

**SETTLEMENT AGREEMENT
BETWEEN
THE UNITED STATES OF AMERICA
AND
THE STATE OF ALABAMA’S MEDICAID AGENCY**

BACKGROUND

1. The parties to this Settlement Agreement (Agreement) are the United States of America (United States) and the State of Alabama’s Medicaid Agency (Alabama Medicaid) (collectively, the Parties).
2. This Agreement resolves an investigation that the United States opened in response to a complaint it received alleging that Alabama Medicaid discriminates against people with Hepatitis C (HCV) and substance abuse disorder (SUD) by imposing non-medically indicated sobriety restrictions for HCV treatment, in violation of the Americans with Disabilities Act (ADA). The United States substantiated that Alabama Medicaid has maintained a non medically-indicated policy and practice of denying individuals who have HCV, and who also have (or who are regarded as having or who have record of) SUD, access to medications to treat their HCV. Specifically, Alabama Medicaid has maintained a blanket sobriety restriction denying access to potentially life-saving direct-acting antiviral agents (DAA) to applicants who used alcohol or illicit drugs at any time during a six-month window prior to treatment, and non-payment for DAA treatment for Medicaid recipients who are found to have used alcohol or illicit drugs during the course of their treatment (Sobriety Policy). The United States contends that by maintaining the Sobriety Policy, Alabama Medicaid has discriminated against individuals who have HCV and who also have, who are regarded as having, and/or who have a record of, SUD.
3. Alabama Medicaid denies the United States’ conclusions above. Alabama Medicaid has cooperated fully in the process of working toward an amicable resolution of this matter and has represented that it will continue to cooperate with the United States in ensuring that Alabama Medicaid recipients with HCV seeking antiviral treatment are no longer subject to the Sobriety Policy. Alabama Medicaid expressly denies that it has violated Title II of the ADA, and by entering into this Agreement, does not admit any wrongdoing. To that end, this Agreement is a negotiated compromise resolution and none of the terms of this Agreement shall be deemed to constitute an admission by Alabama Medicaid of any violation or liability under Title II of the ADA or any other law or regulation.
4. The Parties agree that it is in their best interests, and the United States believes that it is in the public interest, to fully and finally resolve this matter on mutually agreeable terms. The Parties have therefore voluntarily entered into this Agreement.

TITLE II COVERAGE

5. Title II of the ADA (Title II) requires that “no qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of

services, programs, or activities of a public entity, or be subjected to discrimination by any such entity.” 42 U.S.C. § 12132; 28 C.F.R. § 35.130(a). “Services” under Title II include services provided under Medicaid, such as medical evaluation, screening, treatment, and medication. The Title II regulation prohibits states from “deny[ing] a qualified individual with a disability the opportunity to . . . benefit from [a] . . . service” and “afford[ing] a qualified individual with a disability an opportunity to . . . benefit from . . . [a] service that is not equal to that afforded others.” 28 C.F.R. § 35.130(b)(1)(i-ii).

6. Further, under the ADA, “an individual shall not be denied health services . . . on the basis of the current illegal use of drugs if the individual is otherwise entitled to such services.” 42 U.S.C. § 12210(c).
7. Alabama Medicaid is a public entity within the meaning of the ADA, 42 U.S.C. § 12131(1)(B), and therefore is subject to Title II, 42 U.S.C. §§ 12131-34, and its implementing regulation, 28 C.F.R. Part 35.
8. The United States Department of Justice (Department) is responsible for administering and enforcing Title II and its implementing regulation, 28 C.F.R. Part 35. Title II 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. pt. 35, subpt. F.
9. The term “disability” means, with respect to an individual, a physical or mental impairment that substantially limits one or more major life activities of such individual; a record of such an impairment; or being regarded as having such an impairment. 42 U.S.C. § 12102(1).
 - a. Persons with HCV have a disability. HCV is a physical impairment that can result in a range of serious health conditions, many of which affect the liver. These include (but are not limited to) cirrhosis, liver cancer, and liver failure. In such instances, HCV substantially limits one or more major life activities (which include the operation of major bodily functions). 42 U.S.C. § 12102(2); 28 C.F.R. § 35.108(c)(ii). The operation of a major bodily function includes the operation of an individual organ (such as the liver) within a body system. 28 C.F.R. § 35.108(c)(ii).
 - b. Persons with SUD typically have a disability. Under the ADA, “alcoholism” and “drug addiction” are defined as physical or mental impairments. 28 C.F.R. §§ 35.108(b)(2). SUD may substantially limit one or more major life activities, including caring for oneself, learning, concentrating, thinking, communicating, or working. 42 U.S.C. § 12102; 28 C.F.R. § 35.108(c)(1)(i). SUD may also limit the operation of major bodily functions, such as neurological and brain functions. 42 U.S.C. § 12102; 28 C.F.R. § 35.108(c)(1)(ii).

RELIEF

10. Nondiscrimination. Alabama Medicaid will comply with the requirements of Title II, the Title II implementing regulations, and the requirements of this Agreement. *See* 42 U.S.C. § 12132; 28 C.F.R. Part 35.

11. Withdraw Sobriety Policy. Alabama Medicaid withdrew its written policy establishing, and ceased implementing, the Sobriety Policy effective October 1, 2022. Going forward, Alabama Medicaid will not delay, deny, or fail to pay for DAA treatment of HCV based on any Medicaid recipient's use of drugs or alcohol. Alabama Medicaid has taken certain steps¹ toward this end and will take any and all additional steps necessary to effectuate its withdrawal of the Sobriety Policy. Additionally, Alabama will not create any new restrictions for the provision of DAA treatment for Alabama Medicaid recipients related to drug or alcohol use, such as requiring drug or alcohol treatment or counseling.

12. Notify Medicaid Providers. Alabama Medicaid previously provided notice to certain providers. Going forward, Alabama will provide additional notice that will advise providers that Alabama Medicaid has withdrawn its Sobriety Policy. It will further inform providers that they are no longer required to screen Medicaid recipients with HCV for drug or alcohol use as a prerequisite for DAA treatment, and that the use of drugs or alcohol during DAA treatment will no longer result in non-payment for that treatment. Such notice will be provided to the following providers:
 - a. All Alabama Medicaid Providers (including provider agencies and/or independent practitioners who have a direct relationship with Alabama for Medicaid purposes)
 - i. Provider Alerts
 - 1) Method of notice: Electronic message via provider alert system.
 - 2) Frequency of notice: Monthly for one (1) calendar year from the Effective Date.
 - ii. Provider Newsletter
 - 1) Method of notice: Inclusion in the "Provider Insider: Alabama Medicaid Bulletin," which is delivered as an attachment to an electronic message via the provider alert system.
 - 2) Frequency of notice: Quarterly for one (1) calendar year, starting with the January 2023 installment of the newsletter.
 - b. Targeted Alabama Medicaid Providers: All infectious disease specialists and gastroenterologists (including all hepatologists, who under Alabama Medicaid's provider classification are coded as gastroenterologists).

¹ Alabama Medicaid has revised certain relevant forms accordingly, *e.g.*, Form 415, "Alabama Medicaid Pharmacy Hepatitis C Antiviral Agents PA Request Form" (revised to remove the drug and alcohol screening lab report requirement and to remove the question "Has the patient used alcohol or illicit drugs within the last 6 months?") and Form 392, "Alabama Medicaid Pharmacy Patient Consent Form Hepatitis C Agents" (revised to remove the patient sobriety certification and statements regarding how alcohol consumption and drug use may result in non-payment by Medicaid for DAA treatment).

- i. Method of notice: in-person meetings with the provider or, at the request of the provider, a member of the provider’s staff, utilizing Alabama Medicaid contract staff (via Alabama Medicaid’s academic detailer program).
 - ii. Frequency of notice: at least once by October 1, 2023.
 - iii. Additional content of notice: Alabama Medicaid’s contract staff will provide instruction regarding the revised documentation requirements for DAA treatment.
13. Notify Critical State Partners. Within five (5) days of the Effective Date, Alabama Medicaid will provide notice to the Alabama Board of Medical Examiners and the Alabama Department of Public Health (State Partners) that Alabama Medicaid has withdrawn all earlier requirements that people seeking treatment for Hepatitis C (HCV) do not use drugs or alcohol for six months prior to treatment for, and during their treatment for, HCV. The notice will also inform the State Partners that people on Medicaid will no longer be required to have a test for either drug or alcohol use before receiving treatment for HCV. Additionally, the notice will include a request that the State Partners publicize the notice information to their constituents, clients, stakeholders, members, and/or licensees by posting the information on the homepage of their respective websites (<https://www.albme.gov/> and <https://www.alabamapublichealth.gov/>) and via other regular communication channels to their constituents, clients, stakeholders, members, and/or licensees.
14. Notify Medicaid Recipients. By no later than one (1) calendar year after the Effective Date, Alabama Medicaid will mail to all Medicaid recipients a notice in plain English (and will make such notice available in the other languages used to reach Alabama Medicaid recipients, as reflected at https://medicaid.alabama.gov/content/11.0_Recipient/11.7_Other_Language.aspx) that Alabama Medicaid has withdrawn the Sobriety Policy and that, effective immediately, Alabama Medicaid recipients with HCV will not be required to abstain from drug or alcohol use as a prerequisite for DAA treatment, nor will use of drugs or alcohol during DAA treatment result in non-payment for that treatment. The notice will encourage all Alabama Medicaid recipients to talk with their medical providers about whether they should be screened for HCV, and further encourage those with HCV to seek medical care, including evaluation of whether DAA treatment is appropriate for them, regardless of SUD status. Such notice need not be a standalone mailing and may be included with any regular Alabama Medicaid communication to Medicaid recipients.
15. Website Notification. Within five (5) days of the Effective Date (and for the Term of this Agreement), Alabama Medicaid will post in a prominent location of the homepage for Alabama Medicaid, <https://medicaid.alabama.gov/>, the following (or link to this same information from a graphic indicator on the homepage for Alabama Medicaid labeled “Expanded Hepatitis C Treatment Availability”): “Alabama Medicaid has withdrawn all earlier requirements that people seeking treatment for Hepatitis C (HCV) do not use drugs or alcohol for six months prior to treatment for, and during their treatment for, HCV. People on Medicaid will no longer be required to have a test for either drug or

alcohol use before receiving treatment for HCV. HCV can be a life-threatening condition, but it is highly curable for most people when they are given access to medications called direct-acting antiviral agents (DAA). People with HCV are encouraged to talk to their doctors or medical providers about whether DAA treatment is right for them. If it is, otherwise eligible Medicaid recipients can have this treatment paid for by Alabama Medicaid regardless of drug or alcohol use.”

16. Self-Monitoring and Reporting. Alabama Medicaid will prepare and provide to the Department two reports, the first by no later than January 23, 2023, and the second by no later than July 22, 2023, containing the following information:
- a. Alabama Medicaid will notify the Department of the date any benchmark listed in Paragraphs 11-15 above was completed during the appropriate reporting period.
 - b. The results of a review of all requests received by Alabama Medicaid for DAA treatment during the appropriate reporting period (for the first report – from October 1, 2022 through the reporting date, and for the second report – from the first reporting date through the second reporting date). For any such requests that were denied on the basis of the use of drugs or alcohol, Alabama Medicaid will remedy the denial and report the following information to the Department: the date and nature of the denial, the name of the provider involved, the date and nature of Alabama Medicaid’s remedy of the denial, corrective measures taken by Alabama Medicaid to avoid future denials, and all documentation regarding the denial.
 - c. For any complaint, charge, or grievance (formal or informal) regarding access to DAA treatment for HCV for any reason related to use of drugs or alcohol received by Alabama Medicaid during the appropriate reporting period, Alabama Medicaid will report the following information: the nature of the allegation, the name of the provider involved, Alabama Medicaid’s corrective measures to investigate and promptly address the allegations, and all documentation regarding the allegation (including, but not limited to, correspondence with Medicaid providers regarding the allegation).

17. Delivery of Information to the Department. All reports and materials required pursuant to this Agreement to be delivered to the Department shall be delivered to the undersigned counsel via electronic mail at anne.langford@usdoj.gov, nabina.sinha@usdoj.gov, and carla.ward@usdoj.gov or other persons subsequently specified by the Department.

OTHER PROVISIONS

18. Effective Date. The effective date of this Agreement is the date of the last signature below.
19. Term. The duration of this Agreement will be eighteen (18) months from the Effective Date.

20. Dispute Resolution. Any disputes under this Agreement shall be resolved according to the following procedure:
- a. Notification in Writing. Counsel for the United States shall promptly notify counsel for Alabama Medicaid in writing of any perceived non-compliance with the terms of this Agreement, or any other perceived dispute(s) related to the terms, processes, or obligations set forth in this Agreement.
 - b. Meet and Confer. Unless otherwise agreed to by the Parties in writing, with respect to any particular perceived non-compliance or dispute(s), the Parties agree to meet and confer in good faith within fifteen (15) business days after receipt of a written notification of any perceived non-compliance or dispute(s) pursuant to the previous paragraph.
 - c. Application for Further Relief. If the meeting required by part (b) of this Paragraph does not lead to a resolution of the dispute, then, no sooner than fifteen (15) business days after providing Alabama Medicaid with written notice of an intent to terminate the meet and confer process, the United States may seek to enforce the terms of this Agreement or the ADA with an appropriate Federal District Court.
21. Non-Waiver. Failure by the United States to enforce any provision or deadline of this Agreement shall not be construed as a waiver of its right to enforce any provision or deadline of the Agreement.
22. Titles. Titles and other headings contained in this Agreement are included only for ease of reference and shall have no substantive effect.
23. Timelines. Any timelines for performance fixed by, or pursuant to, this Agreement may be extended by mutual written agreement of the Parties.
24. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed to be an original, but all of which, taken together, shall constitute one and the same Agreement. Electronic signatures are acceptable.
25. Severability. If any term of this Agreement is determined by any court to be unenforceable, the other terms of this Agreement shall nonetheless remain in full force and effect.
26. Binding Nature of Agreement. This Agreement shall be binding upon Alabama Medicaid (as well as its agents and employees).
27. Authority. The signatories represent that they have the authority to bind the respective parties identified below to the terms of this Agreement.

28. Entire Agreement. This Agreement constitutes the entire agreement between the Parties on the matters raised herein and no other statement or promise, written or oral, made by any party or agents of any party, that is not contained in this written Agreement shall be enforceable.
29. Modification of Agreement. Any modification of this Agreement shall be by written agreement of the Parties.
30. Consideration. In consideration of the terms of this Agreement as set forth above, the United States agrees to refrain from filing a civil suit under Title II as a result of the investigation leading to this Agreement, except as provided in this Paragraph and in the Paragraph entitled “Dispute Resolution.” Nothing contained in this Agreement is intended or shall be construed as a waiver by the United States of any right to institute proceedings against Alabama Medicaid for violations of any statutes, regulations, or rules administered by the United States or to prevent or limit the right of the United States to obtain relief under the ADA for violations unrelated to this matter.
31. Review and Enforcement. The United States may review or monitor Alabama Medicaid’s compliance with this Agreement or the ADA at any time. Alabama Medicaid will provide additional documentation that the United States requests to evaluate Alabama Medicaid’s compliance with the Agreement. If the United States believes that the Agreement or any requirement thereof has been breached, following completion of the provisions set forth in Paragraph entitled “Dispute Resolution,” the United States may institute a civil action in an appropriate Federal District Court to enforce this Agreement or the ADA.
32. Other Violations. This Agreement is not intended to remedy any potential violations of the ADA or any other law, other than those specifically addressed by this Agreement. Nothing in this Agreement shall preclude the United States from filing a separate action under the ADA for any alleged violation not covered by this Agreement.
33. Continuing Responsibility. This Agreement does not affect Alabama Medicaid’s continuing responsibility to comply with all aspects of the ADA.

By their signatures below, the Parties respectfully consent to the execution of all aspects of this Agreement.

FOR THE UNITED STATES OF AMERICA:

PRIM F. ESCALONA
United States Attorney

REBECCA B. BOND
Chief

/s/
CARLA C. WARD
Assistant United States Attorney
Northern District of Alabama
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Date: December 5, 2022

/s/
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Date: December 5, 2022

**FOR THE STATE OF ALABAMA'S
MEDICAID AGENCY:**

/s/
STEPHANIE AZAR
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Date: November 30, 2022