

AGREEMENT TO SETTLE CLAIMS

*B.E. and A.R. v. Teeter, United States District Court for the Western District of Washington,
Case No. 2:16-cv-00227*

This Agreement to Settle Claims ("Agreement") is between plaintiffs B.E. and A.R., on their own behalf and on behalf of the "Medicaid HCV Class" (as defined in ¶1.13), and Dorothy F. Teeter, in her official capacity as Director of the Washington State Health Care Authority ("WHCA," as defined in ¶1.18). B.E., A.R. and WHCA are referred to collectively as the "Parties." This Agreement is a full expression of the agreements between the Parties.

RECITALS

This Agreement is made with reference to the following facts:

- A. ***B.E. and A.R. v. Teeter.*** Plaintiffs B.E. and A.R. filed a Complaint against WHCA on February 17, 2016, asserting various claims arising out of WHCA's denial of Medicaid coverage for Harvoni and other direct acting anti-viral drugs ("DAAs") to treat Hepatitis C ("HCV"). The action, brought in the United States District Court for the Western District of Washington, sought relief both on their own behalf and on behalf of a class of similarly situated individuals.
- B. ***Plaintiffs' Claims.*** In the Complaint, B.E. and A.R. assert three separate claims: (1) improper exclusion of qualified individuals from covered medical assistance under the Medicaid Act; (2) violations of Medicaid comparability; and (3) violations of reasonable promptness. The claims all arose out of a coverage policy that WHCA applied to Medicaid enrollees seeking coverage of DAAs ("WHCA HCV Policy"). Plaintiffs alleged that the WHCA HCV Policy excluded care that was medically necessary, and that the exclusion was inappropriately imposed based on the cost of DAAs. Specifically, Plaintiffs challenged the WHCA HCV Policy's exclusion of coverage for certain HCV-infected enrollees based on fibrosis scores.
- C. ***Preliminary Injunction Order.*** On May 27, 2016, the Court granted Plaintiffs' Motion for a Preliminary Injunction ("Injunction Order"). Under the Injunction Order, *inter alia*, WHCA was "ENJOINED from continuing to apply its February 25, 2015 HCV treatment policy, including its exclusion of all treatment based on fibrosis score, and is required to return to providing coverage for prescription medications to treat Hepatitis C virus ("HCV") without regard to fibrosis score, consistent with existing state and federal Medicaid requirements." As a result of the Injunction Order, WHCA revised the WHCA HCV Policy to confirm to the requirements of the Injunction Order.
- D. ***Class Certification Order.*** On July 21, 2016, the Court granted Plaintiffs' Motion for Class Certification, and certified a class under FRCP 23(b)(2) ("Certification Order"). The Court appointed B.E. and A.R. as class representatives, and appointed class counsel.
- E. ***Agreement to Settle Claims.*** After the entry of the Injunction Order and Certification Order, the Parties engaged in discussions in an effort to resolve all claims. These discussions resulted in this Agreement.

AGREEMENT

1. *Definitions.*

- 1.1 “*Action*” shall mean: *B.E. and A.R. v. Teeter*, United States District Court for the Western District of Washington, Case No. 2:16-cv-00227.
- 1.2 “*Agreement Execution Date*” shall mean: the date on which this Agreement is fully executed.
- 1.3 “*Class Counsel*” shall mean: Richard E. Spoonemore and Eleanor Hamburger of SIRIANNI YOUTZ SPOONEMORE HAMBURGER, Amy L. Crewdson of COLUMBIA LEGAL SERVICES, and Kevin Costello of HARVARD LAW SCHOOL CENTER FOR HEALTH LAW AND POLICY INNOVATION.
- 1.4 “*Class Members*” shall mean: those individuals who comprise the Medicaid HCV Settlement Class.
- 1.5 “*Class Period*” shall mean: October 10, 2014 to three (3) years from the effective date of this agreement.
- 1.6 “*Court*” shall mean: the United States District Court for the Western District of Washington.
- 1.7 “*Defendant*” shall mean: Dorothy F. Teeter, in her official capacity as Director of the Washington State Health Care Authority and her successors in interest.
- 1.8 “*Effective Date of Settlement*” shall mean: the date on which all of the conditions to settlement set forth in section 2 have been fully satisfied or waived.
- 1.9 “*Final*” or “*Finality*” shall mean: with respect to any judicial ruling or order in the Action, that the period for any appeals, petitions, motions for reconsideration, rehearing or certiorari or any other proceeding for review (“*Review Proceeding*”) has expired without the initiation of a Review Proceeding, or, if a Review Proceeding has been timely initiated, that there has occurred a full and final disposition of any such Review Proceeding, including the exhaustion of proceedings in any remand and/or subsequent appeal on remand.
- 1.10 “*Final Decision*” shall mean: a decision of the United States Supreme Court or of any federal Court of Appeals that is not appealed within the time permitted for such appeals or that, if appealed, is not accepted for review.
- 1.11 “*HCV*” shall mean: infection with the Hepatitis C virus.
- 1.12 “*Medicaid HCV Class Released Claims*” shall mean: any and all claims, demands, and causes of action, known or unknown, for injunctive and declaratory relief relating to WHCA’s exclusion of coverage for Harvoni and other similar DAAs for the treatment of HCV due to fibrosis score for the class that were brought by the Named Plaintiffs against Defendant in the Action on behalf of a class, including but not limited to claims for injunctive and declaratory relief under the Medicaid Act, attorney’s fees and costs. Class Released Claims shall not include a release of claims for damages to the extent those exist outside this Action or of any claims that could have been brought under state law. This Release shall be binding on

Plaintiffs, the class and all their lawful guardians, heirs, beneficiaries, representatives, assigns, attorneys and agents.

- 1.13 “*Medicaid HCV Class*” shall mean: the class certified by the Court in the Action, specifically defined as

All individuals who:

- (i) are or will be enrolled in Washington State Health Care Authority’s Medicaid Program on or after October 10, 2014;
- (ii) require, or are expected to require treatment for Hepatitis C with Harvoni/ledipasvir-sofosbuvir or other similar direct acting antiviral under the current guidelines adopted by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America; and
- (iii) do not meet the coverage criteria for HCV medication adopted by WHCA in February 2015, as reflected in Appendix 1 to Plaintiffs’ Complaint (Dkt. No. 1-1).

- 1.14 “*Named Plaintiffs*” shall mean: Plaintiffs B.E. and A.R.

- 1.15 “*Parties*” shall mean: Plaintiffs and Defendant.

- 1.16 “*Releasees*” shall mean: Defendant and the Washington Health Care Authority.

- 1.17 “*Settlement*” shall mean: the settlement to be consummated under this Agreement.

- 1.18 “*WHCA*” shall mean: Defendant Dorothy F. Teeter, in her official capacity as Director of the Washington State Health Care Authority and her successors in interest.

2. *Conditions to Effectiveness of the Settlement.*

- 2.1 *General.* The Settlement provided for in this Agreement shall not become binding unless and until each and every one of the conditions in sections 2.2 through 2.4 have been satisfied or waived.

- 2.2 *Court Approval.* The Settlement contemplated under this Agreement must be approved by the Court, as provided herein and pursuant to Fed. R. Civ. P. 23. The Parties agree jointly to recommend to the Court that it approve the terms of the Agreement and the Settlement contemplated hereunder. The Parties agree to promptly take all steps and efforts contemplated by the Agreement, including the following:

- 2.2.1 *Motions for Preliminary Approval and Notices.* The Court shall have preliminarily approved the Agreement (“Preliminary Approval Order”). Class Counsel shall make a motion for preliminary approval and authorization to send notice (“Preliminary Motion”). The Court must conclude that the notice to be sent fairly and adequately describes the terms of the Agreement, gives notice of the time and place of the hearing for final approval of the Settlement, describes how a Class Member may comment

on, object to, or support the Settlement. The Court must also conclude that the manner of providing the notice to Class Members is the best notice practicable under the circumstances.

2.2.2 Issuance of Class Notice.

2.2.2.1 On the date set by the Court in its Preliminary Approval Order, WHCA, at its expense, shall have caused the Court-approved notice to be delivered to the relevant Class Members as follows: (1) All class members who WHCA identifies as potentially having a diagnosis of HCV shall receive notice by direct first class United States mail, forwarding requested, and (2) WHCA shall prominently post, on its webpage, a link to the Agreement and class notice. If the Court requires additional, different, or expanded notice, then any such ordered notice must be provided by WHCA.

2.2.3.2 Class Counsel shall create a webpage that includes at least the following material:

- a. A brief description of the case;
- b. Identification of the class;
- c. A summary of the proposed settlement derived from the class notice;
- d. A timeline and schedule of events, including deadlines for supporting or objecting to the Agreement; and
- e. How to contact class counsel for additional information;
- f. Settlement documents, or links to documents, including:
 - i. class notice;
 - ii. motions for preliminary approval; and
 - iii. all court orders on preliminary approval.
- g. Updates. The webpage created by Class Counsel shall be updated as the following become available:
 - i. Class counsel's application(s) for attorney fees, costs and incentive awards (with all supporting materials);
 - ii. Motion(s) for Final Approval of the settlement (including any objections and class counsel's response to those objections); and

iii. Frequently asked questions.

2.2.4 *Fairness Hearing.* On the date set by the Court in its Preliminary Approval Orders, the Parties shall participate in the hearings ("Fairness Hearings") during or after which the Court will determine by order (the "Final Order"): (i) the proposed Settlement between the Parties is fair, reasonable and adequate and should be approved by the Court; and (ii) the requirements of Fed. R. Civ. P. 23 and due process have been satisfied in connection with the distribution of the notice.

2.2.5 *Motions for Final Approval.* On the date set by the Court in its Preliminary Approval Order, Plaintiffs shall have filed a motion ("Final Approval Motion") for an order giving final approval to this settlement ("Approval Order").

2.3 *Injunction Order.* The Court has entered an Order consistent with section 5.1.1, and will retain jurisdiction for purposes of enforcement of the Order and this Agreement for three (3) years from the effective date of this Agreement.

2.4 *No Termination.* The Settlement shall not have terminated pursuant to section 7.

3. ***Releases.***

3.1 *Releases of the Releasees.* Upon the Effective Date of Settlement, B.E. and A.R., on behalf of themselves and, to the full extent permitted by law on behalf of the Medicaid HCV Class, absolutely and unconditionally release and forever discharge Releasees from any and all Medicaid HCV Released Claims that Plaintiffs or the Medicaid HCV Class has directly, indirectly, derivatively, or in any other capacity ever had or now have. This Release shall be binding on Plaintiffs, the Medicaid HCV Class, and all their lawful heirs, beneficiaries, representatives, assigns, attorneys and agents.

3.2 *Defendant's Release of Named Plaintiffs, the Class and Class Counsel.* Upon the Effective Date of Settlement, Defendant, to the full extent permitted by law, absolutely and unconditionally releases and forever discharges the Plaintiffs, the Medicaid HCV Class, and Class Counsel from any and all claims relating to the Medicaid HCV Class Released Claims.

4. ***Representations and Warranties.*** The Parties, and each of them, represent and warrant that they are voluntarily entering into this Agreement as a result of arm's-length negotiations; in executing this Agreement they are relying upon their own judgment, belief and knowledge, and the advice and recommendations of their own counsel, concerning the nature, extent and duration of their rights and claims hereunder and regarding all matters which relate in any way to the subject matter hereof. The Parties, and each of them, represent and warrant that they have carefully read the contents of this Agreement; they have made such investigation of the facts pertaining to the Settlement, this Agreement and all of the matters pertaining thereto as they deem necessary; and this Agreement is signed freely by each person executing this Agreement on behalf of each party. Each individual

executing this Agreement on behalf of any other Person does hereby represent and warrant to the other parties that he or she has the authority to do so.

5. *Coverage Modifications and Agreements.*

5.1 *HCV Coverage Modifications and Agreements.*

5.1.1 *Coverage of DAAs for Individuals with HCV.* The plaintiffs shall file an unopposed motion to request that the relief granted in the Court's May 27, 2016 Preliminary Injunction Order remain in effect until three (3) years from the date of this Agreement. Specifically, the parties agree that WHCA will not apply its February 25, 2015 HCV treatment policy, including its exclusion of all treatment based on fibrosis score, and will return to providing coverage for prescription medications to treat HCV without regard to fibrosis score, consistent with existing state and federal Medicaid requirements.

In the event medical standards and guidance regarding the above factors changes, or federal Medicaid law relevant to the claims in this case change, however, WHCA may revise its coverage criteria consistent with such changes. Provided, however, if such revisions (1) are made within three years of the Agreement's Effective Date and (2) are not consistent with the AASLD/IDSA's then-current guidance regarding when and in whom to initiate HCV treatment (regardless of the format in which the guidance appears), then WHCA shall provide Class Counsel with 30 days advance written notice of the changes.

Nothing in this agreement prohibits HCA from implementing immediate changes necessary to conform to safety guidance issued by the federal Food and Drug Administration.

5.1.2 *Appeal Rights.* Nothing herein shall be construed to limit or affect a Medicaid HCV Class Member's right to appeal a claims determination under applicable law.

5.2 *Treatment for those Previously Denied.* In addition to reviewing new claims for payment of DAAs under the criteria set forth in Section 5.1.1, any individual who is or was a class member and who would have qualified under the Court's May 27, 2016 Preliminary Injunction Order or the criteria in Section 5.1.1, but was denied under the previous WHCA HCV Policy, shall be provided additional and special notice of his or her right to coverage and, assuming the individual still qualifies for Medicaid and medically qualifies for coverage under the Injunction Order or the criteria in Section 5.1.1, shall be approved for treatment upon request. In addition, class notice shall include a special, separate notice to class members who are no longer Medicaid-eligible. Such special notice will inform those class members that any state-law claims are not waived by this settlement agreement and that if the

class members re-enroll on Medicaid, they will be able to request HCV treatment, despite the prior denial.

6. *Effective Date of Settlement.*

- 6.1 *Effective Date.* This Agreement shall be fully effective and binding on the date on which all of the conditions to settlement set forth in section 2 have been fully satisfied or waived.
- 6.2 *Disputes Concerning the Effective Date of Settlement.* If Parties disagree as to whether each and every condition set forth in section 2 has been satisfied or waived, they shall promptly confer in good faith and, if unable to resolve their differences within ten (10) business days thereafter, shall present their dispute to the Court for resolution.

7. *Termination of Agreement to Settle Claims.*

- 7.1 *Court Rejection.* If the Court declines to preliminarily or finally approve the Settlement, then this Agreement shall automatically terminate, and thereupon become null and void. The Court must both preliminarily and finally approve the Agreement for it to be effective and binding.
- 7.2 *Court of Appeals Reversal.* If the Ninth Circuit Court of Appeals reverses the Court's order approving the Settlement, then, provided that no appeal is then pending from such a ruling, this Agreement shall automatically terminate and thereupon become null and void, on the 31st day after issuance of the order referenced in this section.
- 7.3 *Supreme Court Reversal.* If the Supreme Court reverses the Court's order approving the Settlement, then, provided that no appeal is then pending from such a ruling, this Agreement shall automatically terminate and thereupon become null and void, on the 31st day after issuance of the order referenced in this section.
- 7.4 *Pending Appeal.* If an appeal is pending of an order declining to approve the Settlement, this Agreement shall not be terminated until final resolution of dismissal of any such appeal, except by written agreement of the Parties.

8. *Consequences of Termination.* If the Agreement is terminated and rendered null and void for any reason, then the following shall occur:

- 8.1 *Reversion of Action.* The Action shall revert to its status as of August 3, 2016.
- 8.2 *Releases and Terms Void.* All Releases given or executed pursuant to this Agreement shall be null and void and none of the terms of the Agreement shall be effective or enforceable.

9. *Attorney Fees, Litigation Expenses and Case Contribution Awards.*

- 9.1 *Attorneys Fees and Litigation Expenses.* Defendant agrees to pay Class Counsel's reasonable attorney's fees and costs that are associated with this Action and *In Re A.R.*, No. 07-2015-HCA-03625 only. At least 21 days prior to the date identified by the Court in its Preliminary Approval Order for Class Counsel to file a motion for attorneys' fees and costs, Class Counsel shall provide Defendant with a copy of Class Counsel's time entries (with redactions, where appropriate), hourly rate, and cost ledger. Defendant will have 14 days after receipt to notify Class Counsel in writing whether or not the Defendant will oppose Class Counsel's motion for attorneys' fees and litigation costs. If Defendant notifies Class Counsel in writing by the above-described deadline that it will not oppose Class Counsel's motion for attorneys' fees and litigation costs, Class Counsel will not seek a multiplier or enhancement of their attorney's fees. If Defendant notifies Class Counsel in writing by the above-described deadline that it will oppose Class Counsel's motion for attorneys' fees and litigation costs, Class Counsel may seek a multiplier or enhancement of its attorneys' fees, consistent with existing law and Defendant may respond in the time called for under the rules and seek an order reducing the attorneys' fees sought. If Defendant contests the motion for attorneys' fees and litigation costs, either party reserves the right to appeal the amount of the award. Information about this settlement provision shall be included in the Class Notice.
- 9.2 *Case Contribution Awards.* Upon Finality, WHCA agrees to pay B.E. and A.R. incentive awards in an amount not to exceed \$7,500 each. These incentive awards must be presented to and approved by the Court. This Agreement is not contingent upon an award of incentive payments, and shall not terminate by reason of the Court awarding less than the amount requested. WHCA will take no position with respect to the application for incentive awards provided that the requests do not exceed the amounts set forth herein.

10. Miscellaneous

- 10.1 *Governing Law.* This Agreement shall be governed by the laws of State of Washington without regard to conflict of law principles.
- 10.2 *Severability.* The provisions of this Agreement are not severable.
- 10.3 *Amendment.* Before entry of any Preliminary Approval Order, this Agreement may be modified or amended only by written agreement signed by or on behalf of all Parties. Following entry of any Preliminary Approval Order, this Agreement may be modified or amended only by written agreement signed on behalf of all Parties and approved by the Court.
- 10.4 *Waiver.* The provisions of this Agreement may be waived only by an instrument in writing executed by the waiving party. The waiver by any party of any breach of this Agreement shall not be deemed to be or construed as a waiver of any other breach, whether prior, subsequent, or contemporaneous, of this Agreement.

- 10.5 *Construction.* None of the Parties hereto shall be considered to be the drafter of this Agreement or any provision thereof for the purpose of any statute, case law or rule of interpretation or construction that would or might cause the provision to be construed against the drafter thereof.
- 10.6 *Principles of Interpretation.* The following principles of interpretation apply to this Agreement:
- 10.6.1 *Headings.* The headings herein are for reference purposes only and do not affect in any way the meaning or interpretation of this Agreement.
- 10.6.2 *Singular and Plural.* Definitions apply to the singular and plural forms of each term defined.
- 10.6.3 *References to a Person.* References to a person include references to an entity, and include successors and assigns.
- 10.7 *Survival.* All representations, warranties and covenants set forth in herein shall be deemed continuing and shall survive the Effective Date of Settlement.
- 10.8 *Entire Agreement.* This Agreement contains the entire agreement between the Parties relating to this Settlement.
- 10.9 *Counterparts.* This Agreement may be executed by exchange of executed faxed or PDF signature pages, and any signature transmitted in such a manner shall be deemed an original signature. This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original, but all of which, when taken together, shall constitute one and the same instrument.
- 10.10 *Binding Effect.* This Agreement binds and inures to the benefit of the parties hereto, their assigns, heirs, administrators, executors, and successors-in-interest, affiliates, benefit plans, predecessors, and transferees, and their past and present shareholders, officers, directors, agents, and employees.
- 10.11 *Further Assurances.* Each of the Parties agree, without further consideration, and as part of finalizing the Settlement hereunder, that they will in good faith promptly execute and deliver such other documents and take such other actions as may be necessary to consummate the subject matter and purpose of this Agreement.

SIGNATURES:

BELINDA ELMER

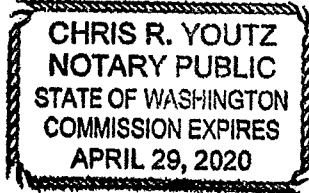
DATED: 11/17/16

By Belinda Elmer

STATE OF WASHINGTON)
) ss.
COUNTY OF KING)

On this day personally appeared before me, the undersigned, a Notary Public in and for the State of Washington, duly commissioned and sworn, BELINDA ELMER, to me known to be the individual described in and who executed the within and foregoing instrument, and acknowledged that he signed the same as his free and voluntary act and deed, for the uses and purposes therein mentioned.

GIVEN under my hand and official seal this 17 day of November, 2016.



[Signature]
NOTARY PUBLIC in and for the State of
WASHINGTON, residing at SEATTLE
My commission expires: 4/29/2020

ADAM RABB

DATED: 11-14-18

By Adam Rabb

STATE OF WASHINGTON)

PEACE) ss.
COUNTY OF KING)

On this day personally appeared before me, the undersigned, a Notary Public in and for the State of Washington, duly commissioned and sworn, ADAM RABB, to me known to be the individual described in and who executed the within and foregoing instrument, and acknowledged that he signed the same as his free and voluntary act and deed, for the uses and purposes therein mentioned.

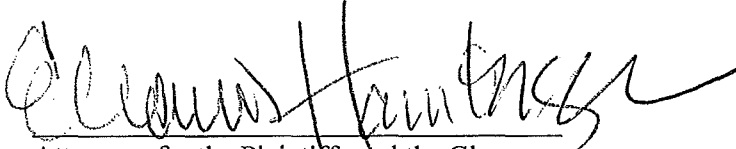
GIVEN under my hand and official seal this 14th day of NOVEMBER, 2016.



Jeffery E. Salvaggio
NOTARY PUBLIC in and for the State of
WASHINGTON, residing at TACOMA
My commission expires: FEB 4, 2020

APPROVED:

SIRIANNI YOUTZ SPOONEMORE HAMBURGER
COLUMBIA LEGAL SERVICES
HARVARD LAW SCHOOL CENTER FOR HEALTH LAW
AND POLICY INNOVATIONS



Attorneys for the Plaintiffs and the Class

WASHINGTON STATE ATTORNEY GENERAL



Attorneys for WHCA