management and Treatment of Hepatitis C (March 16, 2021), Proc. B-C available at <https://clearinghouse.net/resource/3840/>; see also Policy Directive 670.000 § II(B), Wash. Dep't of Corr. (“Screening will be conducted for incarcerated individuals at intake, unless refused, for . . . hepatitis C”), available at <https://clearinghouse.net/resource/3840/>; Policy Statement 13.2.1 §§ 8-02(4)(b), 20-1(B)(a), Penn. Dep't of Corr. (April 4, 2022), available at <https://clearinghouse.net/resource/3840/>; Kristin Walsh & Maya Yoshida-Cervantes, *Hepatitis C Screening in the Santa Clara County Jail: Update and Progress*, Presentation: 7th Annual National Hepatitis Corrections Network Meeting (2019), https://www.hcvinprison.org/images/stories/Walsh_-_HCV_Screening_in_the_Santa_Clara_County_Jail_-_Updates_and_Progress.pdf; Viral Hepatitis: Testing Recommendations for Hepatitis C Virus Infection, Centers for Disease Control and Prevention (July 29, 2020) (describing ongoing risk factors supporting routine testing, including people who currently inject drugs and share needles,

- syringes, or other drug preparation equipment, and people with particular medical conditions), <https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm>; 2022 AASLD/IDSA Guidance, *supra* note 2, at 182-183.
- 160 See Section I(C), *supra*.
- 161 Viral Hepatitis: Testing Recommendations for Hepatitis C Virus Infection, *supra* note 159.
- 162 AASLD/IDSA Guidance, *supra* note 2, at 12-13.
- 163 Hepatitis C Questions and Answers for Health Professionals, Centers for Disease Control and Prevention, *supra* note 37.
- 164 *Id.*
- 165 *Id.*
- 166 See, e.g., *Hepatitis C Reflex Testing*, New York State Department of Health (Sept. 2020), https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis_c/providers/reflex_testing.htm.
- 167 See He et al., *supra* note 100 (“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 19, at 391.
- 168 See, e.g., Ben T. Schoenbachler et al., *Hepatitis C Virus Testing and Linkage to Care in North Carolina and South Carolina Jails, 2012-2014*, 131 PUB. HEALTH REPORTS 98 (2016) (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”), available at <https://journals.sagepub.com/doi/epdf/10.1177/00333549161310S215>.
- 169 Treatment of HCV in a Correctional Setting, Hepatitis C Online, *supra* note 18, at 2.
- 170 *Id.*
- 171 FBOP Guidance, *supra* note 46, at 6.
- 172 See note 167, *supra*; 2022 AASLD/IDSA Guidance, *supra* note 2, at 180-182. 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. FBOP Guidance, *supra* note 46, at 6.
- 173 Scripts like this one, developed to assist in implementing opt-out HIV testing, may be useful. *Implementing Opt-Out HIV Screening in Your Health Center*, HEALTH INFORMATION TECHNOLOGY, EVALUATION, & QUALITY CENTER (Nov. 20, 2020) (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), <https://hiteqcenter.org/Resources/HITEQ-Resources/implementing-opt-out-hiv-screening-in-your-health-center>. 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*, High-Impact HIV Prevention in Healthcare Organizations (2018), https://www.pcdc.org/wp-content/uploads/Resources/Category-C-PCDC-Opt-out-HIV-Testing-Final-Cleared-3.29.18_R.pdf.
- 174 Settlement Agreement, *Postawko*, *supra* note 149, § III(A)(5); Settlement Agreement, *Ligons*, *supra* note 149, § I(B)(2); Settlement Agreement, *Chimenti*, *supra* note 149 § 4; FBOP Guidance 8-11; Medical Directive 319.02, Nev. Dep’t of Corr. (July 2020), available at <https://clearinghouse.net/resource/3840/>.
- 175 Brianna L. Norton et al., *Low Adherence Achieves High HCV Cure Rates Among People Who Inject Drugs Treated with Direct-Acting Antiviral Agents*, 7(10) OPEN FORUM INFECTIOUS DISEASE, (Aug. 2020), <https://pubmed.ncbi.nlm.nih.gov/33134406/>.
- 176 Sunil S. Solomon et al., *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 GASTROENTEROL HEPATOL 307 (2022), <https://pubmed.ncbi.nlm.nih.gov/35026142/>.
- 177 Maine Dep’t of Corr. Policy 18.8.3: Management and Treatment of Hepatitis C (March 16, 2021), Proc. D, available at <https://clearinghouse.net/resource/3840/>; Settlement Agreement, *West*, *supra* note 149, ¶ 6; Settlement Agreement, *Stafford*, *supra* note 149, § IV(9); Settlement Agreement, *Ligons*, *supra* note 149, §§ I(B)(6), I(C)(3); Settlement Agreement, *Chimenti*, *supra* note 149 § 4; CT Doc 8.18(6)a; Consent Decree, *Geissler*, *supra* note 148, ¶¶ 37-44; Consent Decree, *In Re HCV*, *supra* note 149, ¶ 38; AASLD/IDSA Guidance at 65; FBOP Guidance at 22; Exhibit 2: Hepatitis C Virus Treatment Program, VitalCore Health Strategies Health Services Policy and Procedure (January 1, 2021), available at <https://clearinghouse.net/doc/136284/>.
- 178 See, for example, Settlement Agreement, *Stafford*, *supra* note 149, § 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 149, § I(C)(3) (“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 148, ¶ 39 (requiring treatment to be offered within 120 days of diagnosis).
- 179 Consent Decree, *Geissler*, *supra* note 148, ¶ 37, ¶ 38(h); Settlement Agreement, *West*, *supra* note 149, ¶ 6; Settlement Agreement, *Stafford*, *supra* note 149, § IV(9); Settlement Agreement, *Ligons*, *supra* note 149, § I(B)(6); FBOP Guidance, *supra* note 46, at 12-14.
- 180 2022 AASLD/IDSA Guidance, *supra* note 2, at 183-184; FBOP Guidance, *supra* note 46, at 13.
- 181 2022 AASLD/IDSA Guidance, *supra* note 2, at 179-183; see also FBOP Guidance, *supra* note 46, at 12.

- 182 FBOP Guidance, *supra* note 46, at 12.
- 183 FBOP Guidance, *supra* note 46, at 12.
- 184 2022 AASLD/IDSA Guidance, *supra* note 2, at 21.
- 185 Treatment of HCV in a Correctional Setting, Hepatitis C Online, *supra* note 18, at 2.
- 186 Matthew J. Akiyama et al., *Knowledge, attitudes, and acceptability of antiviral hepatitis C treatment among people incarcerated in jail: A qualitative study*, 15(12) PLoS ONE (Dec. 2, 2020), at 2, available at <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0242623>.
- 187 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 Justice Statistics, U.S. DEPT OF JUST., at 4 (Dec. 2021), <https://bjs.ojp.gov/content/pub/pdf/ji20st.pdf>.
- 188 Akiyama et al., *supra* note 19, at 395.
- 189 *Id.* at 395-396.
- 190 Akiyama et al., *supra* note 186, at 10.
- 191 See Chan, *supra* note 101.
- 192 *Id.*
- 193 2022 AASLD/IDSA Guidance, *supra* note 2, at 179.
- 194 FBOP Guidance, *supra* note 46, at 13-14.
- 195 Settlement Agreement, *Lignons*, *supra* note 149, § II; Consent Decree, *Buffkin*, *supra* note 149, § 3(a)(i); see also Exh. C (Hepatitis C Virus (HCV) Educational Pamphlet), Consent Decree, *Geissler*, *supra* note 148.
- 196 2022 AASLD/IDSA Guidance, *supra* note 2, at 18-19.
- 197 See, for example, the Hepatitis Education Project: <https://hepeducation.org/programs/correctional-health-education/>.
- 198 See, e.g., Karla Thornton et al., *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/>; Peer Education Programs, National Hepatitis Corrections Network, <https://www.hcvinprison.org/resources/71-main-content/content/200-peereducation> (listing and describing examples).
- 199 See, e.g., Miranda Surjadi et al., *Formal Patient Education Improves Patient Knowledge of Hepatitis C in Vulnerable Populations*, 56 DIGESTIVE DISEASES & SCIENCES 213 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3008930/>; Samali Lubega et al., *Formal Hepatitis C Education Enhances HCV Care Coordination, Expedites HCV Treatment, and Improves Antiviral Response*, 33:7 LIVER INT. 999 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3692599/>; Diana Partida et al., *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 INFECTIOUS DISEASE (Mar. 2022), <https://academic.oup.com/ofid/article/9/4/ofac103/6540486>.

- 200 Interview with Mandy Altman, Correctional Health Program Manager, Hepatitis Education Project, Director, National Hepatitis Corrections Network (Nov. 3, 2022).
- 201 Consent Decree, Geissler, *supra* note 148, ¶¶ 46-47; Consent Decree, *In Re HCV*, *supra* note 149, ¶ 40; Settlement Agreement, *Stafford*, *supra* note 149, § IV(15)(ii); Superseding Settlement Agreement, *Barfield*, *supra* note 149, ¶ 4.
- 202 *E.g.*, Settlement Agreement, *Postawko*, *supra* note 149, § III(D). Some non-governmental organizations may be available to support staff training efforts. Interview with Mandy Altman, *supra* note 200.
- 203 *E.g.*, Conn. Dep't of Corr. Administrative Directive 8.18, *supra* note 159, § 4; Proposed Settlement Agreement, *Turney*, *supra* note 149, ¶ 3.5.

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Appendix: How to Use the Civil Rights Litigation Clearinghouse

We thought it would be useful to present a how-to for the Civil Rights Litigation Clearinghouse, <http://clearinghouse.net>, which collects, indexes, and makes publicly available for research and observation a growing universe of civil rights cases, and the settlements and court orders those cases have produced, which regulate government and private entities in myriad important ways.

The Clearinghouse collection comprises thousands of cases and litigation documents. Each case has a page that includes a summary of the litigation and related dockets, documents, and resources. And each case has been indexed across various categories, so the database is fully searchable, via the search bar on the homepage, by dozens of criteria including substantive “case type,” legal “cause of action” and/or “constitutional clause” undergirding the legal claim; thematic “issues”; class action status; outcome; available documents, and more. These searches can be run individually or in combination with each other.

The cases relevant to this white paper project form one of the Clearinghouse’s [Special Collections](#), a pre-tagged group of cases: “[Hepatitis C Treatment in Jails and Prisons](#).” To find particular cases within the special collection, use one or multiple of the search features on the left side of the special collection page. You can retrieve the same results from the home page, too, as long as this special collection is selected in the relevant search bar (“Select special collection”).

Search for: Cases and documents ▾

clear search

Search text

Search case name

Select case types

Select special collection

Metadata

Foreign Intelligence Surveillance Act -- Telephony Metadata

Foreign Intelligence Surveillance Court

Healthy Elections COVID litigation tracker

Hepatitis C Treatment in Jails and Prisons

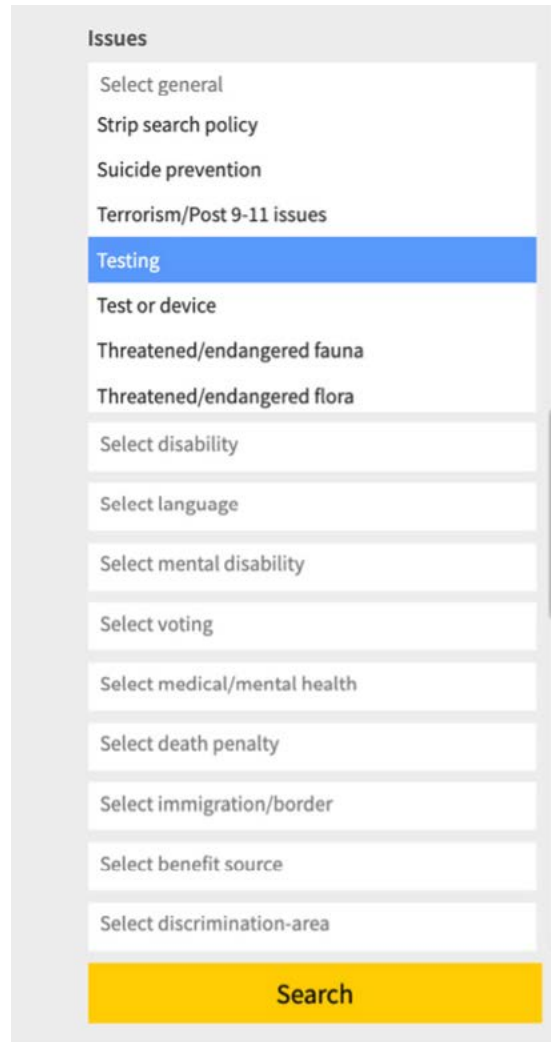
Immigrant Detention Labor Issues

Docket number

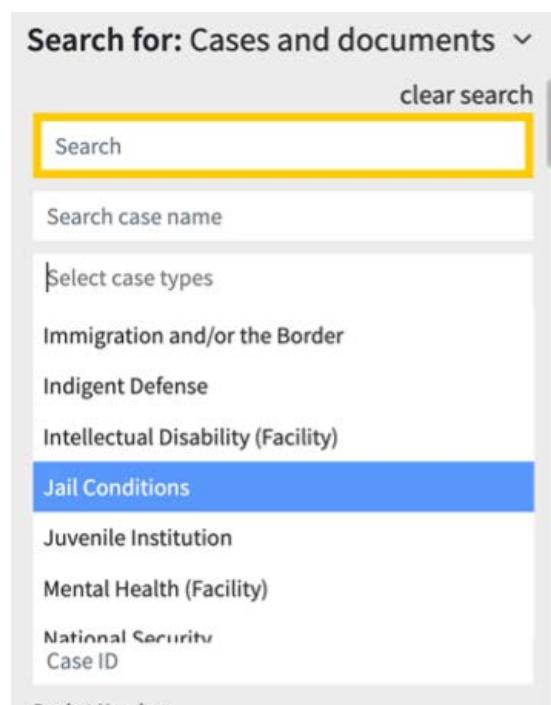
Year — Filing Number

Examples of searches within the special collection may include:

To limit a search to cases also involving HCV testing, select “testing” under the “General” Issues category.



To find cases challenging conditions in jails, choose “Jail Conditions” under “Select case types.” (Or, for prison cases, “Prison Conditions.”)



To find cases that have settled, under “Outcome,” select both “Court Approved Settlement or Consent Decree” and “Private Settlement Agreement” in the “form of settlement” box.

The image shows two screenshots of the 'Outcome' filter section. The left screenshot shows the 'form of settlement' dropdown menu with the following options: 'Select prevailing party', 'Select nature of relief', 'Select source of relief', 'Select form of settlement', and 'Select content of injunction'. The right screenshot shows the same menu with 'Court Approved Settlement or Consent Decree' and 'Private Settlement Agreement' selected, indicated by a yellow highlight and a small 'x' icon.

To find copies of these settlement agreements in our database, under “Document Details,” select “Settlement Agreement” under “document type.”

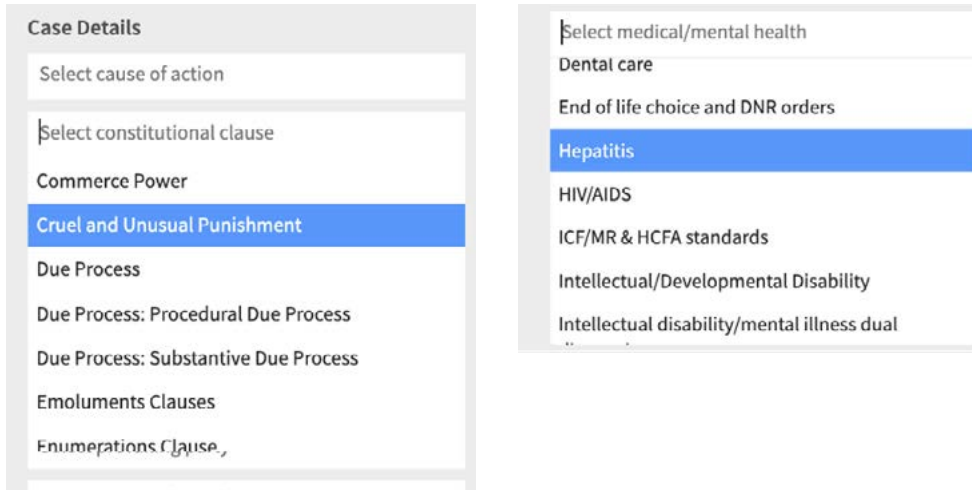
The image shows two screenshots of the 'Document Details' filter section. The left screenshot shows the 'document type' dropdown menu with the following options: 'Search document title', 'Search document text', 'Select document type', 'ECF Number', 'Document ID', and 'MORE'. The right screenshot shows the same menu with 'Settlement Agreement' selected, indicated by a blue highlight.

To limit a search to cases filed, settled, and/or terminated on or after a particular date, use the “Key Dates” search functions.

The image shows the 'Key Dates' search function. It includes the following fields: 'Filing Date' (From and To), 'Settlement / Judgment Date' (From and To), 'Terminating Date' (From and To), and 'Select case ongoing' (dropdown menu).

If you are interested in another group of cases, or in searching the database generally, note: It is possible to perform similar searches, combining various search criteria, across the entire Clearinghouse collection (not just limited to a special collection).

For example, if you wanted to replicate (nearly) the contents of this special collection, you could search for cases by: (a) under case details, in the “select constitutional clause” box, choosing “Cruel and Unusual Punishment;” and (b) under the “issues” category of “medical/mental health,” selecting “Hepatitis.”



Note, too, that creating an account on the Clearinghouse permits saving searches (as well as particular cases and documents) to an account-specific “Bookmarks” page for easy reference later.

