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

Administrative Complaint Against the Alabama Medicaid Agency

Complainants

AIDS Alabama
AIDS Alabama
3529 7th Ave South
Birmingham, AL 35222
Tel: 205-324-9822

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

AIDS Alabama is a non-profit organization incorporated in 1986, and now with offices in Birmingham and Mobile, Alabama. Its mission is to help people with HIV/AIDS live healthy, independent lives and to prevent the spread of HIV. The organization focuses on housing, supportive services, policy and advocacy, prevention education, and free and confidential HIV and Hepatitis C testing. In 1988, AIDS Alabama was awarded a grant from the Health Resources Services Administration (HRSA) to perform a needs assessment and trend analysis for persons living with HIV in the greater Birmingham area. This comprehensive research involved the University of Alabama at Birmingham, persons living with HIV, health care and mental health providers, social service agency directors, city and county representatives, bio-statisticians, social workers, volunteers, and more. That exercise – commenced more than three decades ago -- provides the foundation for much of the work still done by AIDS Alabama today.

AIDS Alabama is the largest HIV/AIDS service provider in the state and helps to fund the other nine AIDS Service Organizations (ASOs) in an effort to cover all 67 Alabama counties. In 2012, AIDS Alabama provided more than 170,000 nights of safe and affordable housing to over 600 low-income, HIV-positive individuals and their families. AIDS Alabama also runs the state's only facility for persons living with HIV disease who are also diagnosed

with a severe mental illness. Another key program is the residential substance abuse program that allows participants to move through an intensive, three-part program that includes follow-up care upon graduation.

AIDS Alabama's prevention, education, and outreach efforts reach thousands of people across the state each year and includes free, confidential testing and connection to care, education, services, and housing. AIDS Alabama also dedicates resources to improving federal and state policies impacting persons living with or at risk for HIV/AIDS in Alabama. Coinfection with HIV and Hepatitis C is common, and coinfected 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 AIDS Alabama have substance use disorder as well.[2] This complaint addresses a policy that harms many people in the community that AIDS Alabama serves.

The Center for Health Law and Policy Innovation (CHLPI) of Harvard Law School advocates for legal, regulatory, and policy reforms in health and food systems, with a focus on the health, public health, and food needs of systemically marginalized individuals. 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

[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-virushiv-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].

health care and food systems. 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. Recently, CHLPI has successfully litigated on behalf of Texas Medicaid beneficiaries and removed Texas Medicaid's disease severity restrictions for DAA treatment.[3] "As a result of the lawsuit, [the Texas Health & Human Services Commission] rewrote its policy, expanding access to DAAs to Medicaid enrollees diagnosed with HCV regardless of liver damage, and removing sobriety and prescriber requirements for HCV treatment."[4]

I. INTRODUCTION

1. 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 DAA treatment to every patient with chronic 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").[5]

[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].
[4] Id.
[5] AASLD & IDSA, HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C (last updated Oct. 5, 2021) [hereinafter HCV Guidance], https://www.hcvguidelines.org/sites/default/files/full-guidance-pdf/AASLD-IDSA_HCVGuidance_October_05_2021.pdf [https://perma.cc/MR8R-FU6K].

2. Contradicting the standard of care, Alabama Medicaid systematically denies life-saving HCV treatment to many Medicaid beneficiaries with substance use disorder ("SUD"). It does so by maintaining a policy (the "Policy") which includes a blanket sobriety restriction denying Medicaid coverage to any applicant who used drugs or alcohol 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 for Medicaid beneficiaries with SUD in violation of Title II of the Americans with Disability Act ("ADA").

3. AIDS Alabama and CHLPI bring this administrative complaint on behalf of all Alabama Medicaid enrollees disabled by SUD and diagnosed with chronic HCV. Although DAA treatment is the appropriate standard of care for these individuals, the Policy renders them ineligible for coverage because of their disability.

4. Title II of the ADA authorizes the United States 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). 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.[6]

[6] 28 C.F.R. § 35.171 (2010); see also DOJ, Americans with Disabilities Act Title II Technical Assistance Manual § II-9.2000 ("A complaint may be filed with… the Department of Justice.").

5. The DOJ should investigate the Policy and work with Alabama 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 CONCERNING HCV

6. Hepatitis C virus is an infectious and life-threatening blood borne infection. Hepatitis C can lead to serious liver damage, cirrhosis, liver cancer, liver failure, and ultimately even death.[7]

7. Hepatitis C is most commonly transmitted through infected blood. Individuals most at risk of HCV include recipients of blood transfusions or organ transplants before 1992, current or former drug users, health care workers exposed to needle sticks containing HCV-infected blood, and children born to mothers with HCV.[8]

8. The annual incidence rate of HCV infection in the United States increased approximately fourfold from 2005 to 2017, with the greatest increase happening among persons aged 20-39 years.[9] The rapid increase in HCV infection among young adults coincides with the opioid epidemic.[10] A new study in the United States has found that the

[7] Mayo Clinic, Hepatitis C, https://www.mayoclinic.org/diseases-conditions/hepatitis-c/symptoms-causes/syc-20354278 [https://perma.cc/LHS2-ESNE]; CDC, Hepatitis C Information, https://www.cdc.gov/hepatitis/hcv/index.htm [https://perma.cc/YZT4-P5RU]; Mousumi Khatun & Ratna B. Ray, Mechanisms Underlying Hepatitis C Virus-Associated Hepatic Fibrosis, Cells, Oct. 2019, at 1 (2019).
[8] CDC, Hepatitis C Questions and Answers for Health Professionals, https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm [https://perma.cc/848P-JC9X].
[9] A. Blythe Ryerson et al., Vital Signs: Newly Reported Acute and Chronic Hepatitis C Cases – United States, 2009-2018, 69 MMWR Morbidity & Mortality Wkly Rep. 399, 399 (2020) [hereinafter Ryerson, Vital Signs].
[10] Jon E. Zibbell et al., Increases in Hepatitis C Virus Infection Related to Injection Drug Use Among Persons Aged ≤30 Years—Kentucky, Tennessee, Virginia, and West Virginia, 2006–2012, 64 MMWR Morbidity & Mortality Wkly Rep. 453 (2015).

number of millennials diagnosed with HCV is increasing and is now comparable to that of baby boomers, also a key population within the HCV epidemic.[11]

9. As of 2021, an estimated 3.2 million Americans are infected with HCV.[12] Each year, an estimated 15,000 people die from HCV-related liver disease, which is higher than the death rate from HIV.[13] HCV is the leading indication for liver transplants in the United States.[14]

10. The dangers of HCV are widespread. 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.

11. Even in the initial stages of the disease, individuals infected with HCV can experience serious symptoms, including fatigue, poor appetite, jaundice, itchy skin, ascites, swelling, weight loss, confusion, drowsiness, slurred speech, spider angiomas, nausea, fever, and muscle aches.[15]

12. HCV causes a number of serious extrahepatic effects. Such effects include kidney disease, hypertension, lymphoma, intractable fatigue, joint pain, arthritis, vasculitis, thyroid disease, depression, memory loss, sore muscles, mental changes, heart attacks, diabetes, nerve damage, jaundice, and various cancers.[16]

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[11] Ryerson, Vital Signs, supra note 9.
[12] 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].
[13] Id.
[14] G. Tsoulfas et al., Hepatitis C Virus and Liver Transplantation, 13 Hippokratia 211, 214 (2009).
[15] Mayo Clinic, Hepatitis C, https://www.mayoclinic.org/diseases-conditions/hepatitis-c/symptoms-causes/syc-20354278 [https://perma.cc/LHS2-ESNE].
[16] Patrice Cacoub, Extrahepatic Manifestations of Chronic Hepatitis C Virus Infection, 3 Ther. Adv. Infect. Dis. 3, 3-9 (2016).

13. The U.S. Surgeon General has referred to HCV as a "silent epidemic."[17] For many infected individuals, there can be few noticeable symptoms in early stage infection; some people remain unaware of their infection until serious, late stage complications arise. "51% of persons living with hepatitis C infection do not know they have the virus," and as a result, "they are at risk for life threatening liver disease and cancer and unknowingly transmitting the virus to others."[18]

14. Failure to treat HCV increases the risk of a number of adverse health effects, including irreversible liver damage, liver and other various cancers, likelihood of need for liver transplant, mental and physical suffering, and preventable death.

III. FACTUAL ALLEGATIONS CONCERNING SUBSTANCE USE DISORDER

15. Substance use disorder is an umbrella term that encompasses, among other things, both drug addiction and alcoholism.[19] 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."[20] Throughout this Complaint, the term

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[17] Surgeon General Regina M. Benjamin, Surgeon General's Perspective, 127 Public Health Reports 244, 244 (May-June 2012) https://www.cdc.gov/hepatitis/pdfs/surgeongeneral-phr_may-june2012.pdf [https://perma.cc/WRX2-ZTLM]

[18] HHS, Viral Hepatitis in the United States: Data and Trends, https://www.hhs.gov/hepatitis/learn-about-viral-hepatitis/data-and-trends/index.html [https://perma.cc/QZG8-T9AS].

[19] Mayo Clinic, Drug Addiction (Substance Use Disorder), https://www.mayoclinic.org/diseases-conditions/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].

[20] 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),

"substance use disorder" is used to refer to both alcohol use disorder and substance use disorder involving the use of drugs, including opioid use. According to the Substance Abuse and Mental Health Services Administration (SAMHSA)'s 2020 National Survey on Drug Use and Health, approximately 19.3 million people aged 18 or older had a SUD in the past year. [21] The prevalence of SUD amongst Americans is reflected in Medicaid. "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."[22]

16. SUD is accompanied by changes in the brain's wiring, which causes people to have an intense craving for a particular substance.[23] 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.[24] 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

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https://www.mayoclinic.org/diseases-conditions/drug-addiction/symptoms-causes/syc-20365112 [https://perma.cc/TUV5-VERB].

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

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

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

[24] Id.

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.[25]

17. 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."[26]

18. 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.[27] This increase was recorded across every ethnic and racial groups.[28] According to federal data, drug overdose deaths also reached record levels

[25] American Psychiatric Association, Substance Use Disorder, in The Diagnostic and Statistical Manual of Mental Disorders Fifth Edition [hereinafter DSM-5], 483, 483-484 (2013).
[26] 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/department-justice-awards-more-300-million-fight-opioid-and-stimulant-crisis-and-address [https://perma.cc/ZSE8-KP2A].
[27] 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].
[28] 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].

during the first year of the pandemic.[29] The Center for Disease Control ("CDC") reported that in a twelve-month time period from October 2020 to October 2021, drug overdose deaths increased approximately 31% in Alabama, from 965 deaths in 2020 to 1263 deaths in 2021.[30] A recent survey of Alabama residents that was published by the Alabama Department of Public Health revealed that "mental health and substance abuse [is] the second greatest current health concern in Alabama"—second only to access to care.[31]

19. 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.[32] Injection drug use accounts for the majority of new HCV infections – approximately 70% of new HCV patients are injection drug users.[33] 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.[34]

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[29] CDC, Provisional Drug Overdose Death Counts, https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-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-opiods-coronaviurs-pandemic.html [https://perma.cc/5FVE-Q4GB].
[30] CDC, Provisional Drug Overdose Death Counts, https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm [https://perma.cc/EC2L-YAJ3].
[31] Alabama Department of Public Health, Mental Health and Substance Abuse, https://www.alabamapublichealth.gov/healthrankings/mental-health-and-substance-abuse.html [https://perma.cc/8HGZ-TA37].
[32] 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].
[33] Id.
[34] 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).

20. Despite the fact that people injecting drugs are the most vulnerable to HCV, only 13% of the people who inject drugs have been provided with DAA treatment.[35]

21. Experts urge that in order to reach the World Health Organization's goal of eliminating HCV by 2030, treating people who inject drugs is a priority.[36]

IV. FACTUAL ALLEGATIONS CONCERNING THE EFFICACY OF HCV TREATMENT FOR PEOPLE WITH SUBSTANCE USE DISORDER

a. Direct-Acting Antiviral Treatment is a Breakthrough Therapy that Can Cure HCV Before It Causes Significant, Potentially Irreversible Liver Damage and Severe Health Effects

22. In 2011, the Food and Drug Administration ("FDA") approved the first wave of direct-acting antivirals for treatment of chronic HCV, and specialists heralded "the beginning of the end of chronic HCV."[37] The FDA designated DAAs a "breakthrough therapy,"[38] a classification reserved for drugs that provide substantial improvement over available therapies for patients with 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. In fact, Alabama Medicaid Agency's Pharmacy and Therapeutics

[35] 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).
[36] 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.
[37] 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).
[38] "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).

Committee states that DAAs are preferred over older regiments "due to a higher SVR rate, improved side effects profile, and reduced pill burden"[39] and recognize that "data from clinical trials support the FDA-approved indications" of DAA agents.[40]

23. 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.[41] 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.[42] This compounds the benefits of DAA treatment across the population and is essential in halting the current HCV epidemic in Alabama and across the United States.

24. If administered correctly, DAA treatment regimens "achieve SVR rates of more than 95%."[43] This means that DAA treatment regimens have more than a 95% success rate for

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[39] Alabama Medicaid Agency's Pharmacy and Therapeutics Committee, Minutes (May 9, 2018), https://medicaid.alabama.gov/documents/4.0_Programs/4.3_Pharmacy-DME/4.3.6_PandT_Committee/4.3.6.1_PandT_Committee_Meetings/4.3.6.1.1_Meetings_2018/4.3.6.1.1_Minutes_5-9-18.pdf [https://perma.cc/9VAF-QKS5].

[40] Id. In fact, the Pharmacy and Therapeutics Committee Meeting Clinical Packet for the May 8, 2019 meeting includes the recommendation from the AASLD that states, "There are no data to support pretreatment screening for illicit drugs or alcohol use in identifying a population more likely to successfully complete HCV therapy. These requirements should be abandoned, because they create barriers to treatment, add unnecessary cost and effort, and potentially exclude populations that are likely to obtain substantial benefit from therapy." Alabama Medicaid Agency's Pharmacy and Therapeutics Committee, Clinical Packet (May 8, 2019), https://medicaid.alabama.gov/documents/4.0_Programs/4.3_Pharmacy-DME/4.3.6_PandT_Committee/4.3.6.1_PandT_Committee_Meetings/4.3.6.1.2_Meetings_2019/4.3.6.1.2_Clinical_Packet_5-8-19.pdf [https://perma.cc/YFW4-APXT].

[41] 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].

[42] 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].

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

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."[44]

b. DAAs are the Standard of Medical Care for Treatment for People with HCV, Including People with SUD

25. The FDA has approved DAA use for nearly all patients with chronic HCV.[45]

26. 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 collaborated to publish treatment guidelines for HCV ("HCV Guidance") that establishes the national standard of care for HCV treatment, and "disseminates up-to-date, peer-reviewed, unbiased, evidence-based recommendations to aid clinicians making decisions regarding the testing, management, and treatment of HCV infection." [46] The HCV Guidance recommends DAA treatment for nearly all patients with chronic HCV, with very few enumerated exceptions.[47] People with substance use disorder, and people with a history of drug and alcohol use, are not excluded under the AASLD and IDSA recommendations.[48] In fact, the HCV Guidance clearly states that "[d]ata do not support exclusion of HCV-

[44] Id. at 166.
[45] 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-all-genotypes-hepatitis-c-pediatric-patients [https://perma.cc/KXA3-SF4E].
[46] 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).
[47] AASLD & IDSA, HCV Guidance, https://www.hcvguidelines.org/sites/default/files/full-guidance-pdf/AASLD-IDSA_HCVGuidance_October_05_2021.pdf [https://perma.cc/MR8R-FU6K].
[48] Id.

infected persons from consideration for hepatitis C therapy based on alcohol intake or use of illegal drugs."[49]

27. 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. On November 15, 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."[50] 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."[51]

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[49] Id.

[50] CMS, 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 [https://perma.cc/S3LZ-LCW3] [hereinafter CMS HCV Guidance].

[51] Id. "Courts have accorded CMS' interpretations of the Medicaid Act, such as that found in the *State Medicaid Manual*, 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).

c. Denying DAA Treatment Based on Drug and Alcohol Use Does Cannot Be Justified on Medical Necessity Grounds

28. Medical and scientific studies emphasize the point that "HCV treatment should be universally offered to all eligible patients."[52] 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."[53] Instead, the fact that a patient has SUD "should result in intensified HCV management and care."[54] In other words, instead of denying treatment for patients with SUD, people with SUD are precisely the population that should be prioritized for DAA treatment due to their increased risk of more aggressive liver disease.

i. DAA Treatment is Medically Necessary

29. DAA treatment is medically necessary for everyone who is diagnosed with HCV.[55] See B.E. v. Teeter, 2016 WL 3033500, at *4 (W.D. Wash. 2016) ("[T]here is a consensus among medical experts and providers that the life-saving DAAs are 'medically necessary' for all HCV-infected persons.").

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[52] Antonio Saviano et al., Hepatitis C Treatment in Patients with Substance Use Disorder: The Faster the Better, 11 Hepatobiliary Surg. Nutr. 129, 130 (2022).
[53] Id.
[54] 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.").
[55] CMS HCV Guidance, https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf [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 and alcohol abuse as a condition for payment for DAA HCV drugs.").

30. Even under Alabama Medicaid's own definitions, DAA treatment for beneficiaries with HCV is medically necessary. Alabama Medicaid's Alabama Medicaid Management Information System Provider Manual ("Manual") defines "medical necessity" or "medically necessary care" to mean "any health care service, intervention, or supply (collectively referred to as 'service') that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing, or treating an illness, [including mental illnesses and substance use disorders], injury, disease, condition, or its symptoms, in a manner that is: in accordance with generally accepted standards of medical practice; clinically appropriate in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury, disease, or condition."[56] The Manual defines "generally accepted standards of medical practice" as "[s]tandards that are based on credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical community are required when applicable;" or "[a]lternatively, may consider physician specialty society recommendations [clinical treatment guidelines/guidance] and/or the general consensus of physicians practicing in relevant clinical areas."[57] DAA treatment for individuals with substance use disorder is the generally accepted standard of medical practice, clinically appropriate, and considered effective for the treatment of HCV.[58]

[56] Alabama Medicaid, Provider Information 7.1.1., https://medicaid.alabama.gov/content/Gated/7.6.1G_Provider_Manuals/7.6.1.2G_Apr2022/Apr22_07.pdf [https://perma.cc/SN6S-ZM9Q] (square brackets in original).
[57] Id. (square brackets in original).
[58] See supra IV(b).

ii. DAA Treatment is Medically Necessary for Injection Drug Users

31. 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.[59] In this clinical trial, participants received DAA treatment for 12 weeks. 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.[60] Not only did such participants achieve high SVR rates, there was also no difference in SVR rates among those with and without recent drug use.[61] 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. After analyzing the 38 studies, the 2018 paper concluded that high SVR rates were achieved across the numerous studies, concluding that the "study showed favorable DAA

[59] 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).
[60] Id. at 16. Whereas Alabama Medicaid demands sobriety for six months, this study demonstrates that drug and alcohol use as recent as one month prior to DAA treatment does not affect the efficacy of the treatment.
[61] Id. at 17.

treatment outcome among people with recent drug use and those receiving opioid substitution therapy."[62]

32. Similarly high SVR rates were reported for HCV patients actively using drugs in a study conducted at a primary care clinic in the Bronx, New York.[63] 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.[64] The overall SVR rate was 96% and patients who actively used drugs actually had higher SVR rates than those who did not use drugs.[65] 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."[66]

33. On top of curing HCV, opioid injection drug use and sharing has been observed to decrease following DAA HCV treatment.[67] 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.[68] 62% of the

[62] 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).
[63] Brianna L. Norton et al., High HCV Cure Rates for People Who Use Drugs Treated with Direct Acting Antiviral Therapy at an Urban Primary Care Clinic, 47 Int. J. Drug Policy 196 (2017).
[64] Id. at 198.
[65] Id.
[66] Id. at 200.
[67] 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).
[68] Id.

participants had injected drugs in the past month.[69] The study found that drug and alcohol use remained stable or decreased slightly during follow-ups with participants who completed DAA treatment. Furthermore, the study found that sharing of injection equipment underwent a gradual decrease over time.[70] 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.

34. 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] Reinfection rates among persons who inject drugs ("PWID") were higher but still very low (2.6/100 person – years), and the study concluded, "Taken together, these data support that concerns about reinfection should not limit HCV treatment among [people who inject drugs]."[72] While people who inject drugs should be provided with harm-reduction and prevention services following treatment to reduce reinfection risks, 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.

[69] Id. at 2372.
[70] Id. at 2374.
[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.

iii. **DAA Treatment is Medically Necessary for Alcohol Users**

35. Similar to studies analyzing SVR rates for participants with recent drug use, high SVR rates were observed in clinical studies involving participants who drank alcohol – even those considered to be unhealthy drinkers.[73] One study looked at more than 17,000 participants who initiated HCV treatment with DAA therapy. 23% of the participants were categorized as low-level drinkers while 9% were categorized as unhealthy drinkers.[74] The study reported favorable clinical outcomes for most patients and found "no significant differences in the proportion achieving SVR across levels of drinking."[75] In conclusion, the study stated, "As such, our findings support clinicians in following the current clinical guidelines [such as the AASLD HCV guideline], which do not recommend excluding persons who consume alcohol."[76]

36. Similar results were observed in a cohort study that included HCV-infected patients from across Canada.[77] The study included data from consenting patients who received DAA treatment between 2016 and 2019. 30% of the patients reported current alcohol use, and the proportion of patients initiating DAA treatment did not vary by alcohol use status.[78] The study found that SVR rates were high for patients with alcohol use and patients without alcohol use, and concluded, "Patients engaged in HCV treatment have highly favorable treatment uptake and outcomes regardless of alcohol use. Public health

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[73] Judith I. Tsui et al., Alcohol Use and Hepatitis C Virus Treatment Outcomes Among Patients Receiving Direct Antiviral Agents, 169 DRUG AND ALCOHOL DEPENDENCE 101 (2016).
[74] Id. at 5.
[75] Id. at 6.
[76] Id. at 8.
[77] Matt Driedger et al., Direct-Acting Antiviral Treatment Uptake and Sustained Virological Response Outcomes are Not Affected by Alcohol Use, 3 Canadian Liver Journal 283 (2021).
[78] Id. at 283.

interventions should be directed toward facilitating access to care for all patients irrespective of alcohol use."[79]

37. Denying DAA treatment based on alcohol use cannot be justified by medical necessity. Alcohol can severely damage the liver, and there are some studies that warn people living with HCV against excessive alcohol use—regardless of whether they are being treated with DAAs.[80] However, such warnings should *not* be misinterpreted to support a false assumption that DAA treatment will be any less effective for patients with heavy alcohol use. To the contrary, the studies cited above show DAA treatment is effective, including for patients with heavy alcohol consumption. DAA treatment is the medical standard of care for people with HCV regardless of their alcohol use.

V. FACTUAL ALLEGATIONS CONCERNING ALABAMA MEDICAID'S POLICY OF DENYING HEPATITIS C TREATMENT ON THE BASIS OF ALCOHOL AND DRUG USE

38. The Medicaid program is operated cooperatively between the federal and state governments. 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).

39. All fifty states participate in Medicaid. Vestal v. First Recovery Group, LLC, 292 F. Supp. 3d 1304, 1310 (M.D. Fl. 2018). 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

[79] Id.
[80] Maryam Alavi et al., The Contribution of Alcohol Use Disorder to Decompensated Cirrhosis Among People with Hepatitis C: An International Study, 68 J. Hepatol. 393, 397 (2017).

level, Medicaid in Alabama is administered by the Alabama Medicaid Agency, which acts as the single state agency responsible for Alabama's state Medicaid plan.[81]

40. The Medicaid statute categorizes certain services as mandatory for the Medicaid program to provide and others as optional. The provision of prescription drugs is an optional service under the Act. See 42 U.S.C. § 1396(a)(12). If a state opts to provide coverage of prescription drugs, it is subject to the restrictions found in the Act and related regulations. 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 Alabama, have opted to provide prescription drugs as part of their Medicaid programs.[82]

41. State Medicaid plans that opt into the prescription drug benefit, including Alabama Medicaid, are generally required 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). On November 5, 2015, CMS issued guidance to state

[81] Alabama Medicaid, Alabama Medicaid Administrative Code, https://medicaid.alabama.gov/content/9.0_Resources/9.2_Administrative_Code.aspx [https://perma.cc/5PE3-UNSQ].

[82] Alabama Medicaid, Alabama Medicaid Covered Services Handbook, https://medicaid.alabama.gov/documents/4.0_Programs/4.1_Covered_Services/4.1_Covered_Services_Handbook_3-2-22.pdf [https://perma.cc/8QTT-F829]; see also Alabama Medicaid, Alabama Medicaid State Plan, https://medicaid.alabama.gov/documents/9.0_Resources/9.8_State_Plan/9.8_State_Plan_PDF_Version_bookmarked_04.11.22.pdf [https://perma.cc/SG9V-23B5].

Medicaid agencies to direct that DAAs should be included in Medicaid coverage of outpatient prescription drugs.[83]

42. Alabama Medicaid, as of 2022, covers FDA-approved DAA medications such as Harvoni, Zepatier, Epclusa, Vosevi, and Mavyret.[84]

43. Although Alabama Medicaid includes DAA medications in its formulary, the Policy denies treatment to otherwise eligible Medicaid enrollees who cannot prove they did not use drugs or alcohol within the last six months. Alabama Medicaid's Policy also discontinues DAA treatment to Medicaid enrollees who are found to have used drugs or alcohol during the course of their treatment.

44. Alabama Medicaid does not publish detailed clinical criteria guidelines for HCV treatment, but it does publish a required prior authorization form (Form 415), as well as a required patient consent form (Form 392), on its website. See Ex. 1. According to the required prior authorization form, the medical professional who prescribes DAA treatment must provide information regarding their patient's alcohol and drug use, including a copy of the patient's drug and alcohol screening lab report.

45. First, Form 415, the "Hepatitis C Antiviral Agents PA Form," requires providers to provide answer to the following question: "(For patients > 12 years of age) Has the patient used alcohol or illicit drugs within the last 6 months? (A copy of the patient's drug

[83] See CMS HCV Guidance, https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf [https://perma.cc/S3LZ-LCW3].

[84] Alabama Medicaid, NDC Look Up, https://www.medicaid.alabamaservices.org/alportal/NDC%20Look%20Up/tabId/5/Default.aspx, [https://perma.cc/R436-JDND]. This website informs users whether a drug is covered by Alabama Medicaid. All listed drugs are indicated as "covered" according to the website.

and alcohol screening lab report must be submitted with the request.)"[85] Furthermore, Form 392, "Patient Consent Form of Hepatitis C Agents," forces patients to "consent" to the following statements:

> I will not drink alcohol. Alcohol can hurt my liver. If I drink alcohol Medicaid may not pay for my hepatitis C medicine.
>
> I will not use illegal substances or drugs. Using dirty needles can cause another form of hepatitis C and can make me even sicker. If I use substances Medicaid may not pay for my hepatitis C medicine.[86]

46. The Policy effectively denies access to everyone who admits or is shown to have used drugs and alcohol within the last six months. As a result of the Policy, Medicaid enrollees who suffer from SUD in addition to HCV are completely cut off from accessing Medicaid coverage for DAA treatment.

47. In 2014, 37 states had sobriety restrictions for HCV treatment.[87]As of 2022, Alabama is only one of six remaining states to have a 6-month sobriety restriction along with Arkansas, Mississippi, South Carolina, and South Dakota.[88] Alabama is an outlier as the

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[85] Alabama Medicaid, Hepatitis C Antiviral Agents PA Request Form (Dec. 1, 2021), https://medicaid.alabama.gov/documents/9.0_Resources/9.4_Forms_Library/9.4.14_PA_Forms/9.4.1.4_PH_PA_Form_415_Hep_C_12-1-21.pdf [https://perma.cc/2PVK-HL9W]; see also Alabama Medicaid, Hepatitis C Antiviral Agents Prior Authorization (PA) Criteria Instructions (March 1, 2021), https://medicaid.alabama.gov/documents/9.0_Resources/9.4_Forms_Library/9.4.14_PA_Forms/9.4.14_PH_PA_Form_415_Hep_C_External_Criteria_Instructions_3-1-21.pdf [https://perma.cc/69JW-CSV9].

[86] Alabama Medicaid, Patient Consent Form For Hepatitis C Agents (Feb. 9, 2017), https://medicaid.alabama.gov/documents/9.0_Resources/9.4_Forms_Library/9.4.3_Consent_Forms/9.4.3_HepC_Consent_Revised_2-9-17.pdf [https://perma.cc/8QVJ-QSW2].

[87] Center for Health Law and Policy Innovation & National Viral Hepatitis Roundtable, 2017 National Summary Report, Hepatitis C: State of Medicaid Access (Oct. 2017), https://stateofhepc.org/wp-content/uploads/2021/07/State-of-HepC_2017_FINAL.pdf [https://perma.cc/NPP7-KDXR].

[88] Center for Health Law and Policy Innovation & National Viral Hepatitis Roundtable, Report Update, Hepatitis C: State of Medicaid Access (Jan. 2022), https://stateofhepc.org/wp-content/uploads/2022/01/HCV_State-of-Medicaid-Access_Jan-2022_v2.pdf

vast majority of the states that previously imposed sobriety restrictions have eliminated them by recognizing the standard of care and recommendations from the CMS, AASLD, and IDSA.

VI. THE POLICY CAUSES SIGNIFICANT HARM

48. As of 2021, over 30,000 people were estimated to be living with HCV in Alabama, according to Alabama Public Health.[89] Due to the "silent" nature of the disease, it is highly likely that the estimates are much lower than the actual population living with HCV.

49. The Policy prevents people living in Alabama and enrolled in Alabama Medicaid, who have (1) been diagnosed with chronic HCV, and (2) are disabled due to SUD, from accessing DAA treatment.

50. By denying treatment coverage to Alabama Medicaid enrollees who have been diagnosed with chronic HCV and who admits or is shown to have used drugs and alcohol within the last six months, the Policy prohibits otherwise qualified individuals with SUD from receiving medically necessary, life-saving treatment.

51. According to a 2018 report to Congress submitted by the Secretary of the U.S. Department of Health and Human Services, a total of 485,531 beneficiaries were enrolled in Alabama Medicaid in 2018.[90] Of that total number 44,897 (9.2%) were treated for a

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[https://perma.cc/RDF8-4WR7]. Three additional states – Iowa, North Dakota, and West Virginia – have a shorter 3-month sobriety restriction

[89] See Alabama Department of Public Health, Hepatitis, https://www.alabamapublichealth.gov/hepatitis/index.html [https://perma.cc/V7ZC-ARQ7].

[90] HHS, T-MSIS Substance Use Disorder (SUD) Data Book (2018): Treatment of SUD in Medicaid, 17, https://www.medicaid.gov/medicaid/data-systems/downloads/2018-sud-data-book.pdf, [https://perma.cc/V28F-BDDK].

SUD.[91] Given the high prevalence of HCV among those who inject drugs,[92] it is highly likely that a significant portion of individuals treated for a SUD are also infected with HCV. As such, the Policy can reasonably be estimated to affect thousands of Medicaid beneficiaries.

52. Without access to coverage for DAA treatment, Medicaid beneficiaries at all stages of the infection are at a significantly higher risk for severe hepatic and extrahepatic symptoms. Although DAAs rid the body of HCV, they cannot always reverse the damage that has already been caused to the liver and other organ systems. Delay of DAA treatment to individuals with HCV can cause irreversible hepatic and extrahepatic damage.[93] See, e.g., Teeter, 2016 WL 3033500, at *5 (W.D. Wash. 2016) (describing an HCV patient who was denied treatment under his state's Medicaid policy for so long that he ultimately "suffered such severe liver damage that DAA treatment may no longer be an available option").

53. Not surprisingly, delaying treatment to individuals with HCV can also increase psychological stressors including anxiety, illness uncertainty (the inability to determine

[91] Id.
[92] See supra III(a).
[93] Harvey W. Kaufman et al., Decreases in Hepatitis C Testing and Treatment During the COVID-19 Pandemic, 61 American Journal of Preventative Medicine 369, 373 (2021) ("Consequences of delays in identification of hepatitis C-infected individuals and their subsequent receipt of curative treatment will increase potential transmission of HCV infection to others and, in the long term, increase the risk of disease progression of untreated individuals. Patients with advanced liver disease because of HCV infection are at risk for death and frequently need hepatic transplantation.").

the meaning of illness-related events), and depressive symptoms.[94] Patients who are cured of HCV with treatment report an improvement in their mental well-being.[95]

54. Removal of Medicaid restrictions—like Alabama's Policy—have been associated with increased HCV treatment rates. A 2022 retrospective cohort study of adults with HCV in Indiana, for example, revealed that "DAAs had limited impact on HCV treatment until Medicaid restrictions were removed" and that "HCV-related policy changes" were important factors in the increase of HCV treatment rates over the last decade.[96]

VII. ALABAMA MEDICAID'S POLICY VIOLATES THE AMERICANS WITH DISABILITIES ACT

a. 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.

55. 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).[97]

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[94] Stelliana Goutzamanis, et al., Experiences of Liver Health Related Uncertainty and Self-Reported Stress Among People Who Inject Drugs Living with Hepatitis C Virus: A Qualitative Study, 18 BMC Infectious Diseases 151 (2018).

[95] Donna M. Evon et al., "If I Get Cured, My Whole Quality of Life Will Change": Patients' Anticipated and Actualized Benefits Following Cure from Chronic Hepatitis C, 67 Digestive Diseases and Sciences 100 (2022).

[96] Lauren D. Nephew et al., Removal of Medicaid Restrictions Were Associated with Increased Hepatitis C Virus Treatment Rates, but Disparities Persist, 29 JOURNAL OF VIRAL HEPATITIS 366, 371 (2022). Indiana removed sobriety restrictions for Medicaid patients in 2019.

[97] The ADA is a broad mandate of "comprehensive character and sweeping purpose intended to eliminate discrimination against disabled individuals and to integrate them into the economic and

56. 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 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).[98]

57. 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."[99] 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."[100] 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

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social mainstream of American life." Oxford House, Inc. v. Browning, 266 F.Supp.3d 896, 907 (M.D. La. 2017).

[98] Pursuant to 42 U.S.C.A. § 12134, the Attorney General has promulgated regulations enforcing Title II of the ADA and providing guidance on their content. See 28 C.F.R. § 35, et seq. The regulations underscore the broad reach of Title II, and specify that it is unlawful discrimination for a public entity to: "Afford a qualified individual with a disability an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded to others." 28 C.F.R. § 35.130(b)(1)(ii); "[L]imit a qualified individual with a disability in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving the aid, benefit, or service." 28 C.F.R. § 35.130(b)(1)(vii); or "Directly or through contractual or other arrangements, utilize criteria or other methods of administration: (i) That have the effect of subjecting qualified individuals with disabilities to discrimination on the basis of disability; [or] (ii) That have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the public entity's program with respect to individuals with disabilities." 28 C.F.R. § 35.130(b)(3).

[99] DEPARTMENT OF JUSTICEJ, The Americans with Disabilities Act Title II Technical Assistance Manual, § II-3.8000.

[100] Id.

uses illegal drugs, nor could it impose a surcharge on him because of his addiction."[101] 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." [102] 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."[103] This "health services exception" has been recognized since the early days of the ADA and its interpretation has remained consistent from 1993 to 2022.

58. As SAMHSA's and the DOJ's examples show, the "health services" clause in Section 12210(c) is meant to refer to health services in general, not just services provided in association with drug rehabilitation. A state appellate court in Pennsylvania recently analyzed the "health services exception" and indicated the exception covers health services in general. Specifically, the Court stated that "prescription of medication in connection with a health issue," such as prescribing DAA treatment for HCV, was a "health

[101] 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].
[102] 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].
[103] Id.

service" protected by 12210(c). The "health service" at issue in Rokita was medically assisted treatment, or MAT, which is used to treat substance use disorder; the court discussed both clauses of Section 12210(c) ("health services" and "services provided in connection with drug rehabilitation") as two distinct categories. Rokita v. Pennsylvania Department of Corrections, 2022 WL 1086040, *10 (Pa. Commw. Ct. 2022). Ultimately, the Rokita court held that petitioner stated a claim under the ADA, because "it is conceivable that [petitioner] could establish that he has been denied the benefit of a health service by a public entity, by reason of his disability, and that a claim is viable under Title II of the ADA." Id. at *12.

59. In RHJ Medical Center v. City of DuBois, a federal district court analyzed only the "services provided in connection with drug rehabilitation" clause of Section 12210(c), and noted, "If the ADA and [Rehabilitation Act] were interpreted to exempt from its protections individuals with drug addictions seeking help . . . section (c) would be reduced to a nullity and mere surplusage. Some of the very people the acts seek to protect would not be protected." 754 F. Supp. 2d 723, 750 (W.D. Penn. 2010). Similarly, here, if the ADA were interpreted to exempt from protection people with SUD who seek medical treatment ("health services"), "section (c) would be reduced to a nullity and mere surplusage." Id. The question of whether an Alabama Medicaid enrollee who seeks DAA treatment for HCV has engaged in illegal drug use in the last six months is "orthogonal to the question of whether the ADA . . . provides protection for them"—because, by the plain text of 12210(c), it does. Id.

60. The ADA also forbids state and local entities like Alabama Medicaid from denying services to individuals with SUD on the basis of their past substance use. 42 U.S.C. 12102(b) (prohibiting discrimination against people who no longer have an impairment, but who have "a record of such impairment"), 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); see also Thompson v. Davis, 295 F.3d 890, 896 (9th Cir. 2002) ("The ADA protects individuals who have successfully completed or are participating in a supervised drug rehabilitation program and are no longer using drugs."). To the extent that Alabama Medicaid's blanket policy against *any* amount of drug or alcohol use also discriminates against people who are "erroneously regarded as" having substance use disorder, the ADA prohibits that conduct as well. 42 U.S.C. 12102(c) (prohibiting discrimination against individuals who do not in fact have an impairment, but are "regarded as having such an impairment"); 42 U.S.C 12210(b)(3) (prohibiting discrimination against people who are "erroneously regarded as engaging in illegal drug use").

b. The Policy denies meaningful access to Medicaid enrollees with SUD who are "otherwise entitled" to the health services provided by Alabama Medicaid, including access to DAA treatment for people diagnosed with HCV who meet Alabama Medicaid's other clinical criteria for DAA treatment.

i. **Alabama Medicaid is a public entity under the ADA**

61. 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." People First of Alabama v. Merrill, 467 F.Supp.3d 1179, 1214 (N.D. Al. 2020).

62. Medicaid is a financial, 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 Alabama Medicaid, are public entities and are subject to Title II. 42 U.S.C. § 12131(1)(B).

ii. **Medicaid enrollees with SUD are qualified individuals with a disability who, under Alabama Medicaid's Policy, have been denied meaningful access to lifesaving treatment on the basis of SUD.**

63. To state a claim under Title II, a plaintiff must establish "(1) that he is a qualified individual with a disability; (2) that he was 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 was by reason of the plaintiff's disability." Silberman v. Miami Dade Transit, 927 F.3d 1123, 1134 (11th Cir. 2019). Alabama Medicaid enrollees with chronic

HCV who are also disabled due to substance use disorder are qualified individuals with disabilities, and the Policy discriminates against them by reason of their disability.

1. Many Medicaid enrollees with SUD are qualified individuals with disabilities.

64. 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," Pennsylvania Dept. of Corrections v. Yeskey, 524 U.S. 206, 210 (1998), and who has a mental or physical impairment that significantly limits one or more major life activities. MX Group, Inc. v. City of Covington, 293 F.3d 326, 328, 337-39 (6th Cir. 2002). The beneficiaries at issue in this Complaint are "qualified individuals" because they are enrolled in Medicaid and meet the essential eligibility requirements for the receipt of medically necessary DAA treatment through Alabama Medicaid services. Furthermore, the beneficiaries at issue in this Complaint are qualified individuals "with a disability" because SUD is a well-known "impairment" that, for many people with SUD, substantially limits one or more major life activities.[104]

[104] 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. However, the carve-out provision is inapplicable here, because, as explained supra ¶¶ 57-59, Section 12210(c) creates a safe-harbor exception for the provision of health services to individuals who are currently using illegal drugs. Further, some scholars have argued that Section 12210(a)'s failure to protect people with substance use disorder in non-health contexts is contrary to the purpose of the ADA, and that it should be amended out of the statute entirely. "The ADA was enacted to 'assure equality of opportunity, full participation, independent living, and economic self-sufficiency' for individuals with disabilities, after Congress recognized the 'existence of unfair and unnecessary discrimination and prejudice. The [carve-out provision] undercuts this goal. How can a statute purport to promote equality for individuals with disabilities when it explicitly recognizes

65. It is well settled that substance use disorders such as alcoholism and drug use disorder are recognized impairments under the ADA. See, e.g., Alexander v. Wash. Metro Area Transit Auth., 826 F.3d. 544, 548 (D.C. Cir. 2016) (stating that "[t]here is no dispute in this case that [Plaintiff's] alcoholism is an impairment under the ADA"); Bailey v. Georgia-Pacific Corp., 306 F.3d 1162, 1167 (1st Cir. 2002) (citing cases and the ADA's legislative history to support the proposition that "there is no question that alcoholism is an impairment for purposes of the first prong of analysis under the ADA"); 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]").[105]

66. Further, regulations promulgated by the Department of Justice make clear that drug use disorder and alcoholism are considered physical and mental impairments 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" and that

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that substance use disorders are disabilities, but singles out the individuals experiencing their symptoms, and directly excludes them from statutory protection? An individual with diabetes does not lose their disability status under the ADA simply for experiencing hypoglycemia. It is difficult to imagine a world where a single hypoglycemic episode would open an individual with diabetes up to termination from her job and eviction from her apartment. However, that is the world that individuals with substance use disorders experience daily. The ADA cannot stand for equality while it perpetuates inequality. That inequality must be eliminated and the [carve-out provision] must be removed." Ryan Schmitz, Substance Use as a Second Class Disability: A Survey of the ADA's Disarmament of Individuals in Recovery, 73 Maine Law Review 94, 116-117 (2020).

[105] While the currently accepted phrase is substance use disorder or drug use disorder, much of the case law and earlier sources use the phrase "drug addiction."

"alcoholism is a disability."[106] Committee reports that reveal the legislative history of the ADA specifically include "drug addiction" and "alcoholism" as impairments.[107]

67. Many Medicaid enrollees with substance use disorder—such as the beneficiaries at issue in this Complaint —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, speaking, breathing, learning, and working."[108] 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. See, e.g., Reg'l Econ. Cmty. Action Program, Inc. v. City of Middletown, 294 F.3d 35, 47-48 (2d Cir. 2002) (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"); MX Group, Inc. v. City of Covington, 293 F.3d 326, 328, 337-39 (6th Cir. 2002) (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); Oxford House, Inc. v. Browning, 266 F.Supp.3d 896, 910 (M.D. La. 2017) ("The Court finds that the residents… are disabled within the... ADA. [Plaintiff's]

[106] DOJ, ADA Title II Technical Assistance Manual, § II-2.3000.
[107] H.R. REP. NO. 485, at 51.
[108] Id. at 52.

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).[109]

2. Alabama Medicaid's Policy denies lifesaving DAA treatment to Medicaid enrollees with SUD by reason of their disability.

68. The Policy is a blanket exclusion denying Medicaid coverage of HCV treatment on the basis of drug and alcohol use. People with SUD have an "inability to control their use of substances"[110] and as a result, may continue "to use despite the substance causing problems to [Beneficiaries'] physical and mental health.[111]

[109] The Americans with Disabilities Act Amendments Act of 2008 ("ADAAA") broadened the ADA's definition of disability. After several Supreme Court cases narrowly construing the definition of the term "substantially limits," the ADAAA lowered the standard by requiring 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].

[110] See supra note 15.

[111] See supra note 20.

69. By excluding everyone who has used drugs or alcohol within the last six months, Alabama Medicaid's Policy denies treatment to Medicaid enrollees who are disabled due to SUD by reason of their disability.

70. 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).

71. The Policy violates the ADA and discriminates against the beneficiaries at issue in this Complaint through both disparate treatment and disparate impact.

a. Disparate Treatment

72. 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.").

73. 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." Smith v. Aroostook County, 376 F. Supp. 3d 146, 159 (D. Me. 2019). "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 unreasonable in that sense." Kiman v. N.H. Dep't of Corr., 451 F.3d 274, 284-85 (1st Cir. 2019).

74. The Policy's blanket rejection of DAA treatment to anyone who has recently used drugs or alcohol is "so unreasonable as to raise an inference" that the Policy is based in animus against people with SUD. Smith v. Aroostook County, 376 F. Supp. 3d 146, 160-61 (D. Me. 2019). In Smith, 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.

75. Beneficiaries' access to DAA treatment is denied under the Policy because of disability, despite the fact that the medical standard is to treat every HCV patient with DAAs. 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).

b. Disparate Impact (Meaningful Access)

76. 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). This principle has been recently reaffirmed by the Ninth Circuit: "Disparate impact claims are cognizable as authorized by Title II's implementing regulations," and the ADA was "specifically intended to address both intentional discrimination and discrimination caused by 'thoughtful indifference' or 'benign neglect.'" Payan v. Los Angeles Community College District, 11 F.4th 729, 735-737 (9th Cir. 2021).

77. 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).[112]

78. The ADA and regulations implementing the ADA recognize the discriminatory impact that even a facially neutral policy can have. 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. § 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

[112] Alexander v. Choate, 469 U.S. 287 (1985) analyzed a disparate impact claim 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.

benefits]." In an explanatory commentary to 28 C.F.R. § 35.130(b)(3), the drafters 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.'"[113]

79. The Policy has a disparate impact on Medicaid beneficiaries with SUD who are not able to produce clean sobriety results 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).[114] Regardless of Alabama Medicaid's purported reasons, the practice and policy of requiring a lab report and forcing individuals disabled with SUD to consent to not drinking alcohol or using drugs clearly has the effect of preventing otherwise eligible individuals with HCV from receiving life-saving DAA treatment. 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

[113] 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 (hereinafter, Appendix, 28 C.F.R. Part 35").

[114] 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.").

it burdens others."); 28 C.F.R. § 35.130(b)(1)(ii). As stated above, the Policy burdens Beneficiaries because Beneficiaries, due to their SUD, have an "inability to control their use of substances"[115] and as a result, continue "to use despite the substance causing problems to [Beneficiaries'] physical and mental health.[116]

VIII. CONCLUSION

Alabama Medicaid's Policy violates the Americans with Disabilities Act in its treatment of individuals with HCV and SUD, including the beneficiaries at issue in this Complaint. To remedy these violations, and to protect the civil rights of Medicaid beneficiaries with SUD moving forward, the DOJ and its affiliated agencies should promptly require Alabama Medicaid to revise its coverage policies and practices related to DAA treatment for individuals with HCV, including the following:

1. Remove the question, "Has the patient used alcohol or illicit drugs within the last 6 months?" in Form 415;
2. Remove the drug and alcohol lab screening test requirement in Form 415;
3. Revise Form 392 so that alcohol consumption and drug use are no longer reasons to cease DAA treatment;
4. Stop the practice of including alcohol consumption or drug use as a restriction for DAA treatment and as a reason to cease ongoing treatment;
5. Cease the blanket rejection of Medicaid beneficiaries with SUD and HCV seeking DAA treatment;

[115] See supra note 19.
[116] See supra note 24.

6. Educate providers on the current medical standard and science of DAA treatment efficacy on those with SUDs;
7. Educate providers and Alabama Medicaid staff about SUD and how it affects individuals to remove bias against treating patients with SUD.
8. Take steps to promote Alabama Medicaid beneficiaries with HCV to seek a doctor's care, including individualized evaluation of whether DAA treatment is appropriate regardless of SUD status.

Dated: May 9, 2022

Respectfully Submitted,

Robert Greenwald
Faculty Director
Center for Health Law & Policy Innovation
Harvard Law School
Wasserstein Caspersen Clinical Building,
Suite 3130
Cambridge, MA 02138
Phone: 617-390-2584
rgreenwa@law.harvard.edu

Kathie Hiers, CEO
AIDS Alabama

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

Administrative Complaint Against the Alabama Medicaid Agency

EXHIBIT 1:

Alabama Medicaid Prior Authorization Requirements for DAA Treatment for Hepatitis C

Alabama Medicaid Pharmacy
Patient Consent Form
Hepatitis C Agents

PATIENT INFORMATION

Patient Name_____ Patient Medicaid #_____

Patient DOB_____ Patient phone # with area code_____

This document is to help you understand the drugs prescribed to you used to treat hepatitis C. Your doctor should talk to you about some very important things before you begin the medicine. You should understand the following:

- I must take all of these medicines as my doctor tells me for the number of weeks prescribed.
- I understand that Medicaid will pay for only one course of medicine. If I do not take my medicine as prescribed, I will not be approved for another course of therapy.
- If I do not strictly follow the instructions for my medicine, the drug(s) may not work.
- I understand that bloodwork is required even after I finish the medicine. I agree to follow up with my doctor after I finish my medicine.
- I will not drink alcohol. Alcohol can hurt my liver. If I drink alcohol Medicaid may not pay for my hepatitis C medicine.
- I will not use illegal substances or drugs. Using dirty needles can cause another form of hepatitis C and can make me even sicker. If I use illegal substances Medicaid may not pay for my hepatitis C medicine.
- If I am on more than one medicine for hepatitis C, I will take them all as directed. If I stop one of my medicines, then the other will not work.
- The following applies to BOTH **males and females** taking hepatitis C medicines**: Males and females** taking these medicines must use 2 forms of birth control to prevent severe birth defects or baby deaths.
  - I understand this medicine may hurt an unborn child for up to 6 months after I stop the medicine.
  - I understand that a baby may have serious birth defects or die if exposed to these medicines during pregnancy.
  - **I understand that I must use TWO types of birth control EACH TIME I have sex to avoid me or my partner getting pregnant.**
  - **I also understand that I must use 2 forms of birth control for up to 6 months after I finish taking the medicine.**
- If I have questions about my medicine, I will contact my doctor's office for more information.

I understand that my doctor or doctor's representative has explained to me about the hepatitis C drug medicine I am prescribed. I also understand how I am supposed to take the medicine and possible side effects. I have read and understand the above information. I agree to all terms. If I fail on at least one item listed above Medicaid may not pay for my hepatitis C medicine.

Patient Printed Name | Patient Signature | Date

Prescriber Printed Name/NPI | Prescriber Signature | Date

Note: Signed forms should be submitted with each request for hepatitis C medications.

Form 392
Phase-in period: 01/01/17-3/31/17
Required: 4/1/17

Alabama Medicaid Pharmacy
Hepatitis C Antiviral Agents PA Request Form

FAX: (800) 748-0116 | **Fax or Mail** | **P.O. Box 3210**
Phone: (800) 748-0130 | **Kepro** | **Auburn, AL 36831-3210**

PATIENT INFORMATION

Patient Name_____ Patient Medicaid # _____

Patient DOB_____ Patient phone # with area code_____

PRESCRIBER INFORMATION

Prescriber name_____ NPI #_____ License #_____

Phone # with area code_____ Fax # with area code_____

Address (Optional)_____

I certify that this treatment is indicated and necessary and meets the guidelines for use as outlined by the Alabama Medicaid Agency. I will be supervising the patient's treatment. Supporting documentation is available in the patient record.

_____
Prescribing Practitioner Signature **Date**

DRUG/CLINICAL INFORMATION

Drug Code_____ Quantity_____ Day's supply _____

Diagnosis or ICD-9/ICD-10 Code_____ Scheduled start date of therapy _____

Please include patient specific questions below for ALL requests:

- Has the patient previously completed **or** started and discontinued one of the regimens for Hepatitis C included on this form? If yes, which regimen?_____ □ Yes □ No
- Is the patient HIV co-infected? □ Yes □ No □ Unknown
  If yes, has the patient been on a stable regimen of HIV medications for at least 8 weeks? □ Yes □ No
  Include: Viral load_____ copies/ml **and** CD4 count_____ cells/mm^3
- (For patients > 12 years of age) Has the patient used alcohol or illicit drugs within the last 6 months? (A copy of the patient's drug and alcohol screening lab report must be submitted with the request.) □ Yes □ No
- Has the patient been counseled on the proposed regimen to include possible side effects that may occur? □ Yes □ No
- Has the patient been informed of Alabama Medicaid's policy to only approve 1 treatment regimen with one of the hepatitis C products included on this form per lifetime? □ Yes □ No
- Has the patient been informed that re-approvals or extensions of existing approvals will not be allowed due to patient non-compliance? □ Yes □ No
- Is the patient a recipient of an organ from a hepatitis C infected donor? □ Yes □ No

Please check drug being requested below and answer the drug specific questions for the drug selected:

❒ **Daklinza™**

Please indicate the genotype and treatment regimen being requested:

❒ Genotype 1 or 3 without cirrhosis, Daklinza™ + Sovaldi® x 12 weeks

❒ Genotype 1 or 3 with decompensated cirrhosis or post-transplant, Daklinza™ + Sovaldi® + RBV x 12 weeks

❒ **Epclusa® or ❒ Sofosbuvir - velpatasvir**

Please indicate the genotype and treatment regimen being requested:

❒ Genotype 1, 2, 3, 4, 5, or 6 without cirrhosis or with compensated cirrhosis, Epclusa® x 12 weeks

❒ Genotype 1, 2, 3, 4, 5, or 6 with decompensated cirrhosis, Epclusa® + RBV x 12 weeks

❒ Harvoni® or ❒ Ledipasvir - sofosbuvir

Please indicate the genotype and treatment regimen being requested:

- ❒ Genotype 1 treatment-naïve w/out cirrhosis who have pre-treatment HCV RNA less than 6mil IU/ml, Harvoni® x 8 weeks
- ❒ Genotype 1 treatment-naïve w/out cirrhosis who have pre-treatment HCV RNA less than 6mil IU/ml ***and*** HIV co-infected or African-American, Harvoni® x 12 weeks
- ❒ Genotype 1 treatment-naïve w/out cirrhosis or with compensated cirrhosis, Harvoni® x 12 weeks
- ❒ Genotype 1 treatment-experienced w/out cirrhosis, Harvoni® x 12 weeks
- ❒ Genotype 1 treatment-experienced with compensated cirrhosis, Harvoni® x 24 weeks
- ❒ Genotype 1 treatment-naïve or treatment-experienced with decompensated cirrhosis, Harvoni® + RBV x 12 weeks
- ❒ Genotype 1 or 4 treatment-naïve or treatment-experienced liver transplant recipient without cirrhosis or with compensated cirrhosis, Harvoni® + RBV x 12 weeks
- ❒ Genotype 1, aged 3-17 treatment-naive without cirrhosis or with compensated cirrhosis, approve Harvoni® x 12 weeks
- ❒ Genotype 1, aged 3-17 treatment experienced without cirrhosis, approve Harvoni® x 12 weeks
- ❒ Genotype 1, aged 3-17 treatment experienced with compensated cirrhosis, approve Harvoni® + RBV x 24 weeks
- ❒ Genotype 4, 5, or 6 treatment-naïve or treatment-experienced without cirrhosis or with compensated cirrhosis, Harvoni® x 12 weeks
- ❒ Genotype 4, 5, or 6, aged 3-17 without cirrhosis or with compensated cirrhosis, approve Harvoni® x 12 weeks

Please answer drug specific questions below:

- For treatment-naïve patients without cirrhosis, indicate pre-treatment HCVRNA level._____mil IU/ml
- If patient is less than 18 years of age, please indicate weight._____kg

❒ Mavyret®

Please indicate the genotype and treatment regimen being requested:

- ❒ Genotype 1, 2, 3, 4, 5, or 6 without cirrhosis, approve Mavyret® x 8 weeks
- ❒ Genotype 1, 2, 3, 4, 5, or 6 with compensated cirrhosis, approve Mavyret® x 8 weeks
- ❒ Genotype 1, 2, 3, 4, 5, or 6 for ages > 12 years and weighing at least 45 kg who are liver or kidney transplant recipients, approve Mavyret® x 12 weeks
- ❒ Genotype 1 previously treated with an NS5A inhibitor without prior treatment with an NS3/4A PI without cirrhosis or with compensated cirrhosis, approve Mavyret® x 16 weeks
- ❒ Genotype 1 previously treated with an NS3/4A PI without prior treatment with an NS5A inhibitor without cirrhosis or with compensated cirrhosis, approve Mavyret® x 12 weeks
- ❒ Genotype 1, 2, 4, 5, or 6 previously treated with a PRS with compensated cirrhosis, approve Mavyret® x 12 weeks
- ❒ Genotype 1, 2, 4, 5, or 6 previously treated with a PRS without cirrhosis, approve Mavyret® x 8 weeks
- ❒ Genotype 3 previously treated with a PRS without cirrhosis or with compensated cirrhosis, approve Mavyret® x 16 weeks

❒ Sovaldi®

Please indicate the genotype and treatment regimen being requested:

- ❒ Genotype 1 without cirrhosis, Sovaldi™ + Olysio® with or without RBV x 12 weeks
- ❒ Genotype 1 with cirrhosis, Sovaldi™ + Olysio® with or without RBV x 24 weeks
- ❒ Genotype 1, Sovaldi™ + RBV + peg- interferon alpha x 12 weeks
- ❒ Genotype 1 and peg interferon ineligible, Sovaldi™ + RBV x 24 weeks
- ❒ Genotype 1 or 3 without cirrhosis, Daklinza® + Sovaldi™ x 12 weeks
- ❒ Genotype 1 or 3 with decompensated cirrhosis **or** post-transplant, Daklinza® + Sovaldi™ + RBV x 12 weeks
- ❒ Genotype 2, Sovaldi™ + RBV x 12 weeks
- ❒ Genotype 2, aged 3-17 without cirrhosis or with compensated cirrhosis, approve Sovaldi™ + RBV x 12 weeks
- ❒ Genotype 3, Sovaldi™ + RBV x 24 weeks
- ❒ Genotype 3, Sovaldi™ + RBV + peg-interferon x 12 weeks
- ❒ Genotype 3, aged 3-17 without cirrhosis or with compensated cirrhosis, approve Sovaldi™ + RBV x 24 weeks
- ❒ Genotype 4, Sovaldi™ + RBV + peg-interferon x 12 weeks
- ❒ If hepatocellular carcinoma awaiting liver transplant, Sovaldi™ + RBV x 48 weeks

Please answer drug specific questions below:

- Is the requested medication indicated for monotherapy for this patient? □ Yes □ No
- What is the patient's Glomerular Filtration Rate? _____mL/min/1.73m^2
- Is the patient ineligible for peg-interferon therapy (if yes, indicatereason)? _____ □ Yes □ No
- Is the patient a previous interferon/RBV nonresponder? □ Yes □ No
- Has the patient previously been treated with an HCV protease inhibitor? □ Yes □ No
- If patient is less than 18 years of age, please indicate weight._____kg

❒ **Viekira Pak™**

Please indicate the genotype and treatment regimen being requested:

- ❒ Genotype 1a without cirrhosis, Viekira Pak™ or Viekira XR™ + RBV x 12 weeks
- ❒ Genotype 1a with cirrhosis, Viekira Pak™ or Viekira XR™ + RBV x 24 weeks
- ❒ Genotype 1b with or without cirrhosis, Viekira Pak™ or Viekira XR™ x 12 weeks
- ❒ Genotype 1 post-transplant, Viekira Pak™ or Viekira XR™ + RBV x 24 weeks

Please answer drug specific questions below:

- Does the patient have decompensated liver disease or moderate to severe hepatic impairment (Child-Pugh B or C)? □ Yes □ No
- Has the patient received a liver transplant and has normal hepatic function with a Metavir fibrosis score of 2 or lower? □ Yes □ No

❒ **Vosevi®**

Please indicate the genotype and treatment regimen being requested:

- ❒ Genotype 1, 2, 3, 4, 5, or 6 previously treated with a NS5A inhibitor without cirrhosis or with compensated cirrhosis, approve Vosevi™ x 12 weeks
- ❒ Genotype 1a or 3 previously treated with sofosbuvir without an NS5A inhibitor without cirrhosis or with compensated cirrhosis**,** approve Vosevi™ x 12 weeks

❒ **Zepatier®**

Please indicate the genotype and treatment regimen being requested:

- ❒ Genotype 1a treatment-naïve or peg-interferon/RBV experienced without baseline NS5A polymorphism, Zepatier® x 12 weeks
- ❒ Genotype 1a treatment-naïve or peg-interferon/RBV experienced with baseline NS5A polymorphism, Zepatier® + RBV x 16 weeks
- ❒ Genotype 1b treatment-naïve or peg-interferon/RBV experienced, Zepatier® x 12 weeks
- ❒ Genotype 1a or 1b peg-interferon/RBV/protease inhibitor experienced, Zepatier® + RBV x 12 weeks
- ❒ Genotype 4 treatment-naïve, Zepatier® x 12 weeks
- ❒ Genotype 4 peg-interferon/RBV experienced, Zepatier® + RBV x 16 weeks

Please answer drug specific questions below:

- For patient with NS5A polymorphism, is documentation to support polymorphism included? □ Yes □ No

DISPENSING PHARMACY INFORMATION

May Be Completed by Pharmacy

Dispensing pharmacy _____ NPI # _____

Phone # with area code _____ Fax # with area code _____

Alabama Medicaid
Preferred Drug and Prior Authorization Program

Hepatitis C Antiviral Agents Prior Authorization (PA) Criteria Instructions

This document contains detailed instructions on completing the Medicaid Prior Authorization Form, Form 415. When Hepatitis C Antiviral Agents are prescribed, the practitioner will be required to obtain prior authorization (PA). If approval is given to dispense the requested agent, an authorization number will be given. Hepatitis C Antiviral Agents included on this form are Daklinza™, Epclusa®, Harvoni®, ledipasvir-sofosbuvir, Mavyret®, sofosbuvir-velpatasvir, Sovaldi®, Viekira Pak™, Vosevi®, and Zepatier®.

Preferred Hepatitis C Antiviral Agents will be considered “preferred with clinical criteria". These agents will require a prior authorization request be submitted. Clinical criteria must be met in order to be approved. Non-preferred products will continue to require prior authorization. For a non-preferred product to be approved, contraindication to preferred agents must exist or the non-preferred agent must be prescribed for a genotype for which all preferred agents are non-FDA approved.

Table of Contents

Overview
Hepatitis C Antiviral Agents PA Form: PA Request Submittal

Prior Authorization Request Submittal

Electronic Prior Authorization (PA)

Electronic Prior Authorization does not apply to Hepatitis C Antiviral Agents.

Paper Requests

Hepatitis C Antiviral Agents prior authorization requests should be submitted on PA Form 415. Once the form is completed, the paper request can be submitted via fax or mail.

Online Form Submission

Online form submission does not apply to Hepatitis C Antiviral Agents.

Verbal PA Requests

Verbal PA requests cannot be submitted for the Hepatitis C Antiviral Agents.

Section One
Hepatitis C Antiviral Agents PA Form: Patient Information

Below are fields to be completed on the PA Form.

Form States	Your Response
Patient Name	Record the patient's name as it appears on the Medicaid card.
Patient Medicaid #	Record patient's Medicaid number.
Patient DOB	Record patient's date of birth.
Patient Phone # With Area Code	Record the patient's phone number including area code.

Section Two
Hepatitis C Antiviral Agents Form: Prescriber Information

Below are fields to be completed on the PA Form.

Form States	Your Response
Prescriber Name	Record the prescribing practitioner's name.
NPI #	Record the prescribing practitioner's NPI number.
License #	Record the prescribing practitioner's license number.
Phone # With Area Code	Record the prescribing practitioner's phone number with area code.
Fax # With Area Code	Record prescribing practitioner's fax number with area code.
Address (optional)	Prescribing practitioner's mailing address is optional
Prescribing Practitioner Signature/Date	The prescriber should sign and date in this section on the prescribing practitioner signature line.*

**By signing in the designated space, the practitioner verifies that the request complies with Medicaid's guidelines and that he/she will be supervising the patient during treatment with the requested product. The practitioner further certifies that documentation is available in the patient record to justify the requested treatment.*

Section Three
Hepatitis C Antiviral Agents PA Form: Clinical Information

Below are fields to be completed on the PA Form.

Form States	Your Response
Drug Code (NDC)	Enter the NDC.
Quantity	Enter the quantity of the drug being requested.
Day's Supply	Enter the day's supply for the quantity requested.
Diagnosis or ICD-10 Code	Record diagnosis(es) that justifies the requested drug. Diagnosis(es) **or** ICD-10 code(s) may be used. Use of ICD-10 codes provides specificity and legibility and will usually expedite review.
Scheduled Start Date of Therapy	Enter the date the patient will begin therapy.

Specific Clinical Information

For all agents, please include the following information:

- Indicate if the patient previously competed or started and discontinued one of the regimens for hepatitis C that is included on the form.
- Indicate if the patient is infected with HIV.
    - If yes, indicate whether the patient has been on a stable regimen of HIV medication for at least 8 weeks.
    - Include the patient's viral load and CD4 count.
- For recipients > 12 years of age, indicate if the patient has used alcohol or illicit drugs in the past 6 months. Include a copy of the patient's drug and alcohol screening laboratory report (performed at the time the requested medication is prescribed) with the PA request.
- Indicate whether the patient has been counseled on the proposed regimen to include possible side effects that may occur.
- Indicate whether the patient has been informed of Alabama Medicaid's policy to only approve 1 treatment regimen with one of the hepatitis C products included on this form per lifetime.
- Indicate if the patient has been informed that re-approvals or extensions of existing approvals will not be allowed due to patient non-compliance.
- Indicate if the patient is the recipient of an organ from a hepatitis C infected donor.

Please include drug specific information as indicated below:

Daklinza™

- Indicate the specific genotype and which treatment regimen is being requested.

Epclusa® or sofosbuvir-velpatasvir

- Indicate the specific genotype and which treatment regimen is being requested.

Harvoni® or ledipasvir-sofosbuvir

- Indicate the specific genotype and which treatment regimen is being requested.
- For patients that are treatment-naïve without cirrhosis, indicate pre-treatment HCV RNA level.

Mavyret™

- Indicate the specific genotype and which treatment regimen is being requested.
- Indicate if the patient has cirrhosis or moderate to severe hepatic impairment (Child-Pugh B-C).
- Indicate if the patient is a previous interferon/ribavirin non-responder.
- Indicate if the patient has previously been treated with an HCV protease inhibitor.

Sovaldi®

- Indicate the specific genotype and which treatment regimen is being requested.
- Indicate if the medication is indicated as monotherapy.
- Include the patients Glomerular Filtration Rate (GFR).
- Indicate if the patient is ineligible for peg-interferon therapy. If yes, include reason.
- Indicate if the patient is a previous interferon/ribavirin non-responder.
- Indicate if the patient has previously been treated with an HCV protease inhibitor.

Viekira Pak™

- Indicate the specific genotype and which treatment regimen is being requested.
- Indicate if the patient has decompensated liver disease or moderate to severe hepatic impairment (Child-Pugh B-C).
- Indicate if the patient has received a liver transplant and has normal hepatic function with a Metavir fibrosis score of 2 or lower.

Vosevi®

- Indicate the specific genotype and which treatment regimen is being requested.

- Indicate if the patient has previously been treated with an HCV protease inhibitor.

Zepatier®

- Indicate the specific genotype and which treatment regimen is being requested.
- For patients with NS5A polymorphism, include documentation supporting NS5A polymorphism.

Section Four
Hepatitis C Antiviral Agents PA Form: Dispensing Pharmacy Information

(Information in this area may be completed by the pharmacy).

Below are fields to be completed on the PA Form.

Form States	Your Response
Dispensing Pharmacy	Enter the pharmacy name.
NPI #	Enter the pharmacy NPI number.
Phone # With Area Code	Enter the pharmacy phone number with area code.
Fax # With Area Code	Enter the pharmacy fax number with area code.