

IN THE
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

TENNEIL SELNER, on her own behalf and on)	
behalf of a class of those similarly situated,)	
)	
Plaintiff,)	
)	
v.)	No. 1:15-cv-01874-SEB-MPB
)	
SECRETARY OF THE INDIANA FAMILY)	
AND SOCIAL SERVICES ADMINISTRATION,)	
in her official capacity,)	
)	
Defendant.)	

SETTLEMENT AGREEMENT

Introduction and Procedural Background

1. On November 25, 2015, Sarah Jackson filed her Class Action Complaint for Declaratory and Injunctive Relief (ECF No. 1). On November 30, 2016, Tenneil Selner filed her Motion for Permissive Intervention and to Join in Pending Motion for Class Certification (“Motion to Intervene”) (ECF No. 88), to which she appended her Class Action Complaint in Intervention for Declaratory and Injunctive Relief (“Complaint-in-Intervention”) (ECF No. 88-1 through 88-6). The Motion to Intervene was granted on January 3, 2017, and the Complaint-in-Intervention was deemed filed as of that date. (ECF No. 95). Ms. Jackson’s individual claim was thereafter dismissed (ECF Nos. 98 & 99), and the parties agree that the Complaint-in-Intervention is the operative complaint in this cause.

2. In her Complaint-in-Intervention, Ms. Selner alleges generally—on her own behalf and on behalf of a putative class of those similarly situated—that the policy of the

Indiana Family and Social Services Administration governing when Medicaid recipients with chronic Hepatitis C may receive Medicaid reimbursement for several direct-acting antiviral medications, or DAAs, violates federal Medicaid law.

3. The defendant generally denies the allegation made against her, and does not concede the merits of any claim advanced by the plaintiff.

4. The parties agree and understand that in reaching this Settlement Agreement (“Agreement”), defendant has denied and continues to deny any fault, wrongdoing, or liability on her part, the State of Indiana, the Indiana Family and Social Services Administration, or on the part of any of the agency’s officers, employees, or agents, with respect to all of the claims that are made or could be made against her as part of the above-referenced claim. This Agreement has been reached solely to avoid the uncertainties of litigation and the expenses that have been or will be incurred in the defense of this matter.

5. All parties want to reach a settlement of this matter and therefore enter into this Agreement, which is designed to fully settle all issues that were raised or could have been raised by this action, and which all parties intend to be binding upon them.

6. The parties have stipulated to the certification of this cause as a class action pursuant to Rule 23(a) and (b)(2) of the Federal Rules of Civil Procedure. The putative class is defined as follows:

Any and all adult Medicaid recipients in Indiana, current and future, with a diagnosis of chronic Hepatitis C, genotype 1, who have been prescribed one of the direct-acting antiviral medications enumerated in the 2016 Policy or 2018 Policy, by or in consultation with an Infectious Disease or GI specialist, but do not meet the medical requirements of such policy to receive Medicaid reimbursement for that prescribed medication.

The “2016 Policy” refers to the document attached to the parties’ Stipulation to Class Certification as Exhibit 1 and the “2018 Policy” refers to the document attached to the parties’ Stipulation to Class Certification as Exhibit 2. This Agreement is made expressly contingent on the approval of the parties’ stipulation to have this cause certified as a class action, and on the certification of this cause as a class action. In the event that this cause is not certified as a class action, this Agreement shall be deemed null and void.

7. Additionally, given that this Agreement is contingent on the certification of this cause as a class action, the parties recognize that this Agreement may not be finally approved until notice to the class is provided and a fairness hearing is conducted pursuant to Rule 23(e) of the Federal Rules of Civil Procedure, and the Court finds the Agreement to be fair, reasonable, and adequate. Contemporaneously with the parties’ filing of their stipulation to enter into this Agreement, the parties have filed their Joint Motion to Approve Manner and Form of Notice to the Class and to Set Fairness Hearing.

8. The parties intend that, once this Agreement is approved by the Court, all pending claims will be dismissed, with prejudice, subject to the terms and conditions set forth below. However, the parties agree that this Agreement is a contract, supported by good and valuable consideration, and that all contractual remedies for breach of the Agreement remain in full force and effect after this case is dismissed with prejudice.

9. This Agreement is contingent upon approval by the Governor of Indiana upon recommendation by the Attorney General. The defendant will request the necessary approval promptly upon execution of the Agreement by the parties. The parties agree to submit this Agreement to the Court for approval within a reasonable time after the Agreement has been approved by the Governor of Indiana.

Substantive Terms of Agreement

10. By July 1, 2019, the Indiana Family and Social Services Administration (“the agency”) will eliminate any restrictions based on fibrosis level or severity of disease for Medicaid recipients with chronic Hepatitis C to receive Medicaid reimbursement for direct-acting antiviral medications or DAAs. By July 1, 2019, the agency will approve all pending and future requests for prior authorization for the DAAs submitted on behalf of class-members, provided that the class-member on whose behalf a prior authorization request is submitted meets all other requirements to receive Medicaid reimbursement for the DAAs. However, nothing in this Agreement prohibits the agency from continuing to require that prior authorization requests be submitted by or in consultation with a qualified specialist, or from maintaining an “order of preference” amongst the DAAs whereby one DAA may not be approved unless a patient demonstrates that another DAA is not medically appropriate or is less likely to be effective. The plaintiff does not concede that any such requirements are or would be legal.

11. Effective promptly upon the approval of this Agreement, the agency will approve any request for prior authorization for the DAAs submitted on behalf of the named plaintiff, Tenneil Selner.

12. Until July 1, 2019, the 2018 Policy shall remain in effect and shall govern the circumstances under which Medicaid recipients in Indiana with chronic Hepatitis C may receive Medicaid reimbursement for the DAAs. The agency agrees that the phrase “other comorbidity associated with rapid progression,” as used in the 2016 Policy and 2018 Policy, is and shall be interpreted to allow Medicaid recipients with chronic Hepatitis C to receive Medicaid reimbursement for the DAAs, without regard to their level of

fibrosis, either if they possess a co-morbidity that has been shown to be associated with the rapid progression of fibrosis or if their Hepatitis C is actively symptomatic, demonstrating an individual medical need. Such symptoms might include, for instance, debilitating fatigue or debilitating depression associated with Hepatitis C. The agency agrees that it will provide notice of this interpretation to all Medicaid providers through the use of a Medicaid Provider Bulletin. Should the agency choose, this notice may be provided before the approval of this Agreement by the Court, although in no event shall it be sent more than sixty days after the approval of this Agreement.

13. Nothing in this Agreement shall be construed to prohibit the agency from adjusting the prior authorization criteria for a DAA to reflect changes in FDA approval parameters or to reflect changes in the order of preference on the Preferred Drug List.

14. Within 14 days after the approval of this Agreement by the Court and payment of plaintiff's counsels' attorney fees, the parties shall execute and file a stipulation to the dismissal of this cause, with prejudice.

15. For purposes of this Agreement, "the 2016 Policy" shall refer to the "Criteria for Indiana Medicaid Hepatitis C agents," which is attached to this Agreement and incorporated herein as Exhibit 1, and "the 2018 Policy" shall refer to the "Criteria for Indiana Medicaid Hepatitis C agents," which is attached to this Agreement and incorporated herein as Exhibit 2.

16. For purposes of this Agreement, the term "direct-acting antiviral medications" or "DAAs" shall refer to prescription drugs or combinations of drugs that have been approved by the Food and Drug Administration for the treatment of Hepatitis C and/or the Hepatitis C virus and are eligible for reimbursement pursuant to 42 U.S.C. § 1396r-8;

I.C. 12-15-35; I.C. 12-15-35.5; and applicable federal and state regulations. DAAs may be subject to a Preferred Drug List established and approved by the Indiana Drug Utilization Review (DUR) Board.

17. Either party may seek modification of this Agreement in the event of a significant change in facts or law following the approval of this Agreement. Such a proposed modification will be governed by the standards of *Rufo v. Inmates of Suffolk County Jail*, 502 U.S. 367, 393 (1992), which require, *inter alia*, that the party seeking modification “establish that a significant change in facts or law warrants revision of the decree and that the proposed modification is suitably tailored to the changed circumstance.” In the event that the parties are unable to agree on a proposed modification, either party may seek modification by filing an action in a court of competent jurisdiction, which shall be governed by the aforementioned standard.

Miscellaneous Provisions

18. The defendant agrees to pay counsel for the plaintiff \$117,500.00 in full satisfaction of any claims for attorneys’ fees and costs in this case. This payment shall be made within a reasonable time after the Court’s approval of this Agreement.

19. This Agreement is the final, integrated written agreement between the parties and supersedes all prior negotiations or drafts. It may only be modified upon written agreement between the parties, and with approval by the Court as necessary. All parties were fully represented by counsel in the drafting and consideration of the Agreement, and no party shall be construed as the only drafter for purposes of agreement interpretation.

20. Upon approval by the Court, this Agreement is entered into by and between plaintiff, on her own behalf and on behalf of the class identified in paragraph 6, above, in

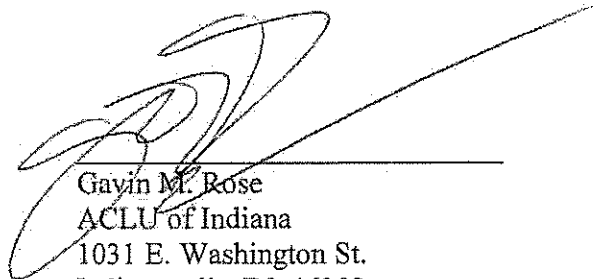
full settlement and satisfaction of any and all claims that were brought or could have been brought by her, as well as any and all claims for injunctive relief that were or could have been brought by members of the class, related to the events alleged in the complaints filed in this action and plaintiff's allegations that she and those similarly situated were denied prior authorization for a DAA in violation of federal Medicaid law, whether in state or federal courts, through and including the date of the approval of this Agreement.

21. Plaintiff agrees that, upon approval by the Court, she is releasing defendant from liability for any injuries, costs, or damages allegedly incurred as a result of or incidentally related to any and all of plaintiff's claims that were brought or could have been brought related to the events alleged in the complaints occurring prior to the approval of this Agreement.

22. Each party shall bear their own costs and expenses associated with this cause, except as specifically provided herein.

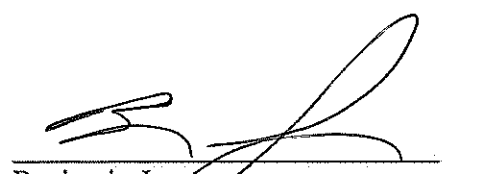
23. This Agreement shall be enforceable by the bringing of an action for declaratory judgment and/or a breach of contract action, or any other cause of action.

For the Plaintiff and the Class:



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