PHR/Volume 135, Supplement 1
MS# 19-0129HHST
Section Header: Commentary
Peripherals: 2 tables
Keywords: health policy, hepatitis, law/legal issues, Medicaid/Medicare, addiction, correctional facilities/prisons

Enforcement of Legal Remedies to Secure Hepatitis C Virus Treatment With Direct-Acting Antiviral Therapies in Correctional Facilities and Medicaid Programs

Robert Greenwald, JD[1]; Phillip Waters, JD[1]; and Sarah Cayer, BA[1]

[1] Center for Health Law and Policy Innovation, Harvard Law School, Cambridge, MA, USA

Corresponding Author:
Phillip Waters, JD, Harvard Law School, Center for Health Law and Policy Innovation, 1585 Massachusetts Ave, Cambridge, MA 02138, USA.
Email: pwaters@law.harvard.edu

Hepatitis C virus (HCV) infection is a communicable disease that affected approximately 3.5 million persons in the United States as of 2017.[1] Despite the introduction of new, highly effective treatments in 2011,[2] HCV infection rates in the United States tripled from 850 in 2010 to 2436 in 2015.[1] This increase was largely a result of the opioid epidemic, with injection drug use the most common method of new HCV transmissions.[3] Additionally, the lack of enforcement of laws that entitle persons to life-saving, medically necessary care such as HCV treatment is a missed opportunity to reverse this trend.

New treatments for HCV infection with direct-acting antiviral (DAA) therapies are curative for patients and eliminate their ability to spread the virus. However, US health systems have not responded to the potential of new treatments by promoting access to them. Instead, because of high initial list prices,[4] state Medicaid programs and correctional health facilities have created rationing. They have limited access to HCV treatment by instituting restrictions that are based on disease severity, as measured by damage to the liver (ie, treating only persons with advanced-stage HCV infection) and prescriber specialty. Additionally, despite the syndemic between the opioid crisis and increasing use of injection drugs, periods of sobriety from drugs and/or alcohol are required before treatment.[5] These restrictions contradict leading medical guidance recommending treatment of virtually all persons with chronic HCV infection and hinder our ability to reduce HCV incidence, let alone end the HCV epidemic.[3] Despite the tension created between scarce resources and public health concerns, the initial budgetary fears cited as justifications for restrictions were less severe than anticipated and have diminished over time, in part because increased competition has led to decreased prices.[6]

Regardless of the rationale used to explain limitations on access to treatment, such restrictions violate federal laws. As a result, litigation to remove barriers to HCV treatment in both correctional facilities and state Medicaid programs has met with success. Litigation seeking to enforce the 8th Amendment to the US Constitution (prohibiting cruel and unusual punishment) has successfully removed disease severity restrictions imposed by correctional facilities in several states.[7-9] Similarly, lawsuits aimed to enforce federal Medicaid law (known colloquially as the "Medicaid Act")[10] have been successful. As of January 2019, most states had removed their disease severity restrictions for HCV treatment; only 13 states (Alabama, Arkansas, Indiana, Iowa, Louisiana, Maryland, Michigan, Montana, Nebraska, Oregon, South Dakota, Texas, and West Virginia) still maintained restrictions in their Medicaid programs. Nineteen states still imposed sobriety restrictions ranging from 1 to 6 months in their Medicaid programs (Table 1).[11]

This commentary reviews the role of the courts in removing HCV treatment restrictions by summarizing and analyzing successful litigation using the Medicaid Act and the 8th Amendment. To

our knowledge, this is the first commentary to synthesize these legal theories. Additionally, we propose a novel legal strategy under the Americans With Disabilities Act (ADA)[12] to challenge sobriety restrictions; this approach has largely been untested but may provide another avenue to further expand access to HCV treatment for persons with a history of substance use.

Methods

The authors have knowledge and experience about the legal mechanisms that have been used to address access to medication in public health care programs in the United States. We conducted keyword-based searches using legal databases (Lexis Advance and Westlaw) to identify decisions in which courts removed HCV treatment restrictions in state Medicaid programs and correctional facilities. We identified the Medicaid Act and the 8th Amendment as proven legal avenues for both individuals and classes of persons seeking relief from medication denials in state Medicaid programs and correctional facilities, respectively. To ensure we captured all relevant legal mechanisms, we additionally searched for all HCV-related litigation in Medicaid and correctional facilities. This search confirmed our initial research and identified the ADA as a potentially relevant enforcement strategy.

Although the Medicaid Act and 8th Amendment appeared to be well-established legal mechanisms for removing HCV treatment restrictions, we found that the ADA remained a largely untested legal theory. To ensure we were capturing all possible enforcement avenues, we expanded our research into the ADA to include both judicial and administrative enforcement actions. We quickly identified that even though HCV may not be easily characterized as a disability under the ADA, persons recovering from substance use disorders have been protected from discrimination in public programs under the ADA. Based on our research, we synthesized the existing legal landscape with respect to removing HCV treatment restrictions and proposed a novel strategy for using the ADA based on original thought and analysis.

HCV Litigation Challenging Disease Severity Restrictions

Since 2016, incarcerated persons and Medicaid enrollees have struck down disease severity rationing of DAA therapies. Incarcerated persons have primarily brought claims under the 8th Amendment, which, in the context of health care, generally forbids prison officials from exhibiting deliberate indifference to the serious medical needs of incarcerated persons.[13] Medicaid beneficiaries have primarily brought claims under the Medicaid Act, which generally requires that states provide enrollees with medically necessary treatment.[14] For both incarcerated persons and Medicaid enrollees,

successful litigation has taken the shape of persons representing themselves, attorneys bringing cases on behalf of their clients, and class-action lawsuits brought by attorneys representing groups of similarly situated persons infected with HCV. The class vehicle is particularly advantageous because any policy change that is affected by a court's ruling applies to the entire state correctional system or Medicaid program rather than a single case.

Class-action lawsuits based on 8th Amendment claims in Florida,[7] Indiana,[8] Pennsylvania,[9] and elsewhere have led to the removal of disease severity restrictions in correctional settings. Each court applied the 8th Amendment's prohibition of "cruel and unusual punishment" to require incarcerated persons to show that government officials are deliberately indifferent to their serious medical need. In these cases, the courts have uniformly recognized that untreated HCV infection is a serious medical need.[15] Additionally, these courts have held that state correctional facilities are exhibiting deliberate indifference by routinely denying DAA therapy based on disease severity (as measured by damage to the liver).[7]

At least 1 court has reached a different conclusion, ruling that a corrections system does not act with deliberate indifference when it applies a wait-and-see approach to persons with HCV infection because, despite the risks of delaying treatment, waiting to treat HCV infection until it becomes symptomatic did not rise to the level of deliberate indifference in this court's opinion.[16,17] This ruling is an outlier. Most courts recognize that a state violates the 8th Amendment when prison officials know that an incarcerated person is infected with HCV yet deny DAA therapy based on disease severity.[15,18,19] Successful class-action lawsuits brought by incarcerated persons have won policy and practice changes that benefit thousands of HCV-infected persons.[7]

Medicaid enrollees are subject to an entirely different set of legal rules and protections, but developments in the courts have likewise yielded promising results. Class-action lawsuits by Medicaid beneficiaries in Washington State,[20] Colorado,[21] Michigan,[22] Missouri,[23] and elsewhere have helped end DAA therapy rationing based on disease severity. In addition, in states such as Delaware,[24] Pennsylvania,[25] Oregon,[26] Rhode Island,[27] and Illinois,[28] formal pre-litigation demands from organized plaintiffs directly led to the removal of disease severity restrictions. In each case, Medicaid beneficiaries claimed that the state Medicaid program had violated federal law by limiting access to DAA therapy based on disease severity. The Medicaid Act requires that states provide necessary medical assistance, ensure comparable treatment and services to similarly situated Medicaid enrollees, and do so with reasonable promptness.[14,29,30] Courts have recognized that a state violates all relevant provisions of the Medicaid Act when it rations access to DAA therapy based on disease severity.[20]

Based on such rulings, plaintiffs have successfully used the Medicaid Act to secure statewide policy changes that expand access to DAA therapy.[22]

The Future: Challenging Sobriety Restrictions

Although a combination of coordinated advocacy, pretrial settlements, and litigation has reduced the use of sobriety restrictions, more work remains.[11] Support for the continued removal of sobriety restrictions has been promoted by both the Centers for Medicare & Medicaid Services (CMS) and leading professional associations of medical providers.

As early as 2015, CMS released legal guidance disapproving of sobriety restrictions. The guidance confirms that sobriety restrictions are impermissible if they unreasonably restrict access to effective HCV treatments.[31] Similarly, the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) also condemn sobriety restrictions. These professional associations caution against sobriety restrictions for persons who inject drugs, observing that successful treatment leads to an overall decrease in HCV prevalence.[3] Moreover, the AASLD points to research[32] showing that persons who inject drugs have high rates of adherence to treatment and clearance of the virus from the body.[3] The AASLD also notes that although excess alcohol use has negative effects on liver health and may speed the progression of HCV infection, data are lacking to support the categorical exclusion of persons from treatment based on alcohol intake.[33] In fact, treatment success with DAA therapy is high regardless of alcohol use, with only minimal variations seen among persons who report unhealthy drinking levels.[34]

The same reasons underlying the condemnation of sobriety restrictions by CMS and AASLD/IDSA might form the basis of successful challenges in court. Early litigation has already demonstrated that sobriety restrictions violate federal law in both correctional settings and state Medicaid programs. In *JEM v Kinkade,* the court ruled that Missouri Medicaid's sobriety restrictions violated the Medicaid Act.[23] Similarly, in *Postawko v Missouri Department of Corrections*, incarcerated plaintiffs argued that sobriety restrictions violated both the 8th Amendment and the ADA.[35] These plaintiffs advanced a theory of discrimination under the ADA that treats HCV infection as the relevant disability, alleging that denying treatment to HCV-infected Medicaid beneficiaries and incarcerated persons is impermissible discrimination on the basis of a disability. However, another court has held that this theory fails because the ADA cannot be used to challenge inadequate medical care.[36]

Despite some successes, case law supporting the elimination of sobriety restrictions is limited. In particular, the ADA represents a vastly under-enforced legal regime that holds great promise for the future of attacking sobriety restrictions. Title II of the ADA prohibits discrimination against persons with disabilities in providing public services.[37] That section of the ADA protects both Medicaid beneficiaries and incarcerated persons. To show a violation of the ADA, the affected person(s) must either have a disability or be so perceived.[38] The ADA defines a disability as "a physical or mental impairment that substantially limits one or more major life activities."[39] Persons with a history of substance use disorder, including those being treated with methadone[40] or Suboxone,[41] qualify as persons with disabilities for purposes of the ADA. The ADA recognizes that drug or alcohol addiction that "substantially limits one or more major life activities" is a disability.[38] Whether a person's condition and particular circumstances satisfy this determination is made on a case-by-case basis. Nevertheless, persons whose history of drug or alcohol use has led to impairment in their ability to live or work or has led them to seek rehabilitation are often deemed "disabled" under the ADA.

Although pursuing litigation is an ongoing option, government enforcement of the ADA may prove to be a more effective avenue for eliminating or reducing sobriety-based restrictions to DAA therapies. The ADA may be a particularly useful tool for opening access, because the US Department of Justice (DOJ) has the authority to enforce the ADA against public entities. For example, the DOJ has drafted and overseen agreements under the ADA that ensure access to public accommodations (which include health services delivered by Medicaid or correctional facilities) for persons receiving methadone and Suboxone for opioid use disorder.[40] If the DOJ identifies a violation of the ADA, it can bring a state or municipality into compliance.

For ADA protections to apply to persons affected by sobriety restrictions, the DOJ must find that the governmental entity is denying treatment that someone is otherwise entitled to receive.[38] As described previously, case law under both the Medicaid Act and the 8th Amendment has found that persons infected with HCV are entitled to receive timely and necessary HCV medical treatment. Given that leading professional associations, medical practitioners, and CMS have all recommended that HCV-infected persons be provided access to DAA therapy and that sobriety restrictions be eliminated, this requirement of the ADA is satisfied.

Finally, for the DOJ to act, it must conclude that a state has denied access to DAA therapy for HCV treatment based on a person's disability. This element of the ADA may be established through several methods, with the most relevant being a theory of "disparate treatment." Disparate treatment is the intentional differentiation between persons on the basis of disability without substantial

justification. Disparate treatment typically entails a discriminatory policy that "on its face applies less favorably to a protected group."[42]

A categorical refusal to treat persons until they reach a minimum length of sobriety is an example of disparate treatment. It treats persons with disabilities—recent substance use disorder—less favorably than persons who do not have disabilities. Courts have historically struck down such policies. For example, courts have invalidated a correctional facility's policy that categorically denied parole to persons with a history of substance use[38] and a local zoning code that explicitly restricted the establishment of addiction treatment centers.[43] In these cases, in which policies explicitly denied a public benefit to persons with actual or perceived substance use disorders, courts have identified the policies as being in violation of the ADA. The same should be true of sobriety restrictions for DAA therapy.

Government actors are likely to defend against such challenges by claiming their sobriety requirements fall within certain ADA exceptions. Defendants will argue that the ADA does not apply to persons who use illicit drugs. Although persons who are using illicit drugs[44] or who have recently ceased using drugs[45] may not be entitled to ADA protection for other public services, they cannot be denied health care on the basis of illicit drug use.[46] The ADA explicitly prohibits the denial of health care based on a disability, and treatment for HCV infection with DAA therapy is undoubtedly health care. States may also assert that the sobriety restriction falls into 1 of 2 categories of disparate treatment allowable under the ADA, such as when a policy "benefits the protected class" or "responds to legitimate safety concerns."[42] No evidence supports such assertions; studies of DAA therapies among persons who inject drugs[3] or misuse alcohol[34] show that the treatment is highly effective and the risk of reinfection is low. In fact, the AASLD recommends prioritizing treatment of injection drug users, because injection drug use is the main factor perpetuating the HCV epidemic.[47] On balance, the justifications for discriminatory sobriety restrictions do not withstand legal scrutiny. The ADA, along with the 8th Amendment and Medicaid Act (Table 2), provides the framework for ending discriminatory sobriety restrictions and securing access to DAA therapies.

Conclusion

Since the introduction of DAA therapies, state correctional facilities and Medicaid programs have erected numerous barriers to accessing HCV treatment. Litigation under the 8th Amendment and the Medicaid Act has been a successful tool for addressing barriers to accessing treatment, but sobriety restrictions that withhold treatment persist in many states. Administrative enforcement of the ADA by

the DOJ may prove to be an effective strategy for eliminating sobriety restrictions. This objective is critically important because expanding access to DAA therapies is necessary to promote individual health and to stop the spread of HCV infection in the United States.

Declaration of Conflicting Interests

The Center for Health Law and Policy Innovation receives financial support from AbbVie, Bristol-Myers Squibb Foundation, Gilead Sciences, and Janssen Pharmaceuticals. These contributions are for general operating and support the Center's advocacy efforts to expand access to treatment for underserved populations, including persons living with HCV infection. No specific support was provided for this article, and any conclusions reached are based on the authors' objective analysis of the law.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

References

1. New hepatitis C infections nearly tripled over five years [news release]. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; May 11, 2017. https://www.cdc.gov/media/releases/2017/p-hepatitis-c-infections-tripled.html. Accessed March 31, 2019.
2. Erickson SC, Qiu W, Maas-Patel CR, Wang SM, Patel BV. Recent trends in the treatment of chronic hepatitis C. *Pharmacy Times.* April 16, 2014. https://www.pharmacytimes.com/publications/ajpb/2014/ajpb_marapr2014/recent-trends-in-the-treatment-of-chronic-hepatitis-c. Accessed March 1, 2019.
3. American Association for the Study of Liver Diseases, Infectious Diseases Society of America. Key populations: identification and management of HCV in people who inject drugs. https://www.hcvguidelines.org/unique-populations/pwid. Updated May 24, 2018. Accessed March 31, 2019.
4. Bruen B, Brantley E, Thompson V, Steinmetz E, Helmchen L. *High-Cost HCV Drugs in Medicaid: Final Report.* Washington, DC: George Washington University, Milken Institute School of Public Health; January 2017. https://www.macpac.gov/wp-content/uploads/2017/03/High-Cost-HCV-Drugs-in-Medicaid-Final-Report.pdf. Accessed March 31, 2019.
5. Center for Health Law and Policy Innovation, Harvard Law School. Hepatitis C: the state of Medicaid access—2017 national summary report. Published October 23, 2017. https://stateofhepc.org/wp-content/uploads/2017/10/State-of-HepC_2017_FINAL.pdf. Accessed March 31, 2019.
6. Kapadia SN, Johnston CD, Marks KM, Schackman BR, Martin EG. Strategies for improving hepatitis C treatment access in the United States: state officials address high drug prices, stigma, and building treatment capacity. *J Public Health Manag Pract.* 2019;25(3):245-252. doi:10.1097/PHH.0000000000000829
7. *Hoffer v Jones*, 290 F Supp 3d 1292 (2017).
8. *Stafford v Carter*, 1:17-CV-00289, Dist Ct SD Indiana (2018).
9. *Chimenti v Wetzel*, 15-3333, East Dist Pa (2018).
10. Medicaid Act, 42 USC §1396 et seq (1965).
11. Center for Health Law and Policy Innovation, Harvard Law School. Hepatitis C: the state of Medicaid access: 1/31/19 update. https://www.chlpi.org/wp-content/uploads/2013/12/HCV_State-of-Medicaid-Access_January-2019-update-1.pdf. Accessed March 31, 2019.

12. Americans With Disabilities Act, Pub L No 101-336, 42 USC §§ 12101-12213 (1990).
13. *Estelle v Gamble*, 429 US 97 (1976).
14. Medicaid Act, 42 USC §1396a(a)(10)(A) (2019).
15. *Abu-Jamal v Wetzel*, 3:16-CV-2000, Md Penn (2017).
16. *Phelps v Wexford Health Sources, Inc*, ELH-16-2675, D Md (2017).
17. *Pevia v Wexford Health Sources, Inc*, ELH-16-1950, D Md (2018).
18. *Allah v Thomas* 16-3103, 3d Cir (2017).
19. *Cunningham v Sessions*, 9:16-cv-1292-RMG, DSC (2017).
20. *BE v Teeter*, C16-227-JCC, WD Wash (2016).
21. *Ryan v Birch*, 17-cv-00904-KLM, D Colo (2017).
22. *MR v Lyon*, 17-cv-11184-DPH-RSW, ED Mich (2018).
23. *JEM v Kinkade*, 2:16-cv-04273-SRB, DC WD Mo (2017).
24. Rini J. State changes hep C medication guidelines, avoids lawsuit. *Delaware Online*. June 7, 2016. https://www.delawareonline.com/story/news/health/2016/06/07/state-changes-hep-c-medication-guidelines-avoids-lawsuit/85554396. Accessed March 31, 2019.
25. Sapatkin D. In major shift, Pa. to expand hepatitis C treatment for Medicaid patients. *The Philadelphia Inquirer*. May 16, 2017. https://www.philly.com/philly/health/health-cents/In-major-shift-Pa-will-expand-hepatitis-C-treatment-for-Medicaid-patients.html. Accessed March 31, 2019.
26. Oregon Health Plan to end rationing of costly hepatitis C cure. *The Seattle Times*. December 19, 2018. https://www.seattletimes.com/seattle-news/northwest/oregon-health-plan-to-end-ration-of-costly-hepatitis-c-cure. Accessed March 31, 2019.
27. Miller GW. R.I. broadens Medicaid coverage for treatment of hepatitis C. *Providence Journal*. July 11, 2018. https://www.providencejournal.com/news/20180711/ri-broadens-medicaid-coverage-for-treatment-of-hepatitis-c. Accessed March 31, 2019.
28. Schencker L. As many as 7,000 Illinois Medicaid patients with hepatitis C gain new access to pricey—but lifesaving—drugs. *Chicago Tribune*. November 14, 2018. https://www.chicagotribune.com/business/ct-illinois-relaxes-restrictions-hepatitis-c-drugs-1115-story.html. Accessed March 31, 2019.
29. Medicaid Act, 42 USC §1396a(a)(10)(B) (2019).
30. Medicaid Act, 42 USC §1396a(a)(8) (2019).
31. US Department of Health and Human Services, Centers for Medicare & Medicaid Services. Assuring Medicaid beneficiaries access to hepatitis C (HCV) drugs.

https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf. November 5, 2015. Accessed March 31, 2019.

32. Grebeley J, Dalgard O, Conway B, et al; SIMPLIFY Study Group. Sofosbuvir and velpatasvir for hepatitis C virus infection in people with recent injection drug use (SIMPLIFY): an open-label, single-arm, phase 4, multicentre trial. *Lancet Gastroenterol Hepatol.* 2018;3(3):153-161. doi:10.1016/S2468-1253(17)30404-1
33. American Association for the Study of Liver Diseases, Infectious Diseases Society of America. HCV guidance: recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org/sites/default/files/full-guidance-pdf/HCVGuidance_May_24_2018b.pdf. Updated May 24, 2018. Accessed March 31, 2019.
34. Tsui JI, Williams EC, Green PK, Berry K, Su F, Ioannou GN. Alcohol use and hepatitis C virus treatment outcomes among patients receiving direct antiviral agents. *Drug Alcohol Depend*. 2016;169:101-109. doi:10.1016/j.drugalcdep.2016.10.021
35. *Postawko v Missouri Department of Corrections*, 2:16-CV-4219-NKL-P, WD Mo (2017).
36. *Ligons v Minnesota Department of Corrections*, 15-CV-2210, D Minn (2019).
37. Americans With Disabilities Act, Pub L No 101-336, 42 USC §12132 (2019).
38. *Thompson v Davis*, 295 F3d 890, 9th Cir (2002).
39. Americans With Disabilities Act, Pub L No 101-336, 42 USC §12102(1)(a) (2019).
40. US Department of Justice. Settlement agreement between the United States of America and Charlwell Operating, LLC under the Americans with Disabilities Act. https://www.ada.gov/charlwell_sa.html. May 10, 2018. Accessed March 31, 2019.
41. US Department of Justice. Settlement agreement between the United States of America and Selma Medical Associates, Inc. under the Americans with Disabilities Act. https://www.ada.gov/selma_medical_sa.html. January 31, 2019. Accessed March 31, 2019.
42. *Community House, Inc. v City of Boise, Idaho*, 490 F3d 1041, 9th Cir (2007).
43. *New Directions Treatment Services v City of Reading*, 490 F3d 293, 3rd Cir (2007).
44. Americans With Disabilities Act, 42 USC §12210(a) (2019).
45. *Brown v Lucky Stores*, 246 F3d 1182 (9th Cir 2001).
46. Americans with Disabilities Act, Pub L No 101-336, 42 USC §12210(c) (2019).

47. American Association for the Study of Liver Diseases, Infectious Diseases Society of America. When and in whom to initiate HCV therapy. https://www.hcvguidelines.org/evaluate/when-whom. Updated September 21, 2017. Accessed March 31, 2019.

Table 1. Sobriety restrictions for hepatitis C virus treatment with direct-acting antiviral (DAA) therapy in state Medicaid programs as of January 31, 2019[a]

		Sobriety Restrictions[c]		
No Restrictions	**Screening and Counseling[b]**	**1 Month**	**3 Months**	**6 Months**
California	Alaska	Florida	Arizona	Alabama
Connecticut	Colorado	Wyoming	Iowa	Arkansas
Hawaii	Delaware		Kansas	Idaho
Indiana	District of Columbia		North Dakota	Minnesota
Maine	Georgia		Texas	Mississippi
Massachusetts	Illinois		West Virginia	Montana
Missouri	Louisiana			Nebraska
Nevada	Kentucky			Ohio
New Jersey	Maryland			Puerto Rico
Oregon	Michigan			South Dakota
Rhode Island	New Hampshire			Tennessee
Utah	New Mexico			
Vermont	New York			
Washington	North Carolina			
	Oklahoma			
	Pennsylvania			
	South Carolina			
	Virginia			
	Wisconsin			

[a] As of January 2019, 13 states maintained disease severity restrictions for HCV treatment in their Medicaid programs: Alabama, Arkansas, Indiana, Iowa, Louisiana, Maryland, Michigan, Montana, Nebraska, Oregon, South Dakota, Texas, and West Virginia.

[b] Inquires about substance use and/or requires health care provider to screen for substance use and provide counseling or referral to treatment as a prerequisite for the approval of HCV DAA therapy coverage.

[c] Minimum length of sobriety required before coverage of DAA therapy is authorized.

Table 2. Litigation strategies to remove treatment restrictions for hepatitis C virus (HCV) direct-acting antiviral (DAA) therapies in Medicaid programs and correctional settings[a]

Category	Medicaid Act	8th Amendment	Americans With Disabilities Act (ADA)
Populations covered	Medicaid beneficiaries	Incarcerated persons	Medicaid beneficiaries and incarcerated persons
Restrictions challenged	Such cases typically challenge disease severity thresholds. Less frequently, sobriety restrictions have been challenged in Medicaid programs.	Such cases typically challenge disease severity thresholds.	The ADA has been used in some settings to challenge disease severity restrictions, with somewhat mixed results. Although untested, it may also be used to challenge sobriety restrictions.
Legal standard	Federal Medicaid law requires that states provide beneficiaries with medically necessary treatment, ensure comparable treatment to similarly situated Medicaid enrollees, and do so with reasonable promptness.	Prohibition against cruel and unusual punishment.	Persons must not be denied services by a government program because of a disability.
Proof needed	Plaintiffs must show that they were denied medically necessary treatment. This proof requires convincing the court that treatment of HCV infection with DAA therapy is the medical standard of care. Plaintiffs may also want to show that similarly situated enrollees (eg, those with more advanced-stage disease) are given treatment while plaintiffs are denied treatment.	Plaintiffs must show that the correctional facility exhibits deliberate indifference to a serious medical need, meaning that untreated HCV infection constitutes a serious medical need and that the correctional facility is intentionally denying care.	Plaintiffs must show that they have a disability and that treatment is being denied because of or by reason of their disability. Proving that treatment is denied because of or based on a disability can be shown via disparate treatment; that is, the intentional differentiation between persons on the basis of disability without substantial justification.
Example case citation	*BE v Teeter*, C16-227-JCC, 2017 US Dist, WD Wash (2017).[20]	*Chimenti v Wetzel*, CV-15-3333, ED Pa (2018).[14]	*Postawko v Missouri Department of Corrections*, 2:16-CV-4219-NKL-P, WD Mo (2017).[35]

[a] This table represents a simplified categorization of past litigation in an effort to assist the non-attorney reader in understanding trends and identifying similarities and differences. Each lawsuit unfolds in its own unique set of circumstances, so this representation should not be understood to be a comprehensive representation of the facts of each case, nor of relevant legal principles or standards.