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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

NATIONAL ASSOCIATION OF CHAIN
DRUG STORES; NATIONAL
COMMUNITY PHARMACISTS
ASSOCIATION, and the WASHINGTON
STATE PHARMACY ASSOCIATION,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity
as Secretary of United States Department
of Health and Human Services, and
ELIZABETH RICHTER, in her official
capacity as Acting Administrator for the
Centers for Medicare & Medicaid Services,

Defendants.

Case No. 2:21-cv-00576

COMPLAINT

Plaintiffs, the National Association of Chain Drug Stores, the National Community
Pharmacists Association, and the Washington State Pharmacy Association, allege the
following for their Complaint against Xavier Becerra, Secretary of United States Department
of Health and Human Services, and Elizabeth Richter, Acting Administrator for the Centers
for Medicare & Medicaid Services, both named in their official capacities:

I. INTRODUCTION

1. Washington’s Medicaid agency (the “State”) does not adequately reimburse
pharmacies for the health care services rendered to Medicaid beneficiaries. The State

1 reimburses its pharmacies serving Medicaid beneficiaries at the lowest rate in the country. Its
2 rate is *less than one-half* the rates paid by all neighboring states. These low rates have been
3 in force and have actually decreased over the past sixteen years.

4 2. In 2016, Centers for Medicare & Medicaid Services (“CMS”) promulgated a
5 new rule that required all States to reassess their reimbursement rates and take into account
6 the actual costs that pharmacies incur in serving Medicaid beneficiaries. State had to provide
7 certain adequate and reliable data to support any change of its rate to ensure that these costs
8 were adequately covered.

9 3. In response to that rule, the State insisted that its low rates remained
10 appropriate even though it never conducted a cost-of-dispensing study or otherwise
11 considered adequate and reliable data to support that conclusion—notwithstanding the fact
12 that such studies were performed or data was provided by nearly every other state. The State
13 then submitted its unchanged rate to CMS for federal approval.

14 4. Over the past several years—from 2017 through the end of 2020—CMS has
15 taken the consistent position that the State’s reimbursement rate violated federal law.

16 5. In September of 2018, CMS formally disapproved the State’s formal rate
17 proposal—known as a “State Plan Amendment”—because the State calculated its
18 reimbursement rates unlawfully to keep them at an artificially low level. Consistent with
19 CMS’s longstanding position, and following an administrative evidentiary hearing, on July
20 31, 2020, a CMS Administrative Law Judge (“ALJ”) recommended that the Secretary of
21 United States Department of Health and Human Services (“HHS”) uphold the denial of the
22 State Plan Amendment 17-0002 (the “SPA”).

23 6. Despite an administrative record containing none of the necessary cost data to
24 substantiate the below-cost rates, the Secretary (acting through the former CMS
25 Administrator) instead did an about-face. The Secretary ultimately rejected the agency’s
26 prior statements, guidance, specific regulations, and its own ALJ’s recommended decision.

1 The Secretary's wholesale rejection of CMS's prior positions came in the form of a one-
2 page, summary decision signed the day *before* Inauguration Day and which constituted one
3 of the CMS Administrator's last official acts in office before resigning.

4 7. The Secretary's conduct¹ was arbitrary and capricious because it completely
5 ignored the years of prior and consistent agency communications that the State's
6 reimbursement methodology violated federal law because it did not fulfill the required
7 standards. Moreover, the final administrative decision also wholly ignored the well-reasoned
8 recommended decision by the CMS ALJ who recommended that the State Plan Amendment
9 be denied. The decision also violates CMS's own statutes and regulations governing the type
10 of data needed to support an appropriate pharmacy reimbursement rate methodology.

11 8. The Plaintiffs here, all associations whose members include Washington State
12 pharmacies that serve Medicaid beneficiaries, file this complaint under the Administrative
13 Procedure Act to seek judicial review of the Secretary's final administrative decision.
14 Plaintiffs request that the Court reverse the Secretary's final administrative decision and
15 remand the matter back to the agency directing the Secretary to adopt the ALJ's decision to
16 affirm denial of the SPA. In the alternative, Plaintiffs request the Court reverse the final
17 administrative decision, remand the matter back to the agency directing the Secretary to
18 again review the administrative record and the applicable law for reconsideration of a final
19 determination on the SPA consistent with the Court's Order.

20 **II. PARTIES**

21 9. Plaintiff, National Association of Chain Drug Stores ("NACDS"), represents
22 traditional drug stores, supermarkets, and mass merchants with pharmacies, and supplier
23 _____

24 ¹ Plaintiffs recognize that neither the current named Secretary nor the current CMS Administrator
25 presently in office were involved in the underlying final administrative action. However, the current
26 officials are named in their official capacity only consistent with the requirements of the
Administrative Procedure Act.

1 partners. NACDS is headquartered in Alexandria, Virginia. NACDS includes over 15
2 member-companies in Washington State operating over 960 pharmacies—many of which
3 participate in Washington’s Medicaid program.

4 10. National Community Pharmacists Association (“NCPA”) is a non-profit based
5 in Alexandria, Virginia. NCPA represents the interests of the owners, managers, employees,
6 and patients of 21,000 independent community pharmacies across the United States. These
7 pharmacies and their pharmacists are rooted in the communities that they serve and pride
8 themselves on connecting and consulting with patients. Together, these independent
9 pharmacies represent a \$76 billion health care marketplace and employ more than 250,000
10 individuals on a full- or part-time basis. NCPA advocates on behalf of community
11 pharmacists on public policy issues that directly affect their patients—including those in
12 Washington State.

13 11. Plaintiff, Washington State Pharmacy Association (“WSPA”), represents
14 pharmacists, technicians, and interns practicing within community pharmacies, as well as
15 clinics, nursing homes, and hospitals. WSPA is headquartered in Renton, Washington, and
16 many of its members participate in Washington’s Medicaid program and provide care to
17 Medicaid patients throughout Washington’s urban, rural, and underserved communities.

18 12. Defendant Xavier Becerra is the Secretary of the United States Department of
19 Health and Human Services, which is headquartered in Washington, D.C.

20 13. Defendant Elizabeth Richter is the Acting Administrator for the Centers for
21 Medicare & Medicaid Services, which is headquartered in Woodlawn, Maryland.

22 **III. JURISDICTION AND VENUE**

23 14. This Court has federal question jurisdiction under 28 U.S.C. § 1331.

24 15. Plaintiffs’ claims are pursuant to the Administrative Procedure Act (“APA”)
25 as codified at 5 U.S.C. § 701 et seq. Defendants have failed to comply with, among other
26 things, Section 1902(a)(30)(A) of the Social Security Act (“the Act” or “SSA”) (42 U.S.C. §

1 1396a(a)(30)(A)), and with Federal regulations at 42 C.F.R. §§ 447.502, 447.512, 447.514,
2 and 447.518.

3 16. Plaintiffs are three non-profit associations whose members include many
4 Washington pharmacies participating in the Medicaid program. Collectively, Plaintiffs
5 represent those pharmacies most affected by CMS's final administrative decision approving
6 the SPA. Plaintiffs bring this action to seek judicial review of the Defendants' final
7 administrative decision and request that the decision be reversed as unlawful and arbitrary
8 and capricious and sent back to the agency for further action per the Court's Order.

9 17. Venue in this judicial district is appropriate under 28 U.S.C. § 1391. Plaintiffs
10 each "reside" in this judicial district for the purposes of 28 U.S.C. § 1391 as each association
11 has substantial membership operations in Washington and no real property interests are at
12 stake in this action. The Washington State Pharmacy Association's offices are located within
13 this judicial district. Moreover, a substantial part of the events or omissions giving rise to this
14 claim occurred within this judicial district. The State of Washington's Medicaid State Plan
15 Amendment was submitted by the State Medicaid agency within this district and the
16 applicable reimbursement rates in question are paid to pharmacies within this judicial
17 district. Lastly, the Defendants' agencies, the U.S. Department of Health of Human Services
18 and Centers for Medicare and Medicaid Services both maintain offices and operations within
19 this judicial district.

20 **IV. FACTUAL ALLEGATIONS**

21 **A. Plaintiffs' standing and right to seek judicial review**

22 18. Plaintiffs have multiple members who are suffering actual and cognizable
23 injury as a result of the Secretary's final administrative decision approving the State's SPA.
24 These pharmacies have and will continue to be reimbursed at a rate that is unlawfully too low
25 because it fails to consider or account for the actual costs associated with filling the
26 prescriptions for Medicaid beneficiaries as required by law.

1 19. Further, Plaintiffs’ individual members would otherwise have standing to sue
2 in their own right, the interests Plaintiffs seek to protect are germane to each of the
3 associations’ purpose, and neither the APA claim and single declaratory claim asserted nor
4 the relief requested requires the participation of individual members in the lawsuit.

5 **B. Federal Medicaid Law**

6 20. Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.*, establishing
7 the Medicaid program, authorizes federal financial support to states for medical assistance to
8 low-income persons who are aged, blind, disabled, or members of families with dependent
9 children. The Medicaid program is jointly financed by the federal and state governments, and
10 administered by the states. The states, in accordance with federal law, decide eligible
11 beneficiary groups, types and ranges of services, payment levels for services, and
12 administrative and operative procedures. Payment for services is made directly by states to
13 the individuals or entities that furnish the services. *See* 42 C.F.R. § 430.0.

14 21. In order to receive matching federal financial participation, states must agree
15 to comply with the applicable federal Medicaid law and regulations. *See* 42 U.S.C. § 1396 *et*
16 *seq.*

17 22. Federal law requires each state’s Medicaid program to be administered by a
18 single state agency, which is charged with the responsibility of establishing and
19 implementing a State Medicaid Plan (the “State Plan”) that complies with the provisions of
20 applicable federal Medicaid law. *See* 42 U.S.C. § 1396a(a)(5); 42 C.F.R. § 431.10. Each
21 State Plan must provide for the provision of certain services, including payment for covered
22 outpatient drugs (which are mandatory services that each state that participates in the
23 Medicaid program is required to provide). *See* 42 U.S.C. § 1396r-8.

24 23. Pursuant to 42 U.S.C. § 1396a(a)(30)(A) (“Section 30”), each State Plan
25 must: “assure that payments are consistent with efficiency, economy, and quality of care and
26 are sufficient to enlist enough providers so that care and services are available under the plan

1 at least to the extent that such care and services are available to the general population in the
2 geographic area[.]”

3 24. Each state must submit their State Plan to CMS for approval. *See* 42 U.S.C. §
4 1396a(a); 42 C.F.R. § 430.10. Any amendment to a State Plan must also be submitted to
5 CMS for approval. 42 C.F.R. § 430.12(c).

6 25. The Secretary of HHS, of which CMS is a part, must evaluate each state’s
7 compliance with the Medicaid statute. 42 U.S.C. §§ 1316(a)–(b), 1396a(b).

8 **C. CMS changes how pharmacies are to be reimbursed**

9 26. In February 2016, CMS promulgated a new regulation that fundamentally
10 changed the methodology of how state Medicaid agencies reimburse pharmacies
11 participating in the Medicaid program. *See* 81 Fed. Reg. 5170 (2016) (“CMS Rule”).

12 27. The CMS Rule requires states to adopt reimbursement rates that cover the
13 actual costs incurred by pharmacies participating in Medicaid, by reflecting those costs in
14 two distinct components: (1) the ingredient costs and (2) the professional dispensing fees
15 (dispensing fees). 42 C.F.R. §§ 447.502, 447.512(b), 447.514(b)(1), 447.518(a)(2).

16 28. Further, when proposing changes to *either* the ingredient costs and dispensing
17 fees reimbursement rates, states “must consider *both* the ingredient cost reimbursement *and*
18 the professional dispensing fee reimbursement when proposing such changes to ensure that
19 total reimbursement to the pharmacy provider is in accordance with requirements of Section
20 1902(a)(30)(A) of the [Social Security] Act.” 42 C.F.R. § 447.518(d) (emphasis added).

21 29. The purpose of the CMS Rule is to provide more fair and accurate
22 reimbursements and to do so by moving away from basing ingredient costs on estimated
23 costs to basing them on “Actual Acquisition Cost,” also known as “ACC.” 42 C.F.R. §
24 447.502, 447.512(b), 447.518(a) (2).

25 30. The CMS Rule defines ACC as the “actual prices paid to acquire drug
26 products marketed or sold by specific manufacturers.” 42 C.F.R. § 447.502.

1 31. Similarly, the CMS Rule defines “professional dispensing fees” as requiring
2 that reimbursements adequately cover a list of specified “pharmacy costs” associated with
3 operating pharmacies. *See id.* (definition of “professional dispensing fees” at subparagraph
4 (2)).

5 32. In particular, the CMS Rule defines dispensing fees as those “incurred at the
6 point of sale or service and pays for costs in excess of the ingredient cost of a covered
7 outpatient drug each time a covered outpatient drug is dispensed” and “[i]ncludes only
8 pharmacy costs associated with ensuring that possession of the appropriate covered
9 outpatient drug is transferred to a Medicaid beneficiary.” *Id.* Each state must submit proof
10 that dispensing fees reimbursement rates cover those costs. *Id.* at § 447.518(b).

11 33. Additionally, states must also “*provide adequate data* such as a State or
12 national survey of retail pharmacy providers or other *reliable data* other than a survey to
13 support any proposed changes to ... the components of the reimbursement methodology.” 42
14 C.F.R. § 447.518(d) (emphasis added).

15 34. Finally, states “must submit to CMS the proposed change in reimbursement
16 and the supporting data through a State plan amendment through the formal review process.”
17 *Id.*

18 **D. Washington submits its State Plan Amendment without meeting**
19 **the requirements of the CMS Rule or federal law.**

20 35. In response to the new CMS Rule, in May 2016, the State engaged in a
21 rulemaking that did not properly consider both the ingredient costs and the professional
22 dispensing fees for Washington pharmacies serving Medicaid beneficiaries.

23 36. The State’s rulemaking did adjust the ingredient costs methodology. But
24 modifying the ingredient costs was just one part of the equation. The CMS Rule also requires
25 that states “evaluate each component when they propose changes[,]” which includes the
26 dispensing fee. 42 C.F.R. §§ 447.502, 447.512(b), 447.514(b)(1), 447.518(a)(2).

1 37. The State failed to “evaluate [its] proposed changes in accordance with [the]
2 final [CMS] rule, and . . . [to] consider the impacts of *both* the ingredient cost reimbursement
3 and the professional dispensing fee reimbursement when proposing such changes...” as
4 legally required. 42 C.F.R. § 447.518(d) (emphasis added).

5 38. On March 2, 2017, the State announced that the dispensing fees for all
6 Washington pharmacies across the state would remain flat at their 2009 levels, which ranged
7 from \$4.24 to \$5.25 per prescription depending on the volume at a particular pharmacy.

8 39. The State’s only justification for leaving the rates from 2009 unchanged was
9 that they were still two to four times higher than what *private* insurers pay.

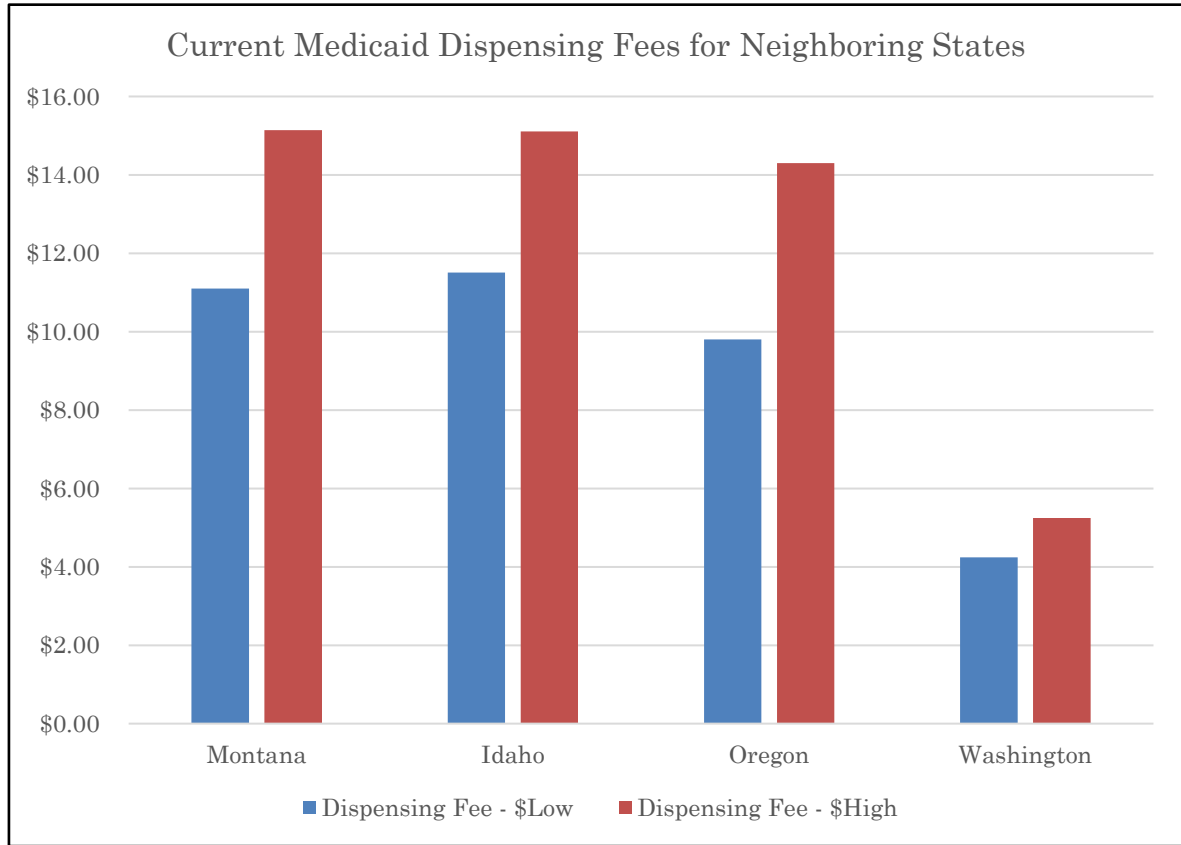
10 40. After adopting its rule, the State prepared a “Concise Explanatory Statement”
11 summarizing the rule, as well as its response to any comments received. But nothing in its
12 statement discussed the cost-based data or assessments used in calculating the adequacy or
13 amount of professional dispensing fees.

14 41. The State’s rule became effective on April 1, 2017. Thereafter, the State
15 submitted its SPA to CMS for consideration.

16 **E. ECMS questions the validity of the State’s decision to leave its**
17 **dispensing fees unchanged**

18 42. Beginning in June 2017, CMS, the federal agency that must ultimately
19 approve the State’s proposed reimbursement rates, questioned the validity of the State’s
20 decision to leave its dispensing fees unchanged, asking the State to submit either a recent
21 Washington state survey of pharmacy providers’ actual cost of dispensing or data from
22 neighboring states’ recent cost of dispensing studies to support the proposed rates.

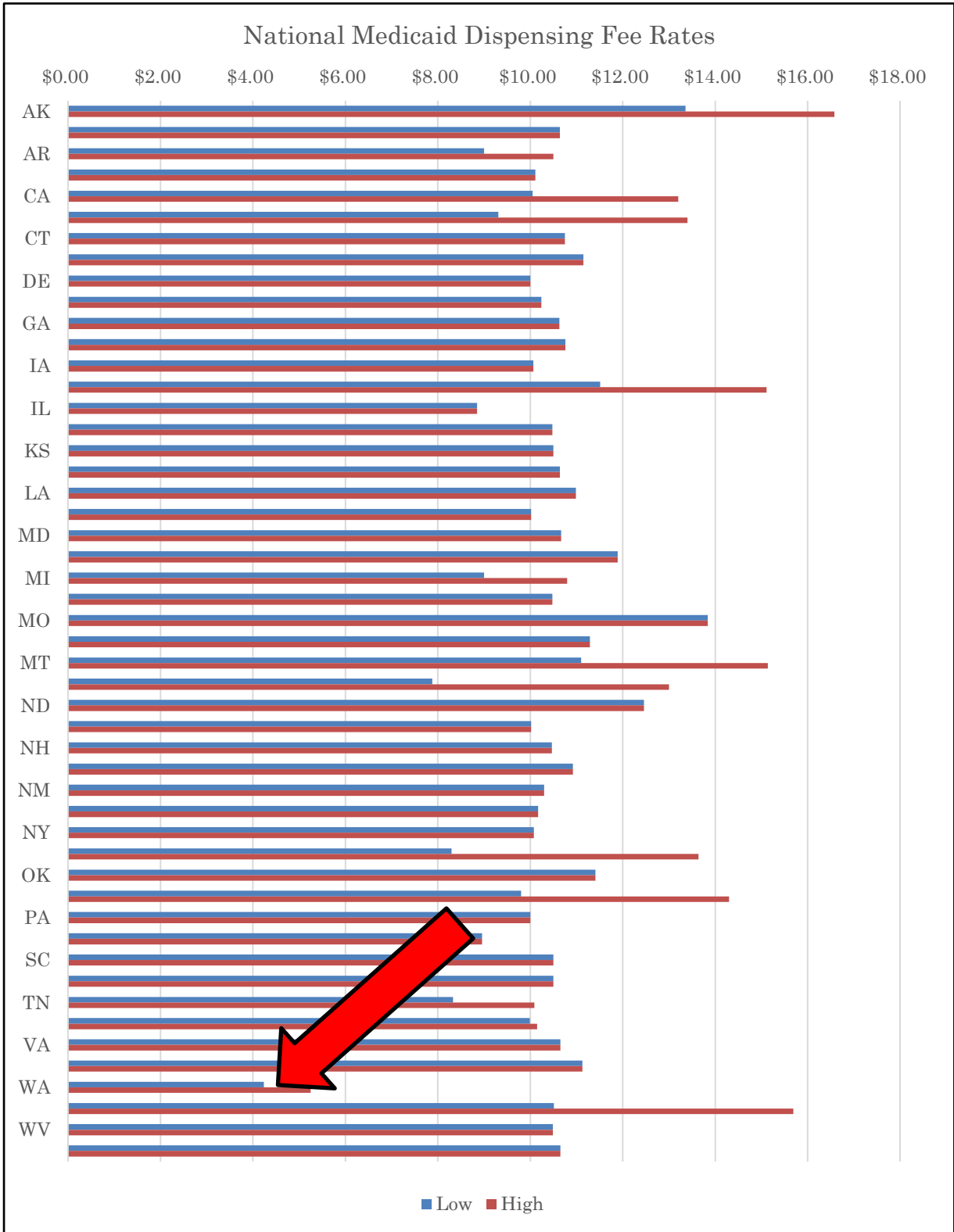
23 43. CMS’s concern was based, in part, on Washington’s status as an outlier on
24 reimbursement rates. As compared to its neighboring states, Washington has the lowest
25 reimbursement rate by far:



44. Beyond its regional neighbors, Washington’s dispensing fee is also dead last in the nation—and by a significant amount.

45. The table below demonstrates that Washington’s dispensing fee is significantly lower than all other approved state dispensing fees.²

² Some states, like Washington, have a “low” and “high” dispensing fee that depends on the volume of prescriptions filled. In general, pharmacies dispensing lower volumes of prescriptions are typically reimbursed at the higher fee, while pharmacies dispensing higher volumes of prescriptions are reimbursed at the lower fee.



1 46. When pressed by CMS, the State conceded that it has no such cost-based
2 survey or data from its own state or from neighboring states that would support its proposed
3 rates.

4 47. CMS asked for additional support that centered upon the actual cost to fill
5 prescriptions beyond the previously submitted fee based studies to justify the State’s
6 proposed dispensing fee reimbursement rate.

7 48. The State declined to provide the requested material and merely reiterated that
8 it was relying upon fee based studies of what *private* insurers pay, arguing that the
9 “aggregate ingredient cost and dispensing fee rates are sufficient to ensure that . . . providers
10 are adequately reimbursed in accordance with the requirements of § 1902(a)(30)(A) of the
11 Social Security Act.”

12 49. On September 10, 2018, CMS disapproved Washington SPA 17-0002. CMS’s
13 Letter from Tim Hill, Acting Director, is attached hereto, and incorporated herein, as **Exhibit**
14 **A.**

15 50. In its disapproval letter, CMS noted that the regulation at 42 C.F.R. §
16 447.518(d) dictates that when a state proposes changes to either the ingredient or dispensing
17 reimbursement to pharmacies, it must consider both costs to ensure that “total reimbursement
18 to the pharmacy provider is in accordance with section § 1902(a)(30)(A) of the Act.” *See id.*

19 51. CMS also quoted the final CMS Rule, which requires that “states must
20 provide information supporting any proposed change to either the ingredient cost or
21 dispensing fee reimbursement which demonstrates that the change reflects actual costs and
22 does not negatively impact access.” *Id.* The letter confirmed that the denial decision was
23 made “after consultation with the Secretary.” *Id.*

1 **F. The State files a request for reconsideration and the SPA denial is**
2 **upheld following an administrative hearing**

3 52. On November 5, 2018, the State filed a request for reconsideration with CMS.

4 53. Through a letter dated December 3, 2018 (published in the Federal Register at
5 83 Fed. Reg. 62869 (Dec. 6, 2018)), the CMS Administrator scheduled a subject hearing in
6 response to the State’s request for reconsideration.

7 54. A hearing was held on June 18, 2019, and on July 31, 2019, a CMS ALJ
8 issued a 16-page, well-reasoned decision that recommended that CMS’s SPA denial be
9 upheld. A true and correct copy of the ALJ’s decision is attached hereto, and incorporated
10 herein, as **Exhibit B**.

11 55. The ALJ decision, in essence, found that the State had failed to support its
12 decision to keep dispensing fee rates unchanged and below cost because it failed to conduct a
13 cost of dispensing survey or otherwise provide any relevant, reliable, or adequate data
14 reflecting the actual cost of dispensing for pharmacies serving Medicaid beneficiaries. *See id.*

15 56. The ALJ further recognized that the administrative record contained evidence
16 that “Washington’s rates were less than one-half the rates being paid in neighboring states”
17 and that the State “did not provide adequate data to support that its 8-year old rates supported
18 the current costs to dispense prescriptions.” *Id.* at 10.

19 57. Under the law, the ALJ recommendation then went to the CMS Administrator
20 to render a final administrative decision on the SPA’s approval or denial.

21 **G. The Principal Deputy Administrator of CMS enters a one-page**
22 **ruling “approving” the State’s SPA.**

23 58. Despite the ALJ’s well-reasoned decision and contrary to years of CMS’s
24 prior communications that the SPA did not meet federal law, on January 19, 2021, the
25 “Principal Deputy Administrator” of CMS entered a one-page final administrative decision
26 that “approved” the State’s SPA (the “CMS Ruling”). A true and correct copy of the CMS
final administrative decision is attached hereto, and incorporated herein, as **Exhibit C**.

1 to confirm that Washington's SPA complied with CMS's own statutes and regulations for a
2 cost-based professional dispensing fee. The State never submitted either a recent Washington
3 state survey of pharmacy providers' *actual cost* of dispensing to Medicaid patients or data
4 from neighboring states' recent cost of dispensing studies to support the proposed rates, as
5 requested by CMS.

6 67. There also was no analysis of whether the rates are consistent with efficiency,
7 economy and quality of care, and there was no analysis of whether the rates are reasonably
8 related to the costs incurred by efficient economical providers. Moreover, the Secretary did
9 not consider the level of service to Washington Medicaid patients relative to the general
10 public (*i.e.*, non-Medicaid patients), as required by federal law. The Secretary failed to
11 consider those important aspects of Section 30(A).

12 68. Further, the Secretary's decision was so conclusory, and lacking in any
13 appropriate legal analysis, that it completely ignored the underlying CMS Rule and violated
14 the agency's own law.

15 69. Finally, the Secretary's decision was directly contrary to years of CMS's prior
16 communications, positions, and policies that the SPA did not meet federal law, as well as the
17 ALJ's well-reasoned decision that recommended the SPA be denied.

18 **VI. COUNT II**
19 **DECLARATORY RELIEF**

20 70. Plaintiffs hereby incorporate by reference the prior paragraphs of this
21 Complaint, as though fully set forth herein.

22 71. An actual and justiciable controversy exists between Plaintiffs and the
23 Secretary regarding whether SPA 17-0002, which lowered ingredient costs while keeping
24 dispensing fees unchanged without considering the costs of dispensing, complied with the
25 requirements of the Federal Medicaid Act and the CMS Rule. Plaintiffs contend that it does
26

1 not comply with the law and, accordingly, that the Secretary's approval of the SPA was
2 arbitrary, capricious, an abuse of discretion, and not in accordance with applicable law.

3 72. Plaintiffs request that this Court declare the SPA as it relates to dispensing
4 fees invalid, unlawful, and otherwise contrary to federal law pursuant to 28 U.S.C. § 2201.

5 73. No administrative appeal process or other administrative remedy is available
6 to Plaintiffs to challenge the dispensing fees reimbursement rates in the SPA or the
7 Secretary's approval of the SPA.

8 **VII. PRAYER FOR RELIEF**

9 WHEREFORE, Plaintiffs pray for judgment as follows:

10 1. For an Order declaring that it was arbitrary, capricious, an abuse of discretion,
11 and not in accordance with applicable law for the Secretary to approve the SPA, which left
12 the dispensing fee reimbursement rates unchanged since 2009;

13 2. For an Order setting aside the Secretary's final administrative decision
14 approving SPA 17-0002 and remanding the matter to CMS and directing the agency to adopt
15 the ALJ's recommendation to uphold the denial of the SPA; or, in the alternative, to review
16 the administrative record and applicable law for reconsideration of a final determination on
17 the SPA consistent with federal law and the Court's Order;

18 3. For a Declaration that the Secretary's approval of SPA 17-0002 was contrary
19 to law and violated the APA and the Medicaid Act;

20 4. For an award of the costs of suit to Plaintiffs, including reasonable attorney
21 fees, as permitted under 42 U.S.C. § 1988 or otherwise, and

22 5. Such other and further relief the Court deems just and proper.

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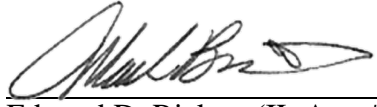
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Dated this 29th day of April, 2021.

SCHWABE, WILLIAMSON & WYATT, P.C.

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