

United States Department of Justice
Civil Rights Division, Disability Rights Section,
950 Pennsylvania Avenue, NW Washington, D.C. 20503

Administrative Complaint Against the Mississippi Medicaid Agency

Complainants

My Brother's Keeper
My Brother's Keeper
407 Orchard Park
Ridgeland, MS 39157
Tel: 769-216-2455

Mississippi Center for Justice
Mississippi Center for Justice
210 E. Capitol Street, Suite 1800
Jackson, MS 39201
Tel: 601-352-2269

Center for Health Law and Policy Innovation
Harvard Law School
1585 Massachusetts Avenue
Cambridge, MA 02138
Tel: 617-496-0901

Michael Saag, M.D.
3220 5th Avenue South
Birmingham, AL 35222
Tel: 205-934-7349

I. Introduction

A. Introduction to Complainants

1. My Brother's Keeper, the Mississippi Center for Justice, Dr. Michael Saag, and the Center for Health Law and Policy Innovation bring this administrative complaint on behalf of all Mississippi Medicaid beneficiaries who are disabled due to substance use disorder and diagnosed with Hepatitis C. Although direct-acting antiviral treatment is the appropriate standard of care for these beneficiaries, Mississippi Medicaid systematically denies them life-saving DAA treatment because of their disability.

My Brother's Keeper

2. My Brother's Keeper (MBK) is a non-profit organization established in 1999, with three offices in the Jackson, Mississippi metropolitan area and two offices in South Mississippi. MBK's mission is to eliminate health disparities among underserved, uninsured/underinsured and other vulnerable populations through health education, health promotion, policy and environmental systems changes, and other health equity approaches. MBK was first established as a non-profit dedicated to the prevention, care, and treatment of persons infected with the human immunodeficiency virus (HIV). MBK's efforts have expanded to include many other health issues and chronic conditions, which has systemically transformed MBK from a grassroots organization into a community-based leader that strives to change the health status of Americans one community at a time.

3. MBK's HIV prevention services are focused on designing and delivering an innovative range of educational and training programs in public health, social policy, action research, information technology, advocacy, coalition development and capacity building. Through its extensive experience, MBK built its commitment to HIV prevention among racial and ethnic minority populations as evident through its service to over 15,000 constituents, who represent community-based organizations (CBO), FBOs, IHLs, and community lay persons. One of MBK's programs is the iCAN project, which offers services including but not limited to rapid HIV testing, free condom distribution, linkages for HIV-positive individuals to HIV care and treatment, and personalized cognitive counseling.
4. Coinfection with HIV and Hepatitis C is common, and coinfecting individuals have an increased risk of progression to decompensated liver disease relative to patients with just Hepatitis C.¹ Additionally, because injection drug use is a risk factor for both HIV and Hepatitis C transmission, many of the community members served by MBK have substance use disorder as well.²

The Mississippi Center for Justice

5. The Mississippi Center for Justice (the Center) is a public interest law firm advancing racial and economic justice through an approach that combines legal services with policy advocacy, community education and media outreach. The Center partners with national, regional and community organizations to develop and implement campaigns designed to create better futures for low-income Mississippians and communities of color in the areas of educational opportunity, financial security, healthcare, affordable housing, and other vital issues.
6. The Center advocates for access to affordable, quality healthcare, specifically working to ensure that Mississippi fully implements the Affordable Care Act and to fight against the discriminatory practices that make it harder for people living with HIV/AIDS to obtain affordable housing, maintain employment and protect their right to privacy. The Center is also working to bridge the gap in access to healthcare for communities of color who suffer from high rates of death from treatable diseases like Hepatitis C.

Michael Saag, M.D.

7. Dr. Michael is Professor Emeritus of Medicine, Microbiology and Public Health at the University of Alabama at Birmingham. During his fellowship in Infectious Diseases, Dr. Saag conceived the concept of a comprehensive HIV outpatient (1917) clinic dedicated to the provision of comprehensive patient care in conjunction with the conduct of high-quality clinic trials, basic science, and clinical outcomes research. Over the last 35 years, the clinic has treated more than 12,000 patients, and has become recognized as one of the best sites for

¹ HHS, Hepatitis C Virus/HIV Coinfection, in Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV, <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/hepatitis-c-virus-hiv-coinfection> [<https://perma.cc/DS9J-RDYD>].

² HHS, Substance Use Disorders and HIV, Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV, <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/substance-use-disorders-and-hiv> [<https://perma.cc/4QHJ-7PP5>].

clinical research and care in the United States. Dr. Saag has published over 500 articles in peer reviewed journals, including the first description of the quasispecies nature of HIV (Nature, 1988), the first use of viral load in clinical practice (Science, 1993), the first description of the rapid dynamics of viral replication (Nature, 1995), the first guidelines for use of viral load in practice (Nature Medicine, 1996), the first proof of concept of fusion inhibition as a therapeutic option (Nature Medicine, 1998), and directed the ‘first-in-patient’ studies of 7 of the 25 antiretroviral drugs currently on the market. Dr. Saag served as Chair of the IAS-USA Antiretroviral Therapy Guidelines (JAMA 2020), and was a Founding Co-Chair of the AASLD-IDS A Hepatitis C Guidelines Panel (2014- 2017; www.hcvguidelines.org) Dr. Saag has received the Myrtle Wreath Award from Hadassah, was listed as one of the top ten cited HIV researchers by Science (1996), and received multiple Argus Awards for Best Lectures to the first-year medical students at UAB. In 2014, Dr. Saag was named the Castle-Connolly National Physician of the Year Award for Clinical Excellence and was inducted into the Alabama Healthcare Hall of Fame. He is Co-Editor of the Sanford Guide. During the COVID epidemic, Dr. Saag has appeared frequently on CNN, MSNBC, Yahoo Finance, and the Paul Finebaum Show and has published frequent Op-Ed features in the Washington Post. Dr. Saag published a memoir entitled, “Positive: One doctor’s encounters with death, life, and the US Healthcare System,” which is in its third printing.

The Center for Health Law and Policy Innovation

8. The Center for Health Law and Policy Innovation (CHLPI) of Harvard Law School works to advance health equity for low-income people living with chronic health conditions by advocating for legal, regulatory, and policy reforms in health and food systems. CHLPI’s broad range of initiatives aim to expand access to high-quality health care and nutritious, affordable food; to reduce health- and food-related disparities; to develop community advocacy capacity; and, to promote more equitable, sustainable and effective health care and food systems.
9. CHLPI has long advocated for the elimination of treatment barriers to Hepatitis C treatment and is committed to ensuring that the cure is made available to all those who need it. CHLPI’s record of accomplishment in litigation and rights enforcement with respect to Hepatitis C in Medicaid stretches back to the groundbreaking preliminary injunction obtained in *B.E. v. Teeter*, No. C16-227-JCC, 2016 WL 3033500 (W.D. Wash. May 27, 2016). Similar work continued in other several other states for years, culminating in the settlement of *Coleman v. Young*, No. 20-cv-00847-RP (W.D. Tex.) in November 2021. In *Coleman*, a class of Texas Medicaid beneficiaries reached an agreement to remove disease severity restrictions, sobriety and prescriber requirements for DAA treatment in Texas Medicaid.³

³ Court Approves Settlement In Class Action Lawsuit Against Texas Medicaid, Expanding Access to Cure for Hepatitis C Virus, Center for Health Law & Policy Innovation, <https://chlpi.org/news-and-events/news-and-commentary/news/court-approves-settlement-in-class-action-lawsuit-against-texas-medicaid-expanding-access-to-cure-for-hepatitis-c-virus>, [<https://perma.cc/P5GK-VNW2>].

B. Need For Enforcement Overview

10. Hepatitis C (“HCV”) is an infectious and life-threatening blood borne infection that can lead to serious liver damage and ultimately even death. Direct-Acting Antivirals (“DAAs”) are highly effective in treating HCV, and the scientific consensus is that DAAs are equally effective for patients that use drugs and alcohol prior to or during treatment. As such, the standard of care is to provide, with *de minimis* exceptions not here at issue, DAA treatment to every patient with HCV, regardless of drug or alcohol use. This standard is reflected in nationally recognized authorities, such as the Guidelines published by the American Association for the Study of Liver Diseases (“AASLD”) and Infectious Disease Society of America (“IDSA”).
11. In contradiction to this standard of care, Mississippi Medicaid systematically denies life-saving HCV treatment. It does so by maintaining a policy (the “Policy”) with a blanket sobriety restriction denying Medicaid coverage to any applicant who used drugs at any time during a six-month window prior to treatment initiation. The Policy has the effect of eliminating access to effective and life-saving DAA treatment in violation of Title II of the Americans with Disability Act (“ADA”). This complaint is brought to vindicate the legal interests of Mississippi Medicaid beneficiaries who are disabled by substance use disorder and diagnosed with Hepatitis C (“Excluded Mississippi Medicaid Beneficiaries”).

C. The Department of Justice’s Enforcement Jurisdiction

12. My Brother’s Keeper, the Mississippi Center for Justice, Dr. Saag, and the Center for Health Law and Policy Innovation bring this administrative complaint on behalf of Excluded Mississippi Medicaid Beneficiaries. Title II of the ADA authorizes the Department of Justice (“DOJ”) to investigate complaints, make findings of fact and conclusions of law, and attempt to secure voluntary compliance where violations are found. 42 U.S.C. § 12133; 28 C.F.R. § 35.170(c).
13. Where a specific protected class of individuals has been subjected to discrimination based on disability by a public entity, an administrative complaint may be filed with the Department of Justice (DOJ), seeking investigation and compliance. 42 U.S.C. § 12133; 28 C.F.R. § 35.170 – 35.175.⁴ It is the role of the DOJ to investigate complaints related to “state and local government support services (*e.g.*, audit, personnel, comptroller, administrative services) [and] all other government functions not assigned to other designated agencies.” 28 C.F.R. § 35.190(b)(3).
14. The DOJ is required to attempt to resolve all complaints in which it finds noncompliance through voluntary agreements enforceable by the Attorney General. 28 C.F.R. § 35.173. If voluntary compliance is not forthcoming, the DOJ should refer this complaint to the Attorney General for consideration of appropriate remedial action, including litigation. 28 C.F.R. § 35.174.

⁴ See also DOJ, *The Americans with Disabilities Act Title II Technical Assistance Manual* § II-9.2000 (“A complaint may be filed with... the Department of Justice.”)

15. The DOJ should investigate the Policy and work with Mississippi Medicaid to remove its sobriety restriction for HCV treatment in order to comply with federal law and the medical standard of care.

II. Factual Allegations

A. Factual Allegations Concerning Hepatitis C

16. Hepatitis C (“HCV”) is a life-threatening, communicable, and chronic blood-borne disease. It is the most common chronic viral infection found in blood and spread via contact with blood.

17. Even in the early stages of the disease, individuals with HCV can experience serious symptoms. Failure to treat HCV increases the risks of adverse health effects including heart attacks, fatigue, depression, jaundice, itchy skin, swelling, sore muscles, joint pain, arthritis, fever, and slurred speech.

18. At all stages of its progression, HCV can cause “hepatic” and “extrahepatic” effects. Hepatic effects directly impact the liver, while extrahepatic effects affect other organ systems and may impact the body more broadly. Extrahepatic effects caused by HCV include kidney disease, hypertension, lymphoma, vasculitis, thyroid disease, mental changes, and various cancers.⁵

19. If HCV is left untreated, chronic liver disease will occur in 60–70% of the cases, cirrhosis in 5–20% of the cases.⁶ 1–5% of people with HCV will die from decompensated cirrhosis or hepatocellular carcinoma.⁷ HCV is the leading indication for liver transplants in the United States.⁸

20. Researchers estimate that approximately 3.9 million people in the United States are living with HCV.⁹ The rate of new HCV cases reported to CDC among persons aged 18–40 years has increased steadily each year since 2013 to 2.8 cases per 100,000 population in 2019.¹⁰ More than half the people who become infected with HCV will develop chronic infection.¹¹

21. Researchers estimate that approximately 22,900 people in Mississippi are living with HCV (around .783% of the total state population).¹² In part due to the stigma that surrounds the illness, many people with HCV have never been tested and are unaware of their infection,

⁵ Patrice Cacoub, Extrahepatic Manifestations of Chronic Hepatitis C Virus Infection, 3 Ther. Adv. Infect. Dis. 3, 3-9 (2016).

⁶ <https://www.nyu.edu/about/news-publications/news/2015/october/nyu-research-development-of-severe-liver-damage-in-midlate-adulthood-among-pwid-wchronic-hcv.html>

⁷ Id.

⁸ Hepatitis C Questions and Answers for Health Professionals, Centers for Disease Control and Prevention (August 7, 2020), <https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm> [<https://perma.cc/4UU3-UF5F>]

⁹ Id.

¹⁰ Id.

¹¹ Id.

¹² Local Data: Mississippi, HepVu (June 2022), <https://hepvu.org/local-data/mississippi/> [<https://perma.cc/DB65-R7HV>]

making it highly likely that such estimates are much lower than the actual population living with HCV.

22. While no surveillance is being published on the number of Mississippi Medicaid enrollees living with HCV, a fair estimate based on the proportion of Mississippi residents with HCV would be at least 6,000 people.¹³ This too is likely a conservative estimate, as a disproportionate number of persons living with HCV in the United States have low income and qualify for Medicaid.¹⁴
23. HCV is transmitted primarily through infected blood. The most common mode of current HCV transmission in the United States is through injection-drug use. HCV can also be spread through blood transfusions and other invasive health-care procedures, and from parent to child during pregnancy and childbirth.¹⁵

B. Factual Allegations Concerning Substance Use Disorder

24. Substance use disorder (“SUD”) is an umbrella term that encompasses, among other things, both drug addiction and alcoholism.¹⁶ SUD is “a mental disorder that affects a person’s brain and behavior, leading to a person’s inability to control their use of substances such as legal or illegal drugs, alcohol, or medications.”¹⁷ Approximately 19.3 million people nationally aged 18 or older had a SUD in the past year,¹⁸ and within the Medicaid population, “of almost 55.9 million Medicaid beneficiaries ages 12 and older with full or comprehensive benefits... 4.6 million (8 percent) were treated for a SUD in 2018.”¹⁹

¹³ As of February 2022, 728,359 individuals were enrolled in Medicaid and CHIP in Mississippi.

¹⁴ Soumitri Barua & Robert Greenwald et al., Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infection in the United States, *ANNALS OF INTERNAL MEDICINE* (2015), <https://www.acpjournals.org/doi/pdf/10.7326/M15-0406>.

¹⁵ *Id.*

¹⁶ Mayo Clinic, Drug Addiction (Substance Use Disorder), <https://www.mayoclinic.org/diseasesconditions/drug-addiction/symptoms-causes/syc-20365112> [<https://perma.cc/TUV5-VERB>]

(“Drug addiction, also called substance use disorder, is a disease that affects a person’s brain and behavior and leads to an inability to control the use of a legal or illegal drug or medication. Substances such as alcohol, marijuana and nicotine also are considered drugs.”); SAMHSA, Mental Health and Substance Use Disorders, <https://www.samhsa.gov/find-help/disorders> [<https://perma.cc/MK7W-WE82>].

¹⁷ National Institute of Mental Health, Substance Use and Co-Occurring Mental Disorders, <https://www.nimh.nih.gov/health/topics/substance-use-and-mental-health> [<https://perma.cc/PC4V-T4VE>]; see also American Psychiatric Association, What is a Substance Use Disorder?, <https://www.psychiatry.org/patients-families/addiction/what-is-addiction> [<https://perma.cc/92GW-VURF>]; Mayo Clinic, Drug Addiction (Substance Use Disorder), <https://www.mayoclinic.org/diseases-conditions/drug-addiction/symptoms-causes/syc-20365112> [<https://perma.cc/TUV5-VERB>].

¹⁸ SAMHSA, Alcohol, Tobacco, and Other Drugs, <https://www.samhsa.gov/find-help/atod> [<https://perma.cc/Q33S-YURM>].

¹⁹ HHS, T-MSIS Substance Use Disorder (SUD) Data Book (2018): Treatment of SUD in Medicaid, <https://www.medicare.gov/medicaid/data-systems/downloads/2018-sud-data-book.pdf>, [<https://perma.cc/V28F-BDDK>].

25. SUD is accompanied by changes in the brain’s wiring, which causes people to have an intense craving for a particular substance.²⁰ Imaging studies demonstrate that substance use disorder is accompanied by changes in the area of the brain that relate to judgment, decision making, learning, memory and behavior control.²¹ According to the Diagnostic and Statistical Manual of Mental Disorders (“DSM-5”), a patient has SUD if they meet two or more of the DSM-5’s enumerated criteria, which include but are not limited to: trying to stop using the substance but being unable to; neglecting responsibilities because of substance use; continuing to use even when it causes relationship problems; giving up important social and recreational activities due to substance use; and continuing to use despite the substance causing problems to the person’s physical and mental health.²²
26. Treating SUD has been identified as a key policy priority at the federal level. For example, in a recent press release, the Department of Justice committed “to supporting programs aimed at addressing the substance use crisis that is devastating communities across the nation,” and warned, “Against the backdrop of the COVID-19 pandemic, the nation is experiencing a precipitous rise in opioid and stimulant misuse and overdoses.”²³
27. Recent studies have found that COVID-19 exacerbated America’s substance use crisis. Americans drank more to cope with the stress of the global pandemic. Binge drinking, emergency room visits for alcohol withdrawal, and the number of alcohol-related deaths all increased in 2020.²⁴ This increase was recorded across every ethnic and racial group.²⁵ According to federal data, drug overdose deaths also reached record levels during the first year of the pandemic.²⁶

²⁰ American Psychiatric Association, What is a Substance Use Disorder?, <https://www.psychiatry.org/patients-families/addiction/what-is-addiction> [https://perma.cc/92GW-VURF].

²¹ Id.

²² American Psychiatric Association, Substance Use Disorder, in The Diagnostic and Statistical Manual of Mental Disorders Fifth Edition [hereinafter DSM-5], 483, 483-484 (2013).

²³ DOJ, Department of Justice Awards More than \$300 Million to Fight Opioid and Stimulant Crisis and to Address Substance Use Disorders, <https://www.justice.gov/opa/pr/departement-justiceawards-more-300-million-fight-opioid-and-stimulant-crisis-and-address> [https://perma.cc/ZSE8-KP2A].

²⁴ American Psychiatric Association, One Year On: Unhealthy Weight Gains, Increased Drinking Reported by Americans Coping with Pandemic Stress, <https://www.apa.org/news/press/releases/2021/03/one-year-pandemic-stress> [https://perma.cc/M3DM-RELL]; Roni Caryn Rabin, Alcohol-Related Deaths Spiked During the Pandemic, a Study Shows, N.Y. Times (Mar. 22, 2022), <https://www.nytimes.com/2022/03/22/health/alcohol-deaths-covid.html> [https://perma.cc/N5UN-RJZM].

²⁵ American Psychiatric Association, One Year On: Unhealthy Weight Gains, Increased Drinking Reported by Americans Coping with Pandemic Stress, <https://www.apa.org/news/press/releases/2021/03/one-year-pandemic-stress> [https://perma.cc/M3DM-RELL]; Roni Caryn Rabin, Alcohol-Related Deaths Spiked During the Pandemic, a Study Shows, N.Y. Times (Mar. 22, 2022), <https://www.nytimes.com/2022/03/22/health/alcohol-deaths-covid.html> [https://perma.cc/N5UN-RJZM].

²⁶ CDC, Provisional Drug Overdose Death Counts, <https://www.cdc.gov/nchs/nvss/vsrr/drugoverdose-data.htm> [https://perma.cc/EC2L-YAJ3]; Abby Goodnough, Overdose Deaths Have Surged During the Pandemic, C.D.C. Data Shows, N.Y. Times (Apr. 14, 2021), <https://www.nytimes.com/2021/04/14/health/overdose-deaths-fentanyl-opioids-coronaviurs-pandemic.html> [https://perma.cc/5FVE-Q4GB].

28. In Mississippi, the annual average prevalence of past-year substance use disorder in 2019 was 6.3%.²⁷
29. Injection drug use is the most common risk factor for HCV infection in the United States. HCV infection rates can exceed 40% in the first few years after an individual begins to inject drugs.²⁸ Injection drug use accounts for the majority of new HCV infections – approximately 70% of new HCV patients are injection drug users.²⁹ Globally, 52.3% of the estimated 15.6 million people – about 8.2 million people – with recent injecting drug use are HCV-antibody positive, which means that they were infected with the HCV virus at some point in time.³⁰
30. Even though people injecting drugs are the most vulnerable to HCV³¹, only 13% of the people who inject drugs have been provided with direct-acting antiviral treatment.³²
31. Experts urge that to reach the World Health Organization’s goal of eliminating HCV by 2030, treating people who inject drugs is a priority.³³

C. Factual Allegations Concerning Direct-Acting Antiviral (“DAA”) Treatment

i. DAA Treatment is a Breakthrough Therapy that Can Cure HCV Before it Causes Significant, Potentially Irreversible Liver Damage and Severe Health Effects

32. In 2011, the Food and Drug Administration (“FDA”) approved the first wave of DAAs for treatment of chronic HCV, and specialists heralded “the beginning of the end of chronic HCV.”³⁴ The FDA designated DAAs a “breakthrough therapy,”³⁵ a classification reserved for drugs that provide substantial improvement over available therapies for patients with

²⁷ SAMHSA, Behavioral Health Barometer,

https://www.samhsa.gov/data/sites/default/files/reports/rpt32841/Mississippi-BH-Barometer_Volume6.pdf.

²⁸ AASLD & IDSA, Key Populations Identification and Management of HCV in People Who Inject Drugs, in HCV Guidance, <https://www.hcvguidelines.org/unique-populations/pwid> [https://perma.cc/9HML-B8N5].

²⁹ Id.

³⁰ Jason Grebely et al., Global, Regional, and Country-Level Estimates of Hepatitis C Infection Among People Who Have Recently Injected Drugs, 114 *Addiction* 150-166 (2019).

³¹ AASLD & IDSA, Key Populations Identification and Management of HCV in People Who Inject Drugs, in HCV Guidance, <https://www.hcvguidelines.org/unique-populations/pwid> [https://perma.cc/9HML-B8N5].

³² Mohammad T. Yousafzai et al., Global Cascade of Care for Chronic Hepatitis C Virus Infection: A Systematic Review and Meta-Analysis, 28 *J. Viral. Hepat.* 1340–1354 (2021).

³³ Andrew Blake & James E. Smith, Modeling Hepatitis C Elimination Among People Who Inject Drugs in New Hampshire, *JAMA Network Open*, Aug. 3, 2021; Laura Krekulova, et. al., Key Role of Multidisciplinary Collaboration towards Global Elimination of HCV Infection, *Int. J. Environmental Research. & Public Health*, March 31, 2022.

³⁴ Marie-Louise Vachon & Douglas T. Dieterich, The Era of Direct-acting Antivirals Has Begun: The Beginning of the End for HCV?, 31 *Seminars in Liver Disease* 399, 399 (2011).

³⁵ “Breakthrough therapy” is a term of art used by the FDA for drugs that treat a serious or life- threatening disease, where preliminary clinical evidence indicates that the drug may demonstrate a substantial improvement over existing therapies. See 21 U.S.C. § 356(a) (defining “breakthrough therapy” and the process for expedited approval of such drugs under the Federal Food, Drug, and Cosmetic Act).

serious or life-threatening diseases. At this time, there is no other treatment for HCV that achieves comparable results with respect to the near eradication of the virus in the human body and prevention of its transmission to uninfected individuals.

33. DAA treatment enables patients to achieve a sustained virologic response (“SVR”), which means that the Hepatitis C virus was not detected in a patient’s blood 12 weeks or more after completing treatment.³⁶ This is considered the *de facto* cure for HCV. Additionally, once a patient has achieved SVR, they are no longer able to transmit the virus to others.³⁷ This compounds the benefits of DAA treatment across the population, and is essential in halting the HCV epidemic in Mississippi and across the United States.
34. DAA treatment regimens typically “achieve SVR rates of more than 95%.”³⁸ This means that DAA treatment regimens have more than a 95% success rate for treating HCV. Severe side effects are rare for modern DAA regimens and “less than 1% of patients have to discontinue therapy due to side effects.”³⁹

ii. DAAs are the Standard of Medical Care for Treatment for People with HCV, Including People with SUD, Both Nationally and in Mississippi

35. The FDA has approved DAA use for patients with HCV.⁴⁰
36. The AASLD is the leading organization of scientists and health care professionals committed to preventing and curing liver diseases. The Infectious Diseases Society of America (“IDSA”) is a community of over 12,000 physicians, scientists and public health experts who specialize in infectious diseases. The AASLD and IDSA collaborate to publish treatment guidelines for HCV (“HCV Guidance”) that “disseminates up-to-date, peer-reviewed, unbiased, evidence-based recommendations to aid clinicians making decisions regarding the testing, management, and treatment of HCV infection.”⁴¹ The HCV Guidance recommends DAA treatment for nearly all patients with chronic HCV, with very few enumerated exceptions.⁴² People with substance use disorder, and people with a history of drug and alcohol use, are not excluded under the AASLD and IDSA recommendations.⁴³ In fact, the

³⁶ U.S. Department of Veterans Affairs, FAQs About Sustained Virologic Response to Treatment for Hepatitis C, <https://www.hepatitis.va.gov/pdf/sustained-virological-response.pdf> [<https://perma.cc/GEV9-5R7H>].

³⁷ American Liver Foundation, Hepatitis C Information Center, <https://liverfoundation.org/for-patients/about-the-liver/diseases-of-the-liver/hepatitis-c/#faqs> [<https://perma.cc/PMG8-WPFS>].

³⁸ L. Sandmann et al., Treatment of Chronic Hepatitis C: Efficacy, Side Effects and Complications, 35 *Visc. Med.* 161, 162 (2019).

³⁹ *Id.* at 166.

⁴⁰ *See, e.g.*, FDA, FDA Approves First Treatment for all Genotypes of Hepatitis C in Pediatric Patients, <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-allgenotypes-hepatitis-c-pediatric-patients> [<https://perma.cc/KXA3-SF4E>].

⁴¹ Marc G. Ghany & Timothy R. Morgan, Hepatitis C Guidance 2019: American Association for the Study of Liver Diseases – Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection, 71 *Hepatology* 686, 686 (2020).

⁴² AASLD & IDSA, HCV Guidance, https://www.hcvguidelines.org/sites/default/files/full-guidancepdf/AASLD-IDSA_HCVGuidance_October_05_2021.pdf [<https://perma.cc/MR8R-FU6K>].

⁴³ *Id.*

HCV Guidance clearly states that “[d]ata do not support exclusion of HCV-infected persons from consideration for hepatitis C therapy based on alcohol intake or use of illegal drugs.”⁴⁴

37. The Centers for Medicare and Medicaid Services (“CMS”), the federal agency that administers Medicaid, has emphasized the importance of access to DAAs for Medicaid beneficiaries. In November 2015, CMS issued guidance, advising state Medicaid agencies to include DAAs in their coverage of outpatient prescription drugs and warning against impermissible restrictions, which CMS warned could include “requiring a period of abstinence from drug and alcohol abuse as a condition for payment for DAA HCV drugs.”⁴⁵ The CMS guidance emphasizes that limitations “should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments using DAA drugs for beneficiaries with chronic HCV infections. States should, therefore, examine their drug benefits to ensure that limitations do not unreasonably restrict coverage of effective treatment using the new DAA HCV drugs.”⁴⁶ CMS has not changed its guidance since. “Courts have accorded CMS’ interpretations of the Medicaid Act [] respectful consideration based on the agency’s expertise, the statute’s complexity and technical nature, and the broad authority delegated to the Secretary of Health and Human Services under the Act.” *Katie A., ex rel. Ludin v. Los Angeles County*, 481 F.3d 1150, 1155, n.11 (9th Cir. 2007).
38. Medical and scientific studies emphasize that “HCV treatment should be universally offered to all eligible patients.”⁴⁷ For example, the authors of a recent study, published in February 2022, concluded that because “SUD is a risk factor for more aggressive liver disease, . . . it should not be a limiting factor for treatment.”⁴⁸ Instead, the fact that a patient has SUD “should result in intensified HCV management and care,” due to their increased risk of more aggressive liver disease.⁴⁹ Thus, patients with SUD should be prioritized for DAA treatment, not excluded from it.⁵⁰

iii. Denying DAA Treatment Based on Drug Use Cannot Be Justified on Medical Necessity Grounds.

39. With *de minimis* exceptions not here at issue, DAA treatment is medically necessary for those diagnosed with HCV.⁵¹ See *B.E. v. Teeter*, 2016 WL 3033500, at *4 (W.D. Wash.

⁴⁴ Id.

⁴⁵ CMS, Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs, [https://perma.cc/S3LZ-LCW3]. [hereinafter CMS HCV Guidance].

⁴⁶ Id.

⁴⁷ Antonio Saviano et al., Hepatitis C Treatment in Patients with Substance Use Disorder: The Faster the Better, 11 *Hepatobiliary Surg. Nutr.* 129, 130 (2022).

⁴⁸ Id.

⁴⁹ Id.; See also Haesuk Park et al., The Impact of Direct-Acting Therapy on End Stage Liver Disease Among Individuals with Chronic Hepatitis C and Substance Use Disorders, 74 *Hepatology* 566, 578 (“Therefore, we suggest that patients with HCV who also have [alcohol liver disease] or use alcohol with other drugs are a group of patients at a particularly high risk for liver related adverse outcomes even with DAA treatment.”).

⁵⁰ See Antonio Saviano et al., Hepatitis C Treatment in Patients with Substance Use Disorder: The Faster the Better, 11 *Hepatobiliary Surg. Nutr.* 129, 130 (2022).

⁵¹ See CMS HCV Guidance, [https://perma.cc/S3LZ-LCW3] (explaining that DAAs are “medically necessary” for those infected with HCV, and expressing concern that “states are also requiring a period of abstinence from drug

2016) (“[T]here is a consensus among medical experts and providers that the life-saving DAAs are ‘medically necessary’ for all HCV-infected persons.”).

40. Even under Mississippi’s own definition, DAA treatment for Medicaid beneficiaries with HCV is medically necessary. Mississippi’s Division of Medicaid defines “medically necessary” or “medical necessity” as “health care services that a provider, exercising prudent clinical judgment, would provide to a patient for the purpose of evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are: (1) Appropriate and consistent with the diagnosis of the treating provider and the omission of which could adversely affect the patient’s medical condition, (2) Compatible with the standards of acceptable medical practice in the United States, (3) Provided in a safe, appropriate and cost-effective setting given the nature of the diagnosis and the severity of the symptoms, (4) Not provided solely for the convenience of the beneficiary or family, or the convenience of any health care provider, (5) Not primarily custodial care (6) There is no other effective and more conservative or substantially less costly treatment service and setting available, and (7) The service is not experimental, investigational or cosmetic in nature.”⁵² DAA treatment for individuals with substance use disorder is the generally accepted standard of medical practice in the United States, clinically appropriate, and considered the most effective treatment for HCV.
41. Several recent scientific studies show that DAA treatment is safe and effective, including for people who inject drugs before or even during therapy. High SVR rates for people with a recent history of injection drug use have been observed in both clinical trials and clinical practice settings. A SIMPLIFY clinical trial, for example, reported SVR rates approaching 95% for people who injected drugs before and during therapy.⁵³ In this clinical trial, participants received DAA treatment for 12 weeks.⁵⁴ 76 of the 103 participants injected drugs in the past month and 27 of them had injected drugs more than once a day in the past month.⁵⁵ Not only did such participants achieve high SVR rates, there was also no significant difference in SVR rates among those with and without recent drug use.⁵⁶ This SIMPLIFY clinical trial affirms findings from previous studies that showed high SVR rates among individuals with recent injecting drug use. One 2018 paper reported on 38 studies analyzing DAA treatment outcomes among more than 3600 participants with recent drug use including those receiving opioid substitution therapy and concluded that high SVR rates were achieved across numerous studies, stating that the “study showed favorable DAA treatment outcome among people with recent drug use and those receiving opioid substitution therapy.”⁵⁷

and alcohol abuse as a condition for payment for DAA HCV drugs.”).

⁵² Mississippi’s Administrative Code Title 23, Part 200, Rule 5.1.

⁵³ J. Grebely et al., Sofosbuvir and Velpatasvir for Hepatitis C Virus Infection in People With Recent Injection Drug Use (SIMPLIFY): an Open Label, Single-Arm, Phase 4, Multicenter Trial, 3 *Lancet Gastroenterol. and Hepatol.* 153 (2018)

⁵⁴ Id.

⁵⁵ Id.

⁵⁶ Id.

⁵⁷ Behzad Hajarizadeh et al., Direct-Acting Antiviral Treatment for Hepatitis C Among People Who Use or Inject Drugs: A Systematic Review and Meta-Analysis, 3 *Lancet Gastroenterol. and Hepatol.* 754, 765 (2018).

42. Similarly high SVR rates were reported for HCV patients actively using drugs in a study conducted at a primary care clinic.⁵⁸ 25% of the patients participating in the study used alcohol in the last 30 days and over half of the patients were actively using drugs.⁵⁹ The overall SVR rate was 96% and patients who actively used drugs actually had higher SVR rates than those who did not use drugs.⁶⁰ The study concluded, “Rates of SVR were similarly high among all patients, regardless of active drug use or [opioid agonist treatment]. While larger real-world studies are needed, we found no clinical evidence to justify restricting access to HCV treatment for patients actively using drugs, receiving [opioid agonist treatment], or both.”⁶¹ DAA treatment also significantly reduces the risk of hepatocellular carcinoma and liver decompensation in patients with or without SUDs.⁶²
43. Additionally, medical studies have found that there is no significant risk of treatment discontinuation for individuals with SUD.⁶³ One such study concluded that “[a]fter adjusting for covariates, there was no difference in the hazard of discontinuation of DAA treatment for those with or without SUDs.”⁶⁴ DAA treatment is also forgiving of missed doses, since SVR can be achieved, despite imperfect adherence to the treatment regimen.⁶⁵
44. On top of curing HCV, opioid injection drug use and sharing has been observed to decrease following DAA treatment.⁶⁶ One recent study pooled analysis of two international trials that evaluated the efficacy and safety of HCV DAA treatment and its impact on clinical and nonclinical outcomes in HCV-infected people.⁶⁷ 62% of the participants had injected drugs in the past month.⁶⁸ The study found that drug and alcohol use remained stable or decreased slightly during follow-ups with participants who completed DAA treatment.⁶⁹ Furthermore, the study found that sharing of injection equipment underwent a gradual decrease over time.⁷⁰ Thus, DAA treatment not only cures individuals with HCV, but also has the added effect of lowering their risk of reinfection through a decrease of injection equipment sharing.

⁵⁸ Behzad Hajarizadeh et al., Direct-Acting Antiviral Treatment for Hepatitis C Among People Who Use or Inject Drugs: A Systematic Review and Meta-Analysis, 3 *Lancet Gastroenterol. and Hepatol.* 754, 765 (2018).

⁵⁹ Id.

⁶⁰ Id.

⁶¹ Id.

⁶² Antonio Saviano et al., Hepatitis C Treatment in Patients with Substance Use Disorder: The Faster the Better, 11 *Hepatobiliary Surg. Nutr.* 129, 130 (2022).

⁶³ Jiang, X., et al., The use of all-oral direct-acting antivirals in hepatitis C virus-infected patients with Substance Use Disorders. *Journal of Managed Care & Specialty Pharmacy* (2021).

⁶⁴ Id.

⁶⁵ Ward, K. M., et al., Nonadherence to ledipasvir/sofosbuvir did not predict sustained Virologic response in a randomized controlled trial of human immunodeficiency virus/hepatitis C virus coinfecting persons who use drugs. *The Journal of Infectious Diseases*, (2021).

⁶⁶ Andreea A. Artenie et al., Patterns of Drug and Alcohol Use and Injection Equipment Sharing Among People With Recent Injection Drug Use or Receiving Opioid Agonist Treatment During and Following Hepatitis C Treatment with Direct-Acting Antiviral Therapies, 70 *Clinical Infectious Diseases* 2369 (2020).

⁶⁷ Id.

⁶⁸ Id.

⁶⁹ Id.

⁷⁰ Id.

45. Reinfection risks exist for any patient who receives DAA treatment. However, a 2020 study using long-term, repeated follow-up assessments found that the “overall rate of reinfection (1.22/100 person – years) was low and consistent.”⁷¹ The study also found that there was no significant increase in the risk of reinfection based on previous drug use and only a minor increase in the risk of reinfection for ongoing injection drug use. As such, the Akiyama study concluded, “Taken together, these data support that concerns about reinfection should not limit HCV treatment among [people who inject drugs].”⁷² Any minimal increased reinfection risk indicates that these individuals should be provided with harm-reduction and prevention services following treatment.⁷³ In any event, the data on reinfection rates do not support the false conclusion that DAA coverage should be withheld from people who inject drugs due to high reinfection risks.
46. Mississippi Medicaid’s Pharmacy & Therapeutics Committee has indicated its support for changing Mississippi Medicaid’s sobriety restriction by voting to change the policy, showing its belief that DAA treatment is medically necessary.
47. The Pharmacy & Therapeutics Committee voted on October 18, 2022 to remove the sobriety restriction for non-complicated Hepatitis C treatment.⁷⁴ The Pharmacy and Therapeutics Committee is an advisory panel who conducts in-depth clinical evaluations and recommends appropriate drugs for preferred status on Mississippi Medicaid’s Preferred Drug List (PDL) and/or drugs for prior authorization.⁷⁵ They are comprised of twelve participating physicians, nurse practitioners, and practicing pharmacists who are active Mississippi Medicaid providers and in good standing with their representative organizations.

D. Factual Allegations Concerning Mississippi Medicaid

48. The Medicaid program is operated cooperatively between the federal and state governments. As of February 2022, 728,359 individuals were enrolled in Medicaid and CHIP in Mississippi, nearly 1 in 4 Mississippi residents.
49. At the federal level, the Medicaid program is administered by CMS. *Moore ex rel. Moore v. Reese*, 637 F.3d 1220, 1235 (11th Cir. 2011). At the state level, Medicaid in Mississippi is

⁷¹ Matthew J. Akiyama et al., Low Hepatitis C Reinfection Following Direct-Acting Antiviral Therapy Among People Who Inject Drugs on Opioid Agonist Therapy, 70 *Clinical Infectious Diseases* 2695, 2697 (2020).

⁷² Id.

⁷³ Substance Abuse and Mental Health Services Administration, Substance Abuse Treatment for Persons With HIV/AIDS 37 Treatment Improvement Protocol (TIP) Series, 187 (2008), https://www.ncbi.nlm.nih.gov/books/NBK64923/pdf/Bookshelf_NBK64923.pdf [<https://perma.cc/W54W-M6B4>]

⁷⁴ Pharmacy and Therapeutics Committee Meeting: October 18, 2022 Meeting Minutes, Mississippi Division of Medicaid, <https://medicaid.ms.gov/wp-content/uploads/2022/11/MS-PT-Meeting-Minutes-101822.pdf> [<https://perma.cc/779G-ERCH>]

⁷⁵ Pharmacy and Therapeutics Committee, Mississippi Division of Medicaid, <https://medicaid.ms.gov/pharmacy-and-therapeutics-committee/> [<https://perma.cc/UU3M-CDNP>].

administered by the Mississippi Division of Medicaid (“Mississippi Medicaid”), which acts as the single government agency responsible for Mississippi’s state Medicaid plan.⁷⁶

50. While participation in the Medicaid program is optional, once a state elects to participate, it “must comply with certain requirements imposed by the Medicaid Act and regulations promulgated by the Secretary of Health and Human Services.” *Alexander v. Choate*, 469 U.S. 287, 289 n.1 (1985). All fifty states have elected to participate in Medicaid. *Vestal v. First Recovery Group, LLC*, 292 F. Supp. 3d 1304, 1310 (M.D. Fl. 2018).
51. All states, including Mississippi, have opted to provide prescription drugs as part of their Medicaid programs.⁷⁷ If a state opts to provide coverage of prescription drugs, it is subject to the restrictions found in the Medicaid Act and related regulations. See *B.E. v. Teeter*, 2016 WL 3033500, *2 (W.D. Wash. 2016).
52. The Medicaid Act requires state Medicaid plans that opt into the prescription drug benefit, including Mississippi Medicaid, to provide coverage for any outpatient drug for its indicated use once the drug manufacturer enters into a rebate agreement and the medicine is approved by the FDA and prescribed by a provider. 42 U.S.C. §§ 1396r-8(a)(1), 1396r-8(d)(1)(B), 1396r-8(k)(2)(A), 1396r-8(k)(6); *Pharm. Research & Mfrs. Of Am. v. Walsh*, 538 U.S. 644, 652 (2003). Pursuant to these requirements, Mississippi covers DAA treatment for some of Medicaid beneficiaries.⁷⁸

E. Factual Allegations Concerning Mississippi Medicaid’s Policy of Denying Hepatitis C Treatment Based on Drug Use

53. On November 5, 2015, CMS issued guidance to state Medicaid agencies to direct that DAAs should be included in Medicaid coverage of outpatient prescription drugs.⁷⁹ Mississippi Medicaid covers FDA-approved DAA medications such as Mavyret, Daklinza, Epclusa, Harvoni, Sovaldi, Vosevi, and Zepatier.⁸⁰
54. Despite including DAAs in its coverage, Mississippi Medicaid denies treatment to otherwise eligible Medicaid enrollees who cannot prove they did not use drugs within six months prior to treatment initiation.⁸¹
55. Mississippi Medicaid publishes a required prior authorization form and an “criteria/additional documentation” form on its website.⁸² The forms require a Mississippi Medicaid prescriber to attest that they have documentation of “[a]bstinence from drugs for at least 6 months; negative urine drug screen required if there is IV drug use history.”⁸³ For Mississippi

⁷⁶ Mississippi Medicaid, Mississippi Medicaid Administrative Code Title 23: Part 100, General Provision, <https://medicaid.ms.gov/wp-content/uploads/2020/07/Title-23-Part-100-General-Provisions-eff-08.01.20-1.pdf>

⁷⁷ <https://medicaid.ms.gov/medicaid-coverage/covered-services/>

⁷⁸ See *infra* n. 79.

⁷⁹ See CMS HCV Guidance, [<https://perma.cc/S3LZ-LCW3>].

⁸⁰ Mississippi Division of Medicaid, Universal Preferred Drug List (July 2022) [<https://perma.cc/7BWV-2Z27>]

⁸¹ Clinical Criteria, <https://perma.cc/6K6N-VTBR>.

⁸² Clinical Criteria, <https://perma.cc/6K6N-VTBR>.

⁸³ *Id.*

Medicaid to approve coverage of DAAs for a patient, a provider must submit both forms.⁸⁴ These forms are attached to this Complaint as Exhibit 1.

56. As a result of the policy, the Excluded Mississippi Medicaid Beneficiaries are excluded from effective and life-saving DAA treatment that they would otherwise be entitled to, as described herein.
57. In 2014, 37 states had sobriety restrictions for HCV treatment. Mississippi is an outlier, as the vast majority of the states that previously imposed sobriety restrictions have eliminated them. As of 2022, Mississippi is only one of seven remaining states to impose a strict, months-long sobriety restriction along with Arkansas, Minnesota, Nebraska, North Dakota, South Carolina, and South Dakota.⁸⁵ Most recently, Alabama Medicaid ended their HCV treatment restrictions based on sobriety in October 2022.⁸⁶

Legal Background

III. Title II of the ADA prohibits state and local entities, including state Medicaid programs, from denying access to its services, programs, and activities on the basis of disability.

58. Title II of the ADA mandates that “no qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subjected to discrimination by any such entity.” 42 U.S.C. § 12132. *See also Olmstead v. L.C. ex rel. Zimring*, 527 U.S. 581, 589-590 (1999).
59. Title V of the ADA contains a carve-out provision, Section 12210(a), that excludes individuals who engage in the current illegal use of drugs from the term “individual with a disability.”⁸⁷ But that carve-out is inapplicable here, because Section 12210(c) creates an explicit “exception to the exception” regarding the provision of health services to individuals who are currently using illegal drugs.
60. The health services exception in Section 12210(c) expressly states that under Title II, if an individual is otherwise entitled to health services provided by a state or local entity, that entity *may not* deny health services to an individual on the basis of SUD—even when the

⁸⁴ Id.

⁸⁵ Center for Health Law and Policy Innovation & National Viral Hepatitis Roundtable, 2022 National Summary Report, Hepatitis C: State of Medicaid Access (June 2022), https://hepc.wpenginepowered.com/wp-content/uploads/2022/06/State-of-Hep-C-Report_2022-1.pdf [<https://perma.cc/U8UP-Q7T6>].

⁸⁶ Alabama Medicaid Removes HCV Treatment Access Restrictions Following Complaint from Harvard Center for Health Law and Policy Innovation, Center for Health Law and Policy Innovation (Oct. 6, 2022), <https://chlp.org/news-and-events/news-and-commentary/health-law-and-policy/alabama-medicaid-removes-hcv-treatment-access-restrictions-following-complaint-from-harvard-center-for-health-law-and-policy-innovation/> [<https://perma.cc/BF2K-FG33>].

⁸⁷ Title V of the ADA contains a limited carve-out provision stating that “the term ‘individual with a disability’ does not include an individual who is currently engaging in the illegal use of drugs, when the covered entity acts on the basis of such use.” 42 U.S.C § 12210(a); see also Thompson v. Davis, 295 F.3d at 896.

individual is currently using illegal drugs as a result of their SUD. 42 U.S.C. § 12210(c); 28 C.F.R. §§ 35.131(b)(1), 36.209(b)(1).

61. Both DOJ and the Substance Abuse and Mental Health Services Administration (“SAMHSA”) interpret Section 12210(c) to conclude that “health services” refers to health services in general, not just services provided in association with drug rehabilitation. The DOJ’s interpretation has remained consistent from 1993 to 2022.
62. As early as 1993, the DOJ interpreted Section 12210(c), to conclude that “the ADA does prohibit denial of health services, or services in provided in connection with drug rehabilitation, to an individual on the basis of current illegal use of drugs, if the individual is otherwise entitled to such services.”⁸⁸ The DOJ gave an illustration of that principle by stating as an example that “a hospital emergency room may not refuse to provide emergency services to an individual because the individual is using drugs.”⁸⁹
63. More recently, in April 2022, guidance published by the DOJ’s Civil Rights Division also highlighted the “health services” provision, noting that “an individual cannot be denied health services, or services provided in connection with drug rehabilitation, on the basis of that individual’s current illegal use of drugs, if the individual is otherwise entitled to such services.”⁹⁰
64. The DOJ’s guidance gives the following example: “A hospital emergency room routinely turns away people experiencing drug overdoses, but admits all other patients who are experiencing health issues. The hospital would be in violation of the ADA for denying health services to those individuals because of their current illegal drug use, since those individuals would otherwise be entitled to emergency services.”⁹¹
65. In 2008, the Substance Abuse and Mental Health Services Administration (SAMHSA) also provided guidance on Section 12210(c), giving a similar example that “a hospital that specializes in treating burn victims could not refuse to treat a burn victim because he uses illegal drugs, nor could it impose a surcharge on him because of his addiction.”⁹²
66. The ADA defines “disability” broadly, to include *current* physical or mental impairments that substantially limit one or more major life activities, but also *past* and *perceived* impairments that substantially limit one or more major life activities. 42 U.S.C. § 12102.

⁸⁸ Department of Justice, The Americans with Disabilities Act Title II Technical Assistance Manual, § II-3.8000 (emphasis added).

⁸⁹ *Id.*

⁹⁰ DOJ Civil Rights Division, The Americans with Disabilities Act and the Opioid Crisis: Combating Discrimination Against People in Treatment or Recovery, https://www.ada.gov/opioid_guidance.pdf [<https://perma.cc/QC44-KKGF>].

⁹¹ *Id.*

⁹² Substance Abuse and Mental Health Services Administration, Substance Abuse Treatment for Persons With HIV/AIDS 37 Treatment Improvement Protocol (TIP) Series, 187 (2008), https://www.ncbi.nlm.nih.gov/books/NBK64923/pdf/Bookshelf_NBK64923.pdf [<https://perma.cc/W54W-M6B4>]

67. The ADA prohibits state and local entities like Mississippi Medicaid from denying services to individuals who have “a record of . . . an impairment” that substantially limits one or more major life activities—in other words, it prohibits state and local entities from discriminating on the basis of a person’s former disability. 42 U.S.C. 12102(b); 42 U.S.C. 12210(b)(1)-(2) (clarifying that the term “individual with a disability” includes individuals who have successfully completed or are currently participating in “a supervised rehabilitation program” and are “no longer engaging in the illegal use of drugs,” as well as individuals who have “otherwise been rehabilitated successfully” and no longer use).
68. The ADA also prohibits discrimination against individuals who are “regarded as having . . . an impairment” that substantially limits one or more major life activities—in other words, individuals who are *perceived* to have a disability. 42 U.S.C. 12102(c); 42 U.S.C. 12210(b)(3) (prohibiting discrimination against people who are “erroneously regarded as engaging in illegal drug use”).

Claim

IV. Mississippi Medicaid’s Policy Violates the ADA

69. This claim restates and incorporates by reference each of the paragraphs above.
70. To state a claim under Title II, a plaintiff must establish “(1) that he is a qualified individual with a disability; (2) that he is either excluded from participation in or denied the benefits of a public entity’s services, programs, or activities, or was otherwise discriminated against by the public entity; and (3) that the exclusion, denial of benefit, or discrimination is by reason of the plaintiff’s disability.” *Wilson v. City of Southlake*, 936 F.3d 326, 330 (5th Cir. 2019); 42 U.S.C. § 12132. The Excluded Mississippi Medicaid Beneficiaries are qualified individuals with disabilities, and the Policy discriminates against them by reason of their disability.

A. Mississippi Medicaid is a public entity under the ADA.

71. Under the ADA, “[a] public entity is any State or local government or any department, agency or other instrumentality of a State or local government.” 42 U.S.C. § 12131(1).
72. Medicaid is a needs-based medical assistance program cooperatively funded by the federal and state governments and administered by the states. The Medicaid Program was established under Title XIX of the Social Security Act of 1965 for the express purpose of enabling each State to furnish medical assistance to people “whose income and resources are insufficient to meet the costs of necessary medical services.” 42 U.S.C. § 1396-1. State Medicaid agencies, like Mississippi Medicaid, are public entities and are subject to Title II. 42 U.S.C. § 12131(1)(B).

B. Many of the Excluded Mississippi Medicaid Beneficiaries are qualified individuals with disabilities.

73. A qualified individual with a disability is anyone “who, with or without reasonable modifications to rules, policies, or practices . . . meets the essential eligibility requirements for the receipt of services or the participation in programs or activities provided by a public entity.” 42 U.S.C. §12131(2); *see, e.g., Pennsylvania Dept. of Corrections v. Yeskey*, 524 U.S. 206, 210 (1998). Title II of the ADA further defines disability as “a mental or physical impairment that significantly limits one or more major life activities.”⁹³ 42 U.S.C. § 12102(1)(A); *see, e.g., MX Group, Inc. v. City of Covington*, 293 F.3d 326, 328, 337-39 (6th Cir. 2002).

i. The Excluded Mississippi Medicaid Beneficiaries meet the essential eligibility requirements for receipt of DAA treatment.

74. The Excluded Mississippi Medicaid Beneficiaries are “qualified individuals” because they are enrolled in Medicaid and meet the essential eligibility requirements for the receipt of medically necessary DAA treatment.⁹⁴ *See also* 42 U.S.C. § 12210(c); 28 C.F.R. §§ 35.131(b)(1), 36.209(b)(1) (stating that if an individual is otherwise entitled to health services provided by a state or local entity, that entity may not deny health services to an individual on the basis of SUD—even when the individual is currently using illegal drugs as a result of their SUD).

75. Mississippi is required to “comply with certain requirements imposed by the Medicaid Act and regulations promulgated by the Secretary of Health and Human Services” as a condition of participating in the Medicaid program. *Alexander v. Choate*, 469 U.S. 287, 289 n.1 (1985). One of the requirements imposed by the Medicaid Act concerns the provision of prescription drugs. *See B.E. v. Teeter*, 2016 WL 3033500, *2 (W.D. Wash. 2016) (stating that an agency that has opted to provide prescription drug coverage must adhere to the Medicaid Act and its regulations.). All states, including Mississippi, have opted to provide prescription drugs as part of their Medicaid programs.⁹⁵

76. The Medicaid Act requires state Medicaid plans that opt into the prescription drug benefit, including Mississippi Medicaid, to provide coverage for any outpatient drug for its indicated use once the drug manufacturer enters into a rebate agreement and the medicine is approved

⁹³ The Americans with Disabilities Act Amendments Act of 2008 (“ADAAA”) broadened the ADA’s definition of disability. After several Supreme Court cases narrowly construed the phrase “substantially limits,” the ADAAA clarified that an impairment that substantially limits a major life activity need not also limit other major life activities to be considered a disability. Furthermore, the ADAAA revised the term “major” to be broadly construed, and stated that whether an activity is a “major life activity” may not be determined based upon the importance of that activity to daily life. *See* U.S. Equal Employment Opportunity Commission, ADA Amendments Act of 2008, <https://www.eeoc.gov/statutes/ada-amendments-act-2008> [<https://perma.cc/6W2R-NMC4>].

⁹⁴ The claims identified in this complaint are distinguishable from those rejected by the District of Mississippi in *Jackson v. Oktibbeha Cnty. Hosp.*, No. 1:10-CV-88-SA-DAS, 2012 WL 39399, at *6 (N.D. Miss. Jan. 9, 2012). “Claims of inadequate medical treatment for a disability are distinguishable from claims that [a plaintiff] was denied access to medical services because of his disability.” *Postawko v. Missouri Dep’t of Corr.*, No. 2:16-CV-04219-NKL, 2017 WL 1968317, at *13 (W.D. Mo. May 11, 2017). The Excluded Mississippi Medicaid Beneficiaries are not seeking medical treatment for their disability of SUD, like the plaintiff in *Jackson*. Instead, they are denied access to medical services for HCV because of their SUD.

⁹⁵ Covered Services: Mississippi Medicaid Health Benefits Overview, Mississippi Division of Medicaid, <https://medicaid.ms.gov/medicaid-coverage/covered-services/> [<https://perma.cc/9GN9-54KF>].

by the FDA and prescribed by a provider. 42 U.S.C. §§ 1396r-8(a)(1), 1396r-8(d)(1)(B), 1396r-8(k)(2)(A), 1396r-8(k)(6); *Pharm. Research & Mfrs. Of Am. v. Walsh*, 538 U.S. 644, 652 (2003).

77. Thus, were it not for the Policy, Excluded Mississippi Medicaid Beneficiaries would qualify for Medicaid coverage of FDA-approved DAA medications such as Mavyret, Daklinza, Epclusa, Harvoni, Sovaldi, Vosevi, and Zepatier that are included in its Preferred Drug List once the medicine is prescribed by a provider.⁹⁶ The Excluded Mississippi Medicaid Beneficiaries meet the essential eligibility requirements for receipt of DAA treatment coverage, but as a result of the Policy, are excluded from effective and life-saving DAA treatment coverage that they would otherwise be entitled to.

78. Title II specifically states that if an individual is otherwise entitled to health services provided by a state or local entity, that entity may not deny health services to an individual on the basis of SUD—even when the individual is currently using illegal drugs as a result of their SUD. 42 U.S.C. § 12210(c); 28 C.F.R. §§ 35.131(b)(1), 36.209(b)(1). The Excluded Mississippi Medicaid Beneficiaries are otherwise entitled to DAA treatment because they meet the essential eligibility requirements.

ii. SUD is a well-known “impairment” that often substantially limits one or more major life activities.

79. It is well settled that substance use disorders including drug use disorder are recognized impairments under the ADA. *See, e.g., Gilmore v. Univ. of Rochester*, 654 F. Supp. 2d 141, 153 (W.D.N.Y. 2009) (quoting *Reg'l Econ. Cmty. Action Program, Inc. v. City of Middletown*, 294 F.3d 35, 46 (2d Cir. 2002)) (stating that “drug addiction is an “impairment,” which can support a finding of a “disability”), *Jeffrey O. v. City of Boca Raton*, 511 F. Supp. 2d 1339, 1347 (S.D. Fla. 2007) (“Alcoholism, like drug addiction, is an impairment under the definitions of a disability set forth in the FHA, the ADA, and the Rehabilitation Act.”); *Oxford House, Inc. v. Browning*, 266 F. Supp. 3d 896, 910 (M.D. La. 2017) (stating that “alcoholism and drug addiction are impairments under the [ADA]”).

80. Further, regulations promulgated by the Department of Justice make clear that substance use disorder is considered a physical and mental impairment under the ADA. 28 C.F.R. § 35.104; 28 C.F.R. § 36.104. The DOJ’s ADA Title II Technical Assistance Manual explicitly states that “[d]rug addiction is an impairment under the ADA.”⁹⁷ Committee reports that reveal the legislative history of the ADA specifically include “drug addiction” and “alcoholism” as impairments.⁹⁸

81. Many of the Excluded Mississippi Medicaid Beneficiaries are qualified individuals with a disability, because substance use disorder substantially limits major life activities such as: “functions such as caring for one’s self, performing manual tasks, walking, seeing, hearing,

⁹⁶ Preferred Drug List, Mississippi Division of Medicaid, <https://medicaid.ms.gov/preferred-drug-list/> [<https://perma.cc/JUS7-MWHH>].

⁹⁷ Department of Justice, ADA Title II Technical Assistance Manual, § II-2.3000.

⁹⁸ H.R. REP. No. 485, at 51.

speaking, breathing, learning, and working.”⁹⁹ Substance use disorders are characterized by impairment of function, usually across several important life areas such as basic hygiene, nutrition, and health; emotional balance and rational decision making; employment; finances; social and family ties; recreational activities; and living in a safe place.¹⁰⁰

82. Moreover, many of the individuals singled out by the Policy as having an “IV drug use history” are individuals with “a record of” disabling impairment. 42 U.S.C. 12102(b). Under the ADA, a disability is “also defined as having a record of a physical or mental impairment that substantially limits one or more major life activities.” *Hinojosa v. Jostens Inc.*, 128 F. App’x 364, 367 (5th Cir. 2005); *see also Lyons v. Katy Indep. Sch. Dist.*, 964 F.3d 298, 302 (5th Cir. 2020) (“The ADA provides protections for individuals who have a disability, had a disability, or are regarded as having a disability.”).
83. To the extent that Mississippi Medicaid’s blanket policy regarding use of illicit drugs in *any* amount relies on stereotypes that conflate the use of illicit drugs with substance use disorder, it is also forbidden by the ADA, because discrimination against people who are incorrectly “regarded as” having a disability is prohibited. 42 U.S.C. 12102(c); 42 U.S.C. 12210(b)(3) (prohibiting discrimination against people who are “erroneously regarded as engaging in illegal drug use”).

C. Mississippi Medicaid’s Policy denies lifesaving DAA treatment to the Excluded Mississippi Medicaid Beneficiaries by reason of their disability.

84. The Excluded Mississippi Medicaid Beneficiaries are protected by Title II because they are being “denied the benefits of a public entity’s services, programs, or activities, or [] otherwise discriminated against by the public entity; and that the exclusion, denial of benefit, or discrimination is by reason of [] disability.” *City of Southlake*, 936 F.3d at 330.
85. The Policy includes a blanket exclusion denying Medicaid coverage of DAA treatment on the basis of recent drug use. People with SUD have an “inability to control their use of

⁹⁹ *Id.* at 52.

¹⁰⁰ *See, e.g., Middletown*, 294 F.3d at 47-48 (in a Title II case, holding that plaintiffs’ substance use disorder was a disability because it substantially limited their ability to care for themselves, given that they could not “live independently without suffering a relapse”); *City of Covington*, 293 F.3d at 328, 337-39 (in a Title II case, holding that plaintiffs, who were recovering from substance use disorder, were substantially limited in the major life activities of “working, functioning socially and parenting,” and that despite their methadone treatments, the plaintiffs remained substantially limited because of the likelihood of relapse); *Browning*, 266 F.Supp.3d at 910 (“The Court finds that the residents... are disabled within the... ADA. [Plaintiff’s] impairment – an addiction to opioids – rendered her unable to maintain steady employment [and]... could not maintain stable housing as a result of her impairment.”); *Start, Inc. v. Baltimore County, Md.*, 295 F.Supp.2d 569, 577 (D. Md. 2003) (finding that individuals with substance use disorder who require methadone therapy were limited in their ability to work, raise children, care for themselves, and function in everyday life); *Swanston v. City of Plano, Texas*, 2021 WL 3847471, *7 (E.D. Tex. 2021) (holding that residents of a sober living home with substance use disorders are disabled because their inability to live independently without relapsing and inability to care for themselves constitutes a substantial limitation).

substances”¹⁰¹ and as a result, may continue “to use despite the substance causing problems to [Beneficiaries’] physical and mental health.”¹⁰²

86. Mississippi Medicaid’s Policy excludes everyone who has used drugs within the last six months. This Policy has no scientific or medical basis. Under Mississippi’s own definition of “medical necessity,” DAA treatment for Medicaid beneficiaries with HCV is medically necessary.¹⁰³ Mississippi Medicaid cannot justify their Policy out of concern for risk of treatment discontinuation or reinfection, as both concerns are refuted by medical literature.¹⁰⁴ Instead, significant scientific consensus exists that DAA treatment is effective for the Excluded Mississippi Medicaid Beneficiaries.¹⁰⁵
87. A disability discrimination claim may be based on “one of three theories of liability: disparate treatment, disparate impact, or failure to make a reasonable accommodation.” *Davis v. Shah*, 821 F.3d 231, 260 (2d Cir. 2016).
88. The Policy violates the ADA and discriminates against the beneficiaries at issue in this Complaint through both disparate treatment and disparate impact.

i. Disparate Treatment

89. By singling out SUD as the only non-medically justifiable criteria to deny treatment, Mississippi Medicaid’s Policy denies treatment to the Excluded Mississippi Medicaid Beneficiaries by reason of their disability.
90. Disparate treatment claims are cognizable under the ADA. *Raytheon Co. v. Hernandez*, 540 U.S. 44, 52 (2003). Disparate treatment claims in the ADA context focus on whether “the disability actually motivated the defendant’s adverse conduct.” *Smith v. Aroostook County*, 376 F. Supp. 3d 146, 158 (D. Me. 2019); *see also Shaikh v. Texas A&M University College of Medicine*, 739 Fed. Appx. 215, 222 (5th Cir. 2018) (“The causal connection between the individual’s disability and the discriminatory action ‘need not be direct’ in order to satisfy the ‘sole reason’ requirement: it is sufficient that the disability caused the individual to do or not do something, which, in turn, caused the discriminatory action.”).
91. Medical treatment decisions, such as those required under the Policy, “can be so unreasonable as to constitute evidence of discrimination under the ADA,” so long as the “showing of medical unreasonableness . . . [is] framed within some larger theory of disability discrimination.” *Aroostook County*, 376 F. Supp. 3d at 159. “For example, a plaintiff may argue that her physician’s decision was so unreasonable – in the sense of being arbitrary and capricious – as to imply that it was pretext for some discriminatory motive, such as animus, fear, or apathetic attitudes. Or, instead of arguing pretext, a plaintiff may argue that her physician’s decision was discriminatory on its face, because it rested on stereotypes of the disabled rather than an individualized inquiry into the patient’s condition – and hence was

¹⁰¹ See *supra* ¶¶ 24-31.

¹⁰² *Id.*

¹⁰³ See *supra* ¶¶ 39-47.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

unreasonable in that sense.” *Kimman v. N.H. Dep’t of Corr.*, 451 F.3d 274, 284-85 (1st Cir. 2019).

92. The Policy’s blanket rejection of DAA treatment to anyone who has recently used drugs is “so unreasonable as to raise an inference” that the Policy is based in animus against people with SUD. *Aroostook County*, 376 F. Supp. 3d at 160- 61 (D. Me. 2019). In *Aroostook County*, the court found that a county jail’s practice of always denying MAT to individuals with SUD—as opposed to making individualized treatment decisions for each person based on their medical needs—was so unreasonable as to raise the inference that the policy discriminated because of disability. *Id.* at 160.
93. No medical or individualized considerations “underl[ie] the decision to deny access to medically necessary treatment,” which makes the Policy “so arbitrary or capricious as to imply that it was pretext for some discriminatory motive” or even “discriminatory on its face.” *Pesce v. Coppinger*, 355 F. Supp. 3d 35, 46 (D. Mass. 2018) (internal quotations and citations omitted).
94. Further, to the extent that the Policy imposes the higher burden of a urine screen on individuals with a history of IV drug use, it discriminates against individuals with a record of a disabling impairment, 42 U.S.C. 12102(b), and impermissibly sweeps within its scope individuals who are regarded as having such an impairment. 42 U.S.C. 12102(c).

ii. **Disparate Impact (Meaningful Access)**

95. Title II’s prohibition against discrimination also extends to “those forms of discrimination which deny disabled persons public services disproportionately due to their disability,” or in other words, to facially neutral practices or requirements that have a disparate impact on the disabled. *Crowder v. Kitigawa*, 81 F.3d 1480, 1483-1484 (9th Cir. 1996).
96. Indeed, according to the Fifth Circuit, an entity’s failure to provide “meaningful access” to a benefit “is itself the harm under Title II, regardless of whether any additional injury follows.” *Luke v. Texas*, 46 F.4th 301, 305-06 (5th Cir. 2022).
97. To assert a disparate impact claim, a plaintiff must allege that a facially neutral government policy or practice has the “effect of denying meaningful access to public services” to people with disabilities. *K.M. v. Tustin Unified School Dist.*, 725 F.3d 1088, 1102 (9th Cir. 2013). “Courts have found denials of meaningful access when people with disabilities are systematically excluded.” *Fuog v. CVS Pharmacy Inc.*, 2021 WL 4355402, *5 (D.R.I. 2021).¹⁰⁶
98. The ADA and regulations implementing the ADA prohibit discriminatory impact arising from a facially neutral policy. 42 U.S.C. § 12101(a)(5). Under 28 C.F.R. § 35.130(b)(3), public entities are forbidden from using “criteria that *have the effect* of subjecting qualified individuals with disabilities to discrimination on the basis of disability.” 28 C.F.R. §

¹⁰⁶ *Alexander v. Choate*, 469 U.S. 287 (1985) analyzed a disparate impact claim under §504 of the Rehabilitation Act of 1974 brought against Tennessee’s Medicaid through the lens of meaningful access and courts have since adopted the lens when adjudicated disparate impact claims brought under the ADA.

35.130(b)(8) further forbids public entities from imposing “eligibility criteria that screens out or tend to screen out an individual with a disability or any class of individuals with disabilities from fully and equally enjoying [public benefits].” In an explanatory commentary to 28 C.F.R. § 35.130(b)(3), the agency specifically noted that the language forbidding “criteria that have the effect of subjecting [the disabled] to... discrimination was intended to prevent public entities from utilizing ‘criteria or methods of administration’ that may be ‘neutral on their face, but deny individuals with disabilities an effective opportunity to participate.’”¹⁰⁷

99. The Policy has a disparate impact on the Excluded Mississippi Medicaid Beneficiaries who are not able to produce proof of sobriety because of their disability, “effectively deny[ing] these persons . . . meaningful access to state services, programs, and activities while such services, programs, and activities remain open and easily accessible by others.” *Crowder v. Kitagawa*, 81 F.3d 1480, 1485 (9th Cir. 1996); 28 C.F.R. § 35.130(b)(1)(vii).¹⁰⁸
100. Regardless of Mississippi Medicaid’s purported reasons, the policy of requiring a negative urine drug screen and excluding individuals who are not abstinent from drugs has a disproportionate effect on individuals with SUD. The requirement “applies equally to all persons” seeking DAA treatment, but the policy “clearly ha[s] the effect of preventing” individuals with substance use disorders “in a manner different and greater than it burdens others.” *Crowder*, 81 F.3d at 1484 (9th Cir. 1996) (“Although Hawaii’s quarantine requirement applies equally to all persons entering the state with a dog, its enforcement burdens visually-impaired persons in a manner different and greater than it burdens others.”); 28 C.F.R. § 35.130(b)(1)(ii). As stated above, the Policy burdens the Excluded Mississippi Medicaid Beneficiaries because the Excluded Mississippi Medicaid Beneficiaries, due to their SUD, have an “inability to control their use of substances” and as a result, continue “to use despite the substance causing problems to [the Excluded Mississippi Medicaid Beneficiaries’] physical and mental health.”

V. Conclusion – Request for Enforcement

Mississippi Medicaid’s Policy impermissibly discriminates against the Excluded Mississippi Medicaid Beneficiaries. The DOJ must enforce the Americans with Disabilities Act to put an end to this discrimination. To remedy these violations, and to protect the civil rights of Medicaid beneficiaries with SUD and HCV moving forward, the DOJ and any other appropriate agency of the federal government should open an investigation. The DOJ should pursue all avenues of enforcement – from efforts to obtain voluntary compliance up to litigation – to cause Mississippi Medicaid to revise its coverage policies related to DAA treatment for individuals with HCV, including the following:

1. Prohibit consideration of drug use as a Medicaid coverage exclusion for DAA treatment;

¹⁰⁷ Preamble to Regulation on Nondiscrimination on the Basis of Disability in State and Local Government Services, Section by Section Analysis, Comment on 28 C.F.R. § 35.130(b)(3), reproduced in Appendix A to Part 35, 28 CFR Parts 0 to 42 (U.S. Gov’t Printing Office, July 1, 1996) 467.

¹⁰⁸ See *California Council of the Blind v. County of Alameda*, 985 F.Supp.2d 1229, 1236 (N.D. Cal. 2013) (stating that when considering the meaningful access requirement of the ADA, courts are guided by the “specific implementing regulations” of the ADA.”).

2. Cease the blanket rejection of Medicaid beneficiaries with SUD and HCV seeking DAA treatment;
3. Remove the requirement, “Counseling regarding abstinence from alcohol, IV drug use, and education on how to prevent HCV transmission,” from the Criteria/Additional Documentation page of the Mississippi Medicaid Hepatitis C packet;
4. Remove the requirement, “Abstinence from drugs for at least 6 months; negative urine drug screen required if there is IV drug use history,” from the Criteria/Additional Documentation page of the Mississippi Medicaid Hepatitis C packet;
5. Educate providers on the current medical standard and science of DAA treatment efficacy on those with SUDs;
6. Educate providers and Mississippi Medicaid staff about SUD and how it affects individuals to remove bias against treating patients with SUD;
7. Take steps to promote Mississippi Medicaid beneficiaries with HCV to seek a doctor’s care, including individualized evaluation of whether DAA treatment is appropriate regardless of SUD status.

Date: November 21, 2022

/s/ Alicia Barnes

Alicia Barnes
My Brother’s Keeper
407 Orchard Park
Ridgeland, MS 39157
Tel: 769-216-2455

/s/ Harya Tarekegn

Harya Tarekegn
Linda Dixon
Mississippi Center for Justice
210 E. Capitol Street, Suite 1800
Jackson, MS 39201
Tel: 601-352-2269

/s/ Michael Saag

Michael Saag, M.D.
3220 5th Avenue South
Birmingham, AL 35222
Tel: 205-934-7349

/s/ Kevin Costello

Kevin Costello
Suzanne Davies
Center for Health Law and Policy Innovation
Harvard Law School
1585 Massachusetts Avenue
Cambridge, MA 02138
Tel: 617-496-0901

**United States Department of Justice
Civil Rights Division, Disability Rights Section,
950 Pennsylvania Avenue, NW Washington, D.C. 20503**

Administrative Complaint Against the Mississippi Medicaid Agency

EXHIBIT 1:

**Mississippi Medicaid Prior Authorization Form and
Criteria/Additional Documentation Form**



STANDARDIZED ONE PAGE PHARMACY PRIOR AUTHORIZATION FORM

Mississippi Division of Medicaid, Pharmacy Prior Authorization Unit, 550 High St., Suite 1000, Jackson, MS 39201

Magnolia Health/Envolv Pharmacy Solutions
Fax to: 1-877-386-4695 Ph: 1-866-399-0928
<https://www.magnoliahealthplan.com/providers/pharmacy.html>

UnitedHealthcare/OptumRx
Fax to: 1-866-940-7328 Ph: 1-800-310-6826
<http://www.uhcommunityplan.com/health-professionals/ms/pharmacy-program.html>

Molina Healthcare/CVS Caremark
Fax to: 1-844-312-6371 Ph: 1-844-826-4335
<http://www.molinahealthcare.com/providers/ms/medicaid/pages/home.aspx>

Medicaid Fee for Service/Change Healthcare
Fax to: 1-877-537-0720 Ph: 1-877-537-0722
<https://medicaid.ms.gov/providers/pharmacy/pharmacy-prior-authorization/>

BENEFICIARY INFORMATION

Beneficiary ID: _____ - _____ - _____ DOB: ____/____/____

Beneficiary Full Name: _____

PRESCRIBER INFORMATION

Prescriber's NPI: _____

Prescriber's Full Name: _____ Phone: _____

Prescriber's Address: _____ FAX: _____

PHARMACY INFORMATION

Pharmacy NPI: _____

Pharmacy Name: _____

Pharmacy Phone: _____ Pharmacy FAX: _____

CLINICAL INFORMATION

Requested PA Start Date: _____ Requested PA End Date: _____

Drug/Product Requested: _____ Strength: _____ Quantity: _____

Days Supply: _____ RX Refills: _____ Diagnosis or ICD-10 Code(s): _____

Hospital Discharge

Additional Medical Justification Attached

Medications received through coupons and/or samples are not acceptable as justification.

PLEASE COMPLETE AND FAX DRUG SPECIFIC CRITERIA/ADDITIONAL DOCUMENTATION FORM FOUND BELOW

Prescribing provider's signature (signature and date stamps, or the signature of anyone other than the provider, are not acceptable)

I certify that all information provided is accurate and appropriately documented in the patient's medical chart.

Signature required: _____ Date: _____

Printed name of prescribing provider: _____

FAX THIS PAGE

SUBMISSION AND/OR APPROVAL OF A DRUG PRIOR AUTHORIZATION REQUEST DOES NOT GUARANTEE MEDICAID PAYMENT FOR PHARMACY PRODUCTS OR THE AMOUNT OF PAYMENT. ELIGIBILITY FOR AND PAYMENT OF MEDICAID SERVICES ARE SUBJECT TO ALL TERMS AND CONDITIONS AND LIMITATIONS OF THE MEDICAID PROGRAM. Confidentiality Notice: This communication, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply telephone (1-877-537-0722) or fax (1-877-537-0720) and destroy all copies of the original message. 06/1/2021

CRITERIA/ADDITIONAL DOCUMENTATION

HEPATITIS C

FAX THIS PAGE



BENEFICIARY INFORMATION

Beneficiary ID: _____ - _____ - _____ DOB: ____/____/____

Beneficiary Full Name: _____

Hepatitis C Therapy PA Request

Diagnosis / Treatment Status (check all that apply) *See Hepatitis-C PA description sheet for approval criteria and intolerance definitions.

- Prescriber is, or has consulted with a gastroenterologist, hepatologist, ID specialist or other hepatic specialist. Requires consult within the past year with documentation of recommended regimen.
- Active HCV infection verified by viral load within the last year: HCV RNA: _____ million IU/mL Date: _____
- Genotype verified by lab: 1a 1b 2 3 4 5 6

HIV status: positive negative (required)

- Patient has not taken amiodarone within 535 days (required if regimen includes Harvoni or Sovaldi)

RBV-Ineligible reason: _____

Hepatic fibrosis stage _____

Last stage evaluation date: _____

Method of cirrhosis/fibrosis stage: _____

- Decompensated cirrhosis
- Compensated cirrhosis Child-Pugh Score and Date: _____
- Post-liver transplant Date: _____
- Hepatocellular carcinoma and awaiting a liver transplant: Transplant date: _____
 - Not yet scheduled
- Dialysis __Yes/___No
- CrCl ____ mL/min Lab Date w/n last year: _____
- Screened for HEP-B and HIV prior to HEP-C treatment start
 - Date of last test: Hep B: ____/____/____ HIV: ____/____/____
 - Timing of the screening for Hep-B/HIV should be based on patient specific risk factors but lab result date must be provided and if > 1 year ago, it should be documented in the record as to why repeat testing is not clinically warranted. **If the patient has had ongoing risk factors of any type, consider retesting in the month prior to HCV therapy. If positive, treatment must be considered per AASLD/IDSA and current NIH HIV guidelines.**
 - Repeat screening should be patient specific.

Patient is: Treatment naïve Relapser

If Relapser, then prior HCV Treatment: last two regimens, if any

Regimen 1: _____ Dates/duration of use: _____ Response: _____

Regimen 2: _____ Dates/duration of use: _____ Response: _____

- Prior partial responder Prior null responder

Stopped prior therapy for other reason: _____

Regimen: _____ Dates/duration of use: _____ Response: _____

Social History (check all that apply)

- Patient is ≥ 18 years of age **OR** meets current AASLD guidelines for treatment

Documentation (available if requested) of:

- Counseling regarding abstinence from alcohol, IV drug use and education on how to prevent HCV transmission.
- Abstinence from drugs for at least 6 months; negative urine drug screen required if there is IV drug use history.

For women of childbearing potential and male patients with female partners of childbearing potential (for RBV regimens only):

- Patient is not pregnant (or a male with a pregnant female partner) and not planning to become pregnant during treatment or within 6 months of stopping treatment.
- Agreement that partners will use 2 forms of effective contraception during treatment and for at least 6 months after stopping tx.
- Verification that monthly pregnancy tests will be performed throughout treatment.

Other Medications (OTC, Herbal and Prescription) Information

Drug name / strength	Frequency / instructions	Quantity	Refills

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PRIOR AUTHORIZATION DESCRIPTION

- Note annotations and respective definitions as described on “Hepatitis C Therapy PA Request Guidelines for Regimen Selection and Definitions” page



Hepatitis C Therapy PA Request Guidelines for Regimen Selection and Definitions

For beneficiaries meeting the criteria, the Mississippi Division of Medicaid (DOM) will approve Hepatitis C treatment PA requests as follows:

- The regimens listed for each clinical scenario below are the preferred regimens for MS Medicaid beneficiaries, based on clinical and cost considerations and are consistent with AASLD/IDSA guidelines.
<http://www.hcvguidelines.org/full-report-view>

OR

- Pediatric formulations of direct acting antivirals (DAA) with FDA approval will be approved for those patients under the age of eighteen when used according to the table below for treatment naïve children as well as in accordance with current AASLD guidelines including for indication and age - Prior authorization is still required prior to the first dose.**

GT	Age (years)	Weight (kg)	Drug	Dose	Weeks
Any	3 to 11	< 20	Mavyret Oral Pellets	Three 50 mg/20 mg packets daily	8
		20 - <30	Mavyret Oral Pellets	Four 50 mg/20 mg packets daily	8
		30 - < 45	Mavyret Oral Pellets	Five 50 mg/20 mg packets daily	8
		45+	Mavyret Tablets	Three 100/40 tablets daily	8
	12+		Mavyret Tablets	Three 100/40 tablets daily	8
	≥ 6	≥ 30	sofosbuvir/velpatasvir 400/100 tablet	One tablet daily	12

OR

- Clinical rationale is provided for using a regimen that is beyond those within the current guidelines, or for selecting regimens using non-preferred drugs on the Mississippi Division of Medicaid Universal Preferred Drug List*

On the PA Request Form, which must be approved prior to the 1st dose, document the clinical condition supporting the requested regimen. Unless otherwise specified, you do not need to attach documentation to the form. You are attesting to the fact that documentation is available in the patient chart for all information you provide.

DEFINITIONS/ANNOTATIONS USED ON PA FORM:

▽ **Low Dose Ribavirin = 600 mg/day and increase as tolerated**

◇ **Ribavirin-Ineligible** (documentation exists in the patient’s chart for at least one of the following):

- Hypersensitivity to RBV
- History of severe or unstable cardiac disease
- Pregnant women and men with pregnant partners
- Diagnosis of hemoglobinopathy (e.g., thalassemia major, sickle cell anemia)
- Baseline platelet count < 70,000 cells/mm³
- ANC < 1500 cells/mm³
- Hb < 12 gm/ml in women or <13 g/dl in men

RENAL DYSFUNCTION Patients with CrCl <50 ml/mm should not be treated with ribavirin.

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Preferred Direct Acting Antivirals

Mavyret (glecaprevir/pibrentasvir) 300/120 mg
sofosbuvir/velpatasvir 400/100 mg

Non-Preferred Direct Acting Antivirals

Harvoni (ledipasvir/sofosbuvir) 90/400 mg
Sovaldi (sofosbuvir) 400 mg
ledipasvir/sofosbuvir 90/400 mg

Pediatric Indicated Direct Acting Antiretrovirals (FDA approved age ranges and indications ONLY)

Mavyret (glecaprevir/pibrentasvir) 400/100 mg
Mavyret Oral Pellets (glecaprevir/pibrentasvir) 50/20mg
Epclusa 200/50 mg tablet
Harvoni (ledipasvir/sofosbuvir) 45/200 mg tablet
Harvoni (ledipasvir/sofosbuvir) 90/400 mg tablet
Harvoni 33.75/150 mg pellet pak
Harvoni 45/200 mg pellet pak
Sovaldi (sofosbuvir) 200 mg
sofosbuvir/velpatasvir 400/100 mg

Vosevi (sofosbuvir, velpatasvir, and voxilaprevir)
Epclusa (sofosbuvir/velpatasvir) 400/100 mg

Preferred (most cost-effective) Regimens Listed Below. Not all available regimens are listed.

NOTE: Adult Guidelines have changed substantially; most recommendations are largely genotype non-specific; exceptions are noted in red

PLEASE CHECK REQUESTED REGIMEN

ADULT: Treatment naïve
No cirrhosis <ul style="list-style-type: none"> <input type="checkbox"/> Mavyret 100/40 mg, three (3) tablets daily for 8 weeks (for GT5/6 and/or HIV/HCV co-infection, 12 weeks is recommended) <input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks
Compensated cirrhosis, HIV negative <ul style="list-style-type: none"> <input type="checkbox"/> Mavyret 100/40 mg, three (3) tablets daily for 8 weeks <input type="checkbox"/> sofosbuvir/velpatasvir 400/100, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)
Compensated cirrhosis, HIV positive <ul style="list-style-type: none"> <input type="checkbox"/> Mavyret 100/40 mg, three (3) tablets daily for 12 weeks <input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)
ADULT: Treatment experienced (with or without compensated cirrhosis)
Sofosbuvir-based regimen <ul style="list-style-type: none"> <input type="checkbox"/> Mavyret 100/40 mg, three (3) tablets daily for 16 weeks
NS3/4 protease inhibitor inclusive regimen (e.g. Zepatier) <ul style="list-style-type: none"> <input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily for 12 weeks
Mavyret <ul style="list-style-type: none"> <input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily for 12 weeks (if compensated cirrhosis, add weight based RBV)
Vosevi or sofosbuvir + Mavyret

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- *Note annotations and respective definitions as described on "Hepatitis C Therapy PA Request Guidelines for Regimen Selection and Definitions" page*



<input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily + weight based RBV for 24 weeks
GT 3 only: sofosbuvir/NS5A (e.g. Harvoni)
<input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily + weight based RBV for 12 weeks
ADULT: Re-infection of Allograft Liver after Transplant
DAA-treatment naïve, no decompensated cirrhosis
<input type="checkbox"/> Mavyret 100/40 mg, three (3) tablets daily for 12 weeks
<input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks
DAA-treatment experienced, no decompensated cirrhosis
<input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily for 12 weeks
IF multiple negative baseline characteristics, consider
<input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily + low dose RBV for 12 weeks
Treatment naïve, decompensated cirrhosis
<input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV for 12 weeks
Treatment experienced, decompensated cirrhosis (Child-Pugh B or C ONLY)
<input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV for 24 weeks
ADULT: Decompensated Cirrhosis
No prior sofosbuvir or NS5A failure
<input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 12 weeks (low dose RBV recommended for Child-Pugh class C cirrhosis)
<input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg daily for 24 weeks (will be approved only for patients with documented ineligibility for RBV)
Prior sofosbuvir or NS5A failure
<input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 24 weeks (low dose RBV if Child-Pugh C)
Other Treatment Regimen requested
Genotype, treatment history, and extent of liver disease: <hr/> <hr/>
Drug names, doses and durations: _____ <hr/>
Clinical rationale for selecting regimens other than those outlined above: <hr/> <hr/>

PRIOR AUTHORIZATION DESCRIPTION

- *Note annotations and respective definitions as described on “Hepatitis C Therapy PA Request Guidelines for Regimen Selection and Definitions” page*



For unique patient populations with renal impairment or HIV: please refer to the current AASLD Guidelines for recommended treatments. <http://www.hcvguidelines.org/full-report-view>

If HIV positive: Please refer to the current AASLD Guidelines for potential drug interactions and recommended dosing adjustments.

DRUG INTERACTIONS

Reference: <http://hep-druginteractions.org/> provides clinically useful, reliable, and current evidence-based information on relevant drug interactions with hepatitis medications.